Biotechnology

ALNEV-FR - NXT PA

April 10, 2017

Closing Price 04/7/2017	**€0.86**
Rating:	Buy
12-Month Target Price:	€5.00
52-Week Range:	€0.66 - €1.33
Market Cap (M):	37
Shares O/S (M):	43.0
Float:	100.0%
Avg. Daily Volume (000):	871
Dividend:	€0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2016A	2017E	2018E
H1	€7,971	€7,250	€6,000
H2	€9,684	€4,800	€6,500
FY	€17,655	€12,050	€12,500
Prior	€15,000	€20,000	€22,000

GAAP EPS

	2016A	2017E	2018E
H1	(€0.16)	(€0.07)	(€0.02)
H2	(€0.17)	(€0.01)	(€0.03)
FY	(€0.32)	(€0.08)	(€0.05)
Prior	(€0.29)	(€0.26)	(€0.24)

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Neovacs S.A.

Buy

Lupus P2b Study Nearing Full Enrollment, Partner Comes on Board for China

Summary

- **Neovacs reported YE16 with a net loss of €13.9M and ended the year with €3.9M in cash. Neovacs will receive €3.3M in non-dilutive funding from the French Government in 1H17 for continued development of INFα-K. In addition, the company has a €13.5M equity line available. Operating expenses are expected to be reduced to €1.8M in 2H17 from €3.6M per quarter in 1H17 following completion of enrollment of the P2b lupus study (expected June 2017). Combined, Neovacs estimates the company has sufficient capital runway into 2H18 and through the next inflection point, P2b POC data for INFα-K in lupus, expected 2Q18.**
- **P2b study update. As of April 2017 the study (N=178) is 83% enrolled and on track to complete enrollment in June 2017 (data 2Q18). Positive data sets the stage for a partner to come on board for a global P3 study. However, in South Korea, partner CDK Pharmaceutical Corp can file for approval on P2b data. Neovacs also announced a partnership with BioSense Global for P3 development and commercialization in China.**
- **Other catalysts. We expect to see more preclinical data for INFα-K as Neovacs works towards initiating a P2a study in 2H17. Data from the P2a study of INFα-K in dermatomysitis is expected in 2H17 as well.**
- **Conclusion. INFα-K continues to advance and is now in the later stages of a POC study. Our view is that a vaccine-driven polyclonal antibody approach like INFα-K has advantages over MAbs (i.e. Medimmune [anifrolumab]) by taking out more INFα types. In addition, like Humira and other MAbs, anifrolumab will likely cost $30K+ every year. Neovacs could treat SLE with INFα-K for just one year at a fraction of the cost.**

Details

INFα-K in SLE: A gene signature gives visibility. INFα, the master regulator of inflammatory genes, is being turned on and causing tissue damage in SLE. In other words, INFα and, thus, SLE, have a "gene signature" and can be measured. The INFα-K phase I/II study showed that polyclonal MAbs neutralize all subtypes of INFα, and the gene signature goes negative; it shuts off. Neovacs now has a target (INFα), a population (mild-mod SLE, INFα-gene-signature positive), and endpoints (immunogenicity, biomarkers, and improved SLE activity score). Most importantly, the company has visibility in the gene signature that may be a predictor of disease activity. Medimmune's anifrolumab phase II POC data show that blocking the INFα receptor has a similar effect to INFα-K in SLE (taking out INFα signaling). In addition, positive phase II data from Medi's Sifalimumab and Genentech's rontalizumab which target the INFα are also validating for Neovacs' approach. The role of INFα in SLE and the data from other studies so far, in our view, may be suggestive of what might be expected in Neovacs' phase IIb study (2Q18).

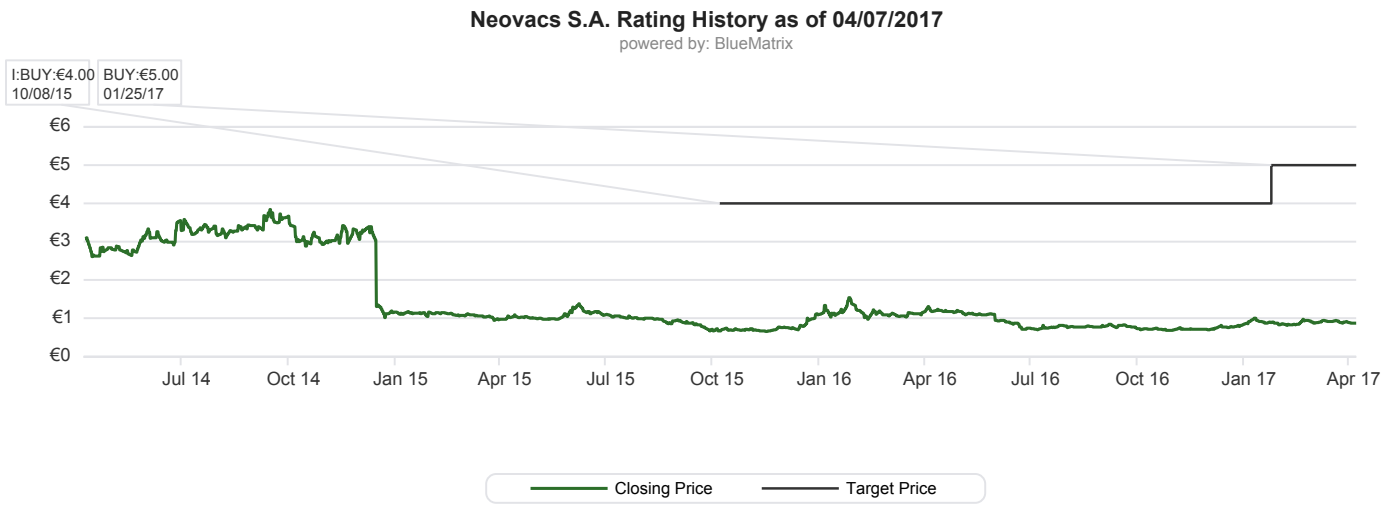
P3 Studies in Lupus. Pending successful results in the P2b study, Neovacs plans to advance INFα-K into P3 studies with a partner. The studies will likely include 400 patients each and with patients randomized 1:1 to INFα-K or placebo. Placebo is the likely comparator as Benlysta (belimumab) is not considered by regulators as a reference product, and Medimmune's MAb (anifrolumab), which is currently in a 360 patient P3 study (vs. placebo), would likely not be approved by the time Neovacs' studies begin.

The opportunity in China. Neovacs announced a partnership with BioSense Global, worth up to €65M in upfront payments and milestones, and double-digit royalties. The undisclosed upfront payment is essentially a right to opt-in based on the P2b data. If positive, BioSense will conduct a P3 study on the ground in China. There are over 1M Lupus patients in China.

Income Statement (€'000) *Euros*																
NeoVacs: YE December	**2014A**	**2015A**	**1H-2016A**	**2H-2016A**	**2016A**	**1H-2017E**	**2H-2017E**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**
Revenue (000's)																
INF-Kinoid, sytemic lupus erythematosus (Europe)											33,567	69,025	106,452	131,340	150,043	192,835
INF-Kinoid, dermatomyositis(Europe)												4,163	8,561	13,203	18,100	27,915
Total Revenues		-	-	-	-	-	-	-	-	-	33,567	73,188	115,014	144,544	168,143	220,750
Out-licensing fees and development milestones						4,000	4,000	8,000	9,000	15,000	20,000	20,200				
INF-Kinoid, systemic lupus erythematosis (U.S.)											7,482	15,385	23,727	29,275	33,443	42,981
INF-Kinoid, systemic lupus erythematosis (China)											2,518	3,236	3,992	4,788	7,033	10,124
INF-Kinoid, dermatomyositis (U.S.)												1,348	2,772	3,563	4,103	4,520
INF-Kinoid, Type 1 diabetes (U.S.)														9,894	15,583	21,816
INF-Kinoid, Type 1 diabetes (EU)														9,973	15,707	21,990
Sales of Services	142	1,181	104	290	394	114	114	227	1,000	1,200	1,440	1,728	2,074	2,488	2,986	3,583
Recovery of provisions and expense transfers	19															
Total Revenues	161	1,181	104	290	394	4,114	4,114	8,227	10,000	16,200	65,006	115,085	147,579	204,524	246,998	325,764
Expenses																
Cost Of Goods Sold		-	-	-	-	-	-	-	-	-	5,035	10,978	16,102	18,791	20,177	22,075
COGS % Sales											15%	15%	14%	13%	12%	10%
Research & Development	652	10,683	6,213	8,445	14,658	9,000	4,000	13,000	15,000	20,000	21,000	19,950	18,953	18,005	17,825	17,647
R&D % Rev's																
General & Administrative Expense	1,995	1,776	1,758	1,239	2,997	1,250	1,275	2,525	7,000	15,000	15,750	16,538	17,364	18,233	19,144	20,101
SG&A %																
Other external purchases and expenses	7,130															
Other expenses	37															
Total expenses	**€ 9,815**	**€ 12,459**	**€ 7,971**	**€ 9,684**	**€ 17,655**	**€ 10,250**	**€ 5,275**	**€ 15,525**	**€ 22,000**	**€ 35,000**	**€ 41,785**	**€ 47,466**	**€ 52,419**	**€ 55,028**	**€ 57,146**	**€ 59,823**
Oper. Inc. (Loss)	(9,654)	(11,279)	(7,867)	(9,394)	(17,261)	(6,137)	(1,162)	(7,298)	(12,000)	(18,800)	23,221	67,619	95,160	149,496	189,852	265,941
Other income	0		(42)	(58)	(100)											
Total other income	(158)	(157)	(42)	(58)	(100)	-	-	-	-	-	-	-	-	-	-	-
Pre-tax income	**€ (9,812)**	**€ (11,436)**	**€ (7,909)**	**€ (9,452)**	**€ (17,361)**	**€ (6,137)**	**€ (1,162)**	**€ (7,298)**	**€ (12,000)**	**€ (18,800)**	**€ 23,221**	**€ 67,619**	**€ 95,160**	**€ 149,496**	**€ 189,852**	**€ 265,941**
Non-recurring earnings, exceptional items	(7)	4,188	41	(76)	(35)											
Taxes (or benefits)	(2,306)	2,565	1,171	2,223	3,394	-	-	-	-	-	-	-	-	-	9,493	21,275
Tax Rate														0%	5%	8%
GAAP Net Income (loss)	**€ (7,513)**	**€ (4,683)**	**€ (6,779)**	**€ (7,153)**	**€ (13,932)**	**€ (6,137)**	**€ (1,162)**	**€ (7,298)**	**€ (12,000)**	**€ (18,800)**	**€ 23,221**	**€ 67,619**	**€ 95,160**	**€ 149,496**	**€ 180,359**	**€ 244,666**
Net Margin																
GAAP -EPS	**€ (0.31)**	**€ (0.15)**	**€ (0.16)**	**€ (0.17)**	**€ (0.32)**	**€ (0.14)**	**€ (0.02)**	**€ (0.16)**	**€ (0.24)**	**€ (0.35)**	**€ 0.42**	**€ 1.23**	**€ 1.73**	**€ 2.71**	**€ 3.26**	**€ 4.41**
Wgtd Avg Shrs (Bas) - '000s	24,000	31,532	42,970	43,013	42,991	43,056	48,099	45,578	50,171	53,524	54,882	54,992	55,102	55,212	55,323	55,433
Wgtd Avg Shrs (Dil) - '000s	24,000	31,532	42,970	43,013	42,991	43,056	48,099	45,578	50,171	53,524	54,882	54,992	55,102	55,212	55,323	55,433

Source: Company reports and Maxim estimates

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 04/09/17
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**75%**	**32%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly outperform nor underperform its relevant index over the next 12 months.	**23%**	**17%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**2%**	**0%**
	**See valuation section for company specific relevant indices*		

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The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Neovacs S.A.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Neovacs S.A. in the next 3 months.

ALNEV-FR: For Neovacs, we use the BTK (Biotechnology Index) as the relevant index.

Valuation Methods

ALNEV-FR: We factor in INFα-K fpr type 1 diabetes. Our therapeutic model assumes that INFα-K could be approved and launch for SLE in the U.S., Europe, and China in 2020 followed by for dermatomyositis in 2021 and type 1 diabetes in 2023. We assume a high risk rate due to the early stage of development and the risk associated with any drug in development for SLE. Our model assumes that Neovacs will seek a partner for sales

outside of Europe and receive a royalty stream for Lupus and Dermatomyositis indications. We assume a global partner and royalty stream for type 1 diabetes. A 30% discount rate is applied to our free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted.

Price Target and Investment Risks

ALNEV-FR: Aside from general market and other economic risks, risks particular to our price target and rating for Neovacs, Neovacs faces multiple risks including: (1) development – the products are in the early stages of development, and may not be successful in current and/or future clinical studies; (2) regulatory – the FDA or EMA may not approve Neovacs' products; the company's ongoing and future studies may not be sufficient to gain approval; (3) commercial – the company lacks the commercial infrastructure to support a product launch, if approved; and (4) financial – the company is not yet profitable and may need to raise additional capital to fund product development.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

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