Biotechnology

**ALNEV-FR** - NXT PA

January 7, 2016

| | |
|---|---|
| **Intraday Price 01/7/2016** | **€1.24** |
| Rating: | Buy |
| 12-Month Target Price: | €4.00 |
| 52-Week Range: | €0.66 - €1.47 |
| Market Cap (M): | 40 |
| Shares O/S (M): | 32.1 |
| Float: | 74.8% |
| Avg. Daily Volume (000): | 687 |
| Dividend: | €0.00 |
| Dividend Yield: | 0.00% |
| Risk Profile: | Speculative |
| Fiscal Year End: | December |

**Total Revenues ('000)**

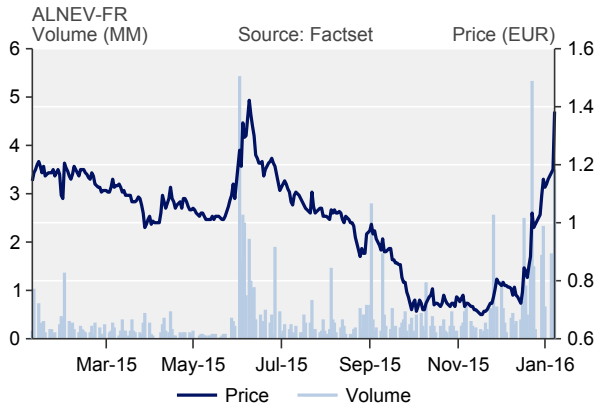
| | 2015E | 2016E | 2017E |
|---|---|---|---|
| H1 | €94A | €2,603 | €5,114 |
| H2 | €150 | €2,603 | €5,114 |
| FY | €244 | €5,207 | €10,227 |

**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) |




# Neovacs S.A.

**Buy**

## Non-Dilutive Funding to Support INF-K Development

### Summary


- **Neovacs announced that the company has secured €5M in non-dilutive funding through a public funding program ("Investments for the Future"). The funds will be used to support the clinical and industrial development of the companies lead active immune therapy (vaccine) INFα-K for Lupus.**
- **The majority of the funds will be used following the ongoing phase IIb POC study to build-out infrastructure to support a scale up in production from clinical batches to commercial scale. Owing to the very small quantities of INFα-K required per patient, the scale up should only need to be moderate.**
- **Recently added partner CDK Pharmaceutical Corp (058820:KS-$1,700.00-NR) in South Korea, which plans to file for registration in 2017 (launch 2018), pending the outcome of the ongoing global INFα-K phase IIb study (data 1Q17E) will continue to be supplied INFα-K from the current batch manufacturer**
- **Conclusion. This is more positive news for Neovacs. Neovacs is set to initiate another phase II studies in both the U.S. and China in 2016E. Additionally, data from Medimmune's (AZN-$33.34-NR) anifrolumab in Lupus shown in 4Q15 (see below), further validates INFα-K. Big pharma should be watching Neovacs.**


### Details

**What should be exciting for Neovacs and its investors is what MedImmune presented:** As a reminder, SLE may be driven by the cytokine INFα turning on dozens of inflammatory genes that cause flares and damage, thus SLE has a 'gene signature' we can quantify. Shutting down INFα signaling should then shut down the other genes (reversing the gene signature) and stop the inflammation (i.e flares). This may be the key to halting SLE. MedImmune's Phase II data (N=305) of its monoclonal antibody (MAb), anifrolumab, which does not target the INFα cytokine, but the INFα receptor (meaning it is the same pathway, knocking out the INFα driver of SLE). Anifrolumab shuts down the INFα gene signature, resulting in improved SLE disease severity scores (**abstract link**). In our opinion, this further validates Neovacs' INFα-K vaccine, which in an early study knocks out all of the 13 INFα subtypes, effectively shutting down the INFα gene signature and thus SLE. INFα-K-treated patients (N=5/6) remained flare-free and gene signature-negative for more than four years (and are still going). The difference is that INFα-k is a cheaper vaccine where as Anifrolumab, a monoclonal antibody like Humira, will likely cost $30K+ every year. Neovacs could treat SLE with INFα-K for just one year at a fraction of the cost, and, so far, the data look positive.

**INFα-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 INFα, the master regulator of inflammatory genes 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. Thus we believe that Neovacs' probability of success rises in the ongoing and upcoming phase II trials. Data expected in 1Q17...stay tuned.

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## DISCLOSURES

**Neovacs S.A. Rating History as of 01/06/2016**

powered by: BlueMatrix


| Maxim Group LLC Ratings Distribution | | As of: 01/06/16 | |
|---|---|---|---|
| | | % 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. | **88%** | **44%** |
| **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%** | **21%** |
| **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* | | |

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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 INFα-K could be approved and launch for SLE in the U.S., Europe, and China in 2020. INFα-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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