

Biotechnology

ALNEV-FR - NXT

December 15, 2015

PA

Closing Price 12/14/2015	€0.72
Rating:	Buy
12-Month Target Price:	€4.00
52-Week Range:	€0.66 - €3.35
Market Cap (M):	23
Shares O/S (M):	32.1
Float:	74.8%
Avg. Daily Volume (000):	380
Dividend:	€0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Revenues ('000)

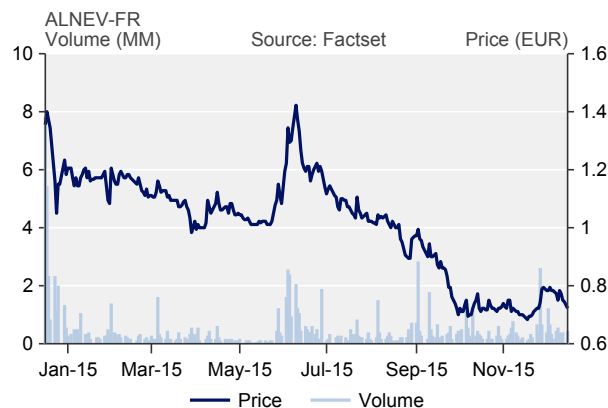
	2015E	2016E	2017E
H1	€94A	€2,603	€5,114
H2	€150	€2,603	€5,114
FY	€244	€5,207	€10,227

Pretax Income ('000)

	2015E	2016E	2017E
H1	(€5,825)A	(€4,897)	(€4,886)
H2	(€6,050)	(€4,897)	(€4,886)
FY	(€11,875)	(€9,793)	(€9,773)

GAAP Net Income (loss) ('000)

	2015E	2016E	2017E
H1	(€4,870)A	(€4,897)	(€4,886)
H2	(€6,050)	(€4,897)	(€4,886)
FY	(€11,875)	(€9,793)	(€9,773)



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Neovacs S.A.

Buy

First Partner Comes on Board For Lupus Immunotherapy

Summary

- Neovacs announced that the company has entered into a licensing agreement for the commercialization of INF α -K in both Lupus and Dermatomyositis with CDK Pharmaceutical Corp (058820:KS-\$1,700.00-NR) in South Korea.
- CKD, pending the outcome of the ongoing phase IIb study, should be able to file for registration by the end of 2017 and potentially launch INF α -K in 2018. Lupus is an orphan indication in South Korea and a phase III study is not necessary.
- CKD is a leader in immune suppressive treatments in this market and has established ties to the Lupus-treating physicians and patients, suggesting that market uptake could be rapid.
- Neovacs, will receive €1M upfront, up to €5M in milestones and an undisclosed royalty on commercial sales. The two companies are also in talks to expand the partnership to VEGF kinoids for cancer indications. As a reminder VEGF is the target of the blockbuster monoclonal antibody Avastin. CKD is already pursuing a biosimilar Avastin but believes the kinoid approach could make more sense.
- Bottom line. This is Neovacs' first commercial partner and further validates the kinoid platform. The advantage for Neovacs is that if the INF α -K phase IIb is successful in lupus and the company launches in South Korea, the company could have data in real-time on hundreds of patients while conducting the phase III pivotal studies in the U.S. and Europe.

Details

Kinoid technology: Active immunotherapy. Cytokines are like mediators of the immune system, and can be overexpressed or abnormally released in autoimmune diseases, cancer, and allergies. Blockbuster anti-cytokine MABs targeting cytokines (like Humira, Remicade, and Avastin) are given as passive immunotherapy and have shown efficacy, but they have limits, specifically, the development of resistance. Kinoids avoid this problem by fusing inactivated cytokines with the immunogenic protein, KLH (keyhole limpet hemocyanin). Kinoids (like INF α -K) are injected into the patient as an active immunotherapy, inducing a polyclonal antibody immune response against the endogenous cytokine driving the disease.

INF α -K in SLE: A gene signature gives visibility. Where is POC in SLE? What is the target? What is the endpoint? It's a challenging indication. We now know that SLE is driven by INF α , the master regulator of inflammatory genes being turned on and causing tissue damage in SLE. In other words, INF α and, thus, SLE, have a "gene signature" and can be measured. The INF α -K phase I/II study showed that polyclonal MABs neutralize all subtypes of INF α , and the gene signature goes negative; it shuts off. Neovacs now has a target (INF α), a population (mild-mod SLE, INF α -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 INF α receptor has a similar effect to INF α -K in SLE (taking out INF α signaling). Thus, it stands to reason that MedImmune's progress with a MAB could be a predictor of the INF α -K phase IIb outcome. However, a cheaper vaccine, as opposed to a MAB, is more attractive from a commercial perspective. Combined, we believe that Neovacs' probability of success is significantly increased in the ongoing and upcoming phase II trials. Data expected in 1Q17...stay tuned.

DISCLOSURES

Neovacs S.A. Rating History as of 12/14/2015

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution

As of: 12/14/15

		% 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.	89%	46%
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.	11%	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.	1%	0%

**See valuation section for company specific relevant indices*

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

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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 managed/co-managed/acted as placement agent for an offering of the securities for Neovacs S.A. in the past 12 months.

Maxim Group received compensation for investment banking services from Neovacs S.A. in the past 12 months.

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: Our therapeutic model assumes that INF α -K could be approved and launch for SLE in the U.S., Europe, and China in 2020. INF α -K approval for dermatomyositis follows in 2021 in the U.S. and Europe. 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. A 30% discount rate is applied to our free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive our price target.

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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