

VALNEVA

Société Européenne with a Management Board and a Supervisory Board

Share capital: €8,555,317.14

Registered office: 70, rue Saint Jean de Dieu, 69007 Lyon

Lyon Companies Register (RCS) No.: Identification no.: 422 497 560

SUMMARY ON THE COMPANY'S SITUATION

1 – SITUATION OF THE COMPANY AND THE GROUP AND ITS ACTIVITY IN THE YEAR UNDER REVIEW, RESEARCH AND DEVELOPMENT/PROGRESS MADE OR DIFFICULTIES ENCOUNTERED

1.1 Composition and formation of the Valneva Group


Valneva SE ("the Company"), with its affiliates, (hereinafter together "the Group") is a European biotechnology company focusing on the development of vaccines and antibody discovery.

The Company results from the June 28, 2013 merger between Intercell AG and Vivalis SA.

Valneva's mission is to excel both in antibody discovery, development and commercialization of vaccines, as well as in programs based on innovative technologies developed by the Company, conducted internally or through collaborations with industrial partners.

1.2 Activities of the Group

Highlights of FY 2013 included:

- The merger between Vivalis and Intercell
 - Bioproduction activity's divestiture by Valneva, to the indian biopharmaceutical company BiologicalE.,
 - €40 million's share capital increase of the Company,
 - Majid Mehtali's passing in August 2013,
 - Signature of a \$30 million's loan agreement at the end of December 2013,
 - Update on Phase II/III interim analysis of Valneva's *Pseudomonas aeruginosa* vaccine candidate,
 - Positive Phase I Results for Valneva's *Clostridium Difficile* Vaccine Candidate.
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1.2.1 Merger between Vivalis and Intercell

Valneva SE was formed in May 2013 through the merger between Austrian biotech company Intercell AG and French biotech company Vivalis SA.

The merger was announced in December 2012 and approved in February/March 2013 by the Extraordinary Shareholders' Meetings of Intercell and Vivalis.

The aim of the merger was to create a fully integrated company specialized in vaccine development and antibody discovery with complementary skills and capabilities as well as diversified sources of revenues (marketed products and partnerships).

Intercell had been created in 1998 as a spin-off of the Research Institute of Molecular Pathology (IMP) in Vienna and was listed on the Vienna Stock Exchange since February 28, 2005. Intercell was manufacturing, marketing and distributing its own Japanese Encephalitis vaccine, had further vaccine candidates in clinical development, and proprietary platforms such as the IC31® adjuvant.

Vivalis had been created in 1999 as a spin-off of Groupe Grimaud, one of the world's leaders in animal genetic selection, and was listed on the Paris Stock Exchange since June 2007. The Nantes-based company had two proprietary technologies, the EB66® duck cell line – a novel vaccine production platform it was licensing to the world's leading pharmaceutical companies (GSK, Sanofi, Boehringer Ingelheim, etc) - and Viva|Screen®, a microarray-based single cell screening platform allowing rapid analysis and discovery of new and rare human monoclonal antibodies.

1.2.2 Bioproduction activity's divestiture by Valneva, to the Indian biopharmaceutical company Biological E.

In early June 2013, Valneva announced the sale of its Clinical Manufacturing Operations (CMO) in France to Biological E., a leading Indian biopharmaceutical company, as part of the Company's strategy to realize cost synergies of EUR 5 to 6 million annually. The sale was completed in November 2013.

1.2.3 €40 million's share capital increase of the Company

At the end of June 2013, Valneva launched a fully underwritten EUR 40 million capital increase with preferential subscription rights to strengthen the Company's financial profile and flexibility. The capital increase was oversubscribed by 146%, and the final gross proceeds amounted to EUR 40.2 million, with the issuance of around 15.2 million new shares. This share capital increase has been approved and recorded on July 5, 2013 by the Management Board of the Company.

1.2.4 Majid Mehtali's passing in August 2013

In August 2013, Valneva had to announce the passing of its Management Board member and Chief Scientific Officer, Majid Mehtali, at the age of 51. His passing was a great loss for the Company but the strong research team built by Majid Mehtali continued his work according to plan.



1.2.5 Signature of a \$30 million's loan agreement at the end of December 2013

In December 2013, Valneva announced it had secured a USD 30 million financing from an investment fund managed by Pharmakon Advisors for its Austrian subsidiary Valneva Austria GmbH, to support the sales growth of the Group's Japanese encephalitis vaccine IXIARO®/JESPECT® and to advance the company's pipeline of clinical candidates.

In addition to the guarantee given by the Company, this loan is secured by the payment of income related to sales of IXIARO / JESPECT on a special account with restricted use, and by a pledge of Valneva Austria shares and Valneva Scotland shares. The loan has a fixed interest rate of 9.5%. From 2016, Valneva will pay a fee of 2.6% to Pharmakon on IXIARO® /JESPECT® vaccine sales revenues made during the loan term.

1.2.6 Positive Phase I Results for Valneva's Clostridium Difficile Vaccine Candidate

The Company announced positive Phase Ia/Ib results for the company's vaccine candidate IC84 to prevent diseases caused by the bacterium Clostridium difficile (C. difficile). The pathogen is one of the main causes of nosocomial diarrhea.

IC84 showed a favorable safety and tolerability profile (primary objectives) in both study populations, elderly subjects and adults.

The vaccine candidate was highly immunogenic in elderly subjects and was able to induce similar immune responses to Clostridium difficile toxins A and B as the ones observed in adults in part Ia of the study (secondary objective).

1.2.7 Update on Phase II/III interim analysis of Valneva's Pseudomonas aeruginosa vaccine candidate

The Company provided an update on the Phase II/III efficacy study interim analysis of its Pseudomonas aeruginosa vaccine candidate - Valneva's vaccine candidate, IC43, is a recombinant subunit vaccine consisting of two outer membrane proteins (OprF and OprI) of Pseudomonas aeruginosa. These outer membrane proteins have been shown to be disease-relevant targets in numerous preclinical and several early clinical trials.

The development partners – Valneva and Novartis Vaccines & Diagnostics have initiated discussions on trial continuation in agreement with the recommendations of a Data Monitoring Committee (DMC) following their data review on the primary efficacy endpoint and safety data from 394 patients.

Although the stringent pre-specified futility criterion in regards to the primary efficacy endpoint was formally met, the difference in all-cause mortality rates (at Day 28) between the vaccine and placebo group in this randomized, placebo controlled double blind study, was considered clinically meaningful and in line with the trend observed in the previous study. Additionally there were no concerns with regard to the observed safety profile.



2 – BUSINESS DEVELOPMENT, RESULTS AND FINANCIAL POSITION

Please, refer to section 3.1.5 of the Registration Document (section 2 of the Management Board's annual report) filed with the Autorités des Marchés Financiers on april 30, 2014, and as available on our website: www.valneva.com.

