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# **FINANCIAL RESULTS FOR 2014**

- FY2014 in line with Company expectations
- Solid cash position of €5.6 million; financial structure significantly strengthened by equity line of up to €20 million
- Inititation of two clinical trials of IFNα-Kinoid in SLE as part of new therapeutic focus

Paris, February 27, 2015 – NEOVACS (Alternext Paris: ALNEV), a leader in active immunotherapies for the treatment of autoimmune diseases, today announced its full-year 2014 financial results, as approved by its Board of Directors on February 26, 2015.

#### **Full Year 2014 Results**

Summary financial information

In K€	2014	2013
Revenues	161	44
Operating costs	9,815	7,941
of which, R&D	7,753	6,194
Operating profit/loss	-9,654	-7,898
Pretax profit/loss	-9,812	-8,028
Exceptionnal items	-7	10
Research tax credit	-2,306	-1,148
Net profit /loss	-7 513	-6 870

Revenues for the year ended December 31, 2014 were €161,046, mainly comprised of the reimbursement of salary and other expenses related to two employees who performed work for another company during 2014 . As Neovacs is still a development stage enterprise, it does not generate sales revenue.

Operating costs increased by 22% year-over-year to €9.8 million in 2014, an increase that was primarily the result of the continuation of the Phase IIb clinical study in Rheumatoid Arthritis that the Company initiated in 2013. R&D expenses were 79% of the Company's total operating costs for 2014, while general and administrative expenditures remained under tight control.

Consequently, full-year operating losses were €9.7, an increase compared to 2013 (€7.9 million). After taking into account €2.3 million in Research Tax Credit, the net loss for the year ended 31 December 2014 was €7.5 million. This compares to a net loss of €6.9 million for the same period in 2013.

### Significant strengthening of financial resources

In order to address its long term financing needs, Neovacs secured a flexible, multiyear equity financing with Kepler Cheuvreux in November 2014. The equity line, through which Neovacs can access up to €20 million is arranged in three tranches of optional equity financing, one of €7 million and two of €6.5 million each. Less than half of the first tranche of financing has been utilized to date.

Available cash balances as of December 31, 2014 were €5.6 million, in line with the Company's projections based on its clinical program. Taking into account the equity financing, Neovacs has the financial resources to cover its expenditures for the next 12 months.

The Company has no debt and benefits from a sound balance sheet.

## 2014 highlights:

## Phase IIb clinical trial of TNF-Kinoid in Rheumatoid Arthritis (RA)

Neovacs initiated mid-2013 a phase IIb clinical trial of TNF-Kinoid in RA, following positive Phase IIa results obtained in 2012<sup>1</sup>. This international, double blind versus placebo study recruited 140 RA patients naïve to anti-TNF treatments. Its primary endpoint was clinical efficacy as measured by changes in DAS28 and ACR20 scores.

The results of the clinical trial were published in December 2014. Although the study confirmed the good safety profile and immunogenicity of the product, it failed to meet its primary endpoint. Several hypotheses are currently being evaluated to determine why TNF-Kinoid did not demonstrate clinical efficacy in RA.

#### Preparation of IFNα-Kinoid studies in Systemic Lupus Erythematosus (SLE or lupus)

In 2014, Neovacs continued to monitor patients from the phase I/II clinical trial of IFN $\alpha$ -Kinoid in SLE who still present Kinoid-induced antibody titers. New data generated from this follow-up analysis allowed the Company to present two posters<sup>2,3</sup> at the EULAR (European League Against Rheumatism) annual meeting in June 2014 and the American College for Rheumatology (ACR) annual meeting in November 2014. These results further support the superiority of a polyclonal antibody strategy over monoclonal antibodies in the treatment of SLE.

Based on these positive results, Neovacs made the strategic decision to initiate two clinical trials with  $IFN\alpha$ -Kinoid in SLE:

- A 160-patient phase IIb clinical trial in Europe, Asia and Latin America;
- A 50-patient phase I/II clinical trial in the United States

<sup>&</sup>lt;sup>1</sup> Results published in January 2012. Press release here: <a href="http://neovacs.fr/news-and-media/press-releases/?y=2012">http://neovacs.fr/news-and-media/press-releases/?y=2012</a>

<sup>&</sup>lt;sup>2</sup> "Serum IFN-alpha, but not IFN-beta or IFN omega, correlates with IFN signature in SLE patients" EULAR14-SCIE-3726. Abstract available at https://b-com.mci-group.com/AbstractList/EULAR2014.aspx

<sup>&</sup>lt;sup>3</sup> "Potent, broad, and specific neutralizing capacities of polyclonal anti-interferon alpha antibodies induced by IFN-Kinoid in SLE patient" EULAR14-SCIE-3713. Abstract available at https://b-com.mci-group.com/AbstractList/EULAR2014.aspx

Preliminary preparation for the clinical trials began in Q4 2014. Most notably, Neovacs secured a sourcing agreement to supply IFN $\alpha$ . Neovacs also formed a Clinical Advisory Board dedicated to lupus in November 2014.

## Preclinical development program of VEGF-Kinoid

In February 2014, Neovacs resumed preclinical activity on VEGF-Kinoid, an anti-VEGF immunotherapy developed in Age-Related Macular Degeneration (AMD) and solid tumors. Neovacs presented promising results for VEGF-Kinoid in AMD at the EVER conference in 2009<sup>4</sup>. First results from this preclinical activity are expected in the third quarter of 2015, with the goal of initiating clinical studies in 2016 for the most advanced VEGF-Kinoid program.

#### Outlook for 2015:

#### New members join Scientific Advisory Board (SAB)

Neovacs formed a scientific committee comprised of leaders in immune therapy, chronic inflammatory and autoimmune diseases in October 2014, with the goal of strengthening the Company's scientific base. The U.S.-based SAB meets several times a year under the Chairmanship of Prof. Jacques Banchereau, PharmD, Ph.D. Neovacs announced changes in its SAB membership to reflect the shift in the Company's therapeutic focus in favor of IFN $\alpha$ -Kinoid and VEGF-Kinoid in February 2015.

Miguel Sieler, Chief Executive Officer of Neovacs, concluded: "Financial results for 2014 are in line with our expectations and reflect a prudent management of expenditures despite the increase in clinical activity over the year. Thanks to a solid cash balance, strengthened by the equity financing in place with Kepler Cheuvreux, we have the financial resources necessary to pursue our clinical development program in 2015. We are integrating what we have learned in our previous trial as we are now focusing our efforts on IFN $\alpha$ -Kinoid and VEGF-Kinoid, two products with vast clinical potential and encouraging preliminary data".

#### **About Neovacs**

Created in 1993, Neovacs is today a leading biotechnology company focused on an active immunotherapy technology platform (Kinoids) with applications in autoimmune and/or inflammatory diseases. On the basis of the company's proprietary technology for inducing a polyclonal immune response (covered by five patent families that potentially run until 2032) Neovacs is focusing its clinical development efforts on IFN $\alpha$ -Kinoid, an immunotherapy being developed for the indication of lupus. Neovacs is also conducting preclinical development works on other therapeutic vaccines in the fields of auto-immune diseases, oncology and allergies. The goal of the Kinoid approach is to enable patients to have access to safe treatments with efficacy that is sustained in these life-long diseases.

## For more information on Neovacs, please visit www.neovacs.fr

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<sup>&</sup>lt;sup>4</sup> European Association for Vision and Eye Research (EVER) 2009, September 30-October 3, Portoroz, Slovenia. Abstract 4352.

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