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VALNEVA
A European company (*Societas Europaea* or SE) with a Management and a Supervisory Board
With a capital of EUR 11,377,832.04
Registered office: 70, rue Saint Jean de Dieu, 69007 Lyon
R.C.S Lyon 422 497 560

SUMMARY ON THE GROUP SITUATION
ARTICLE R.225-81 OF THE FRENCH COMMERCIAL CODE

1. SITUATION OF THE COMPANY AND THE GROUP AND ITS ACTIVITY IN THE YEAR UNDER REVIEW

1.1. Presentation of the Valneva Group

Formed in 2013 through the merger of Intercell AG and Vivalis SA, Valneva is a biotechnology company developing, manufacturing and commercializing innovative vaccines. Furthermore, Valneva conducted research activities in the field of antibodies discovery, until December 31, 2014 (*cf.* Section 1.2.10 hereinafter).

Valneva's mission is to excel in the development and commercialization of innovative vaccines, i with a vision to protect people from infectious diseases, 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: 2014 Annual Operating Highlights

Operating highlights for the Group for 2014 were as follows:

+ Aeras initiates Phase II clinical trial of a tuberculosis vaccine candidate using IC31® adjuvant;
+ Approval and launch in South America of a second veterinary vaccine produced on the EB66® cell line;
+ Continuation of the Phase II/III clinical trial for its pseudomonas aeruginosa vaccine candidate;
+ First ever marketing authorization in Japan for a human vaccine produced in the EB66® cell line;
+ Valneva and Adimmune partner to commercialize Japanese encephalitis vaccine in Taiwan;
+ First ever marketing approval in Europe for a vaccine produced in the EB66® cell line;
+ Texas A&M inauguration of EB66®-based influenza vaccine facility;
+ Publication of pre-clinical data for its Lyme/ Borrelia vaccine candidate in international scientific journal PLOS ONE showing vaccine candidate can provide good safety and immunogenicity;
+ Publication of first phase II data of Valneva's tuberculosis vaccine candidate formulated with IC31® adjuvant showing good safety and immunogenicity;
+ Valneva and Blink Therapeutics Ltd. announce launch of new biotech company specialized in the discovery of innovative monoclonal antibodies;
+ Start of Phase II clinical trial of its Clostridium difficile vaccine candidate.

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1.2.1. Aeras initiates Phase II clinical trial of a tuberculosis vaccine candidate using IC31® adjuvant

On March 11, 2014, the Company distributed the following press release issued by Aeras, a nonprofit biotech advancing the development of tuberculosis vaccines for the world, about the initiation of a Phase II randomized clinical trial for their tuberculosis (TB) vaccine candidate Aeras-404 using Valneva's IC31® proprietary adjuvant.

Aeras-404 (also designated as H4IC) is a novel vaccine candidate developed jointly by Aeras, Statens Serum Institut (**SSI**), a state-owned enterprise under the Danish Ministry of Health and Prevention, integrated in the national Danish health services, tasked with preventing and controlling infectious diseases, biological threats and congenital disorders, and Sanofi Pasteur. It has already been tested in four Phase I studies which showed an acceptable safety profile and immunogenicity.

Aeras thus announced the initiation of the first randomized, controlled tuberculosis (TB) vaccine trial designed to study prevention of Mycobacterium tuberculosis (Mtb) infection by vaccination. The Phase II study of the TB vaccine candidate, H4+IC31® (AERAS-404), will evaluate its safety, immunogenicity, and ability to prevent infection by Mtb, the bacterium that causes TB. The trial, which will be conducted in South Africa, will also evaluate BCG revaccination.

The randomized, placebo-controlled, partially blinded trial will enroll 990 adolescents in the Western Cape Province. The South African Tuberculosis Vaccine Initiative (SATVI) will conduct this Phase II trial in healthy adolescents who have been previously vaccinated with BCG as infants. One-third of the participants will receive a revaccination with BCG; one-third will receive vaccination with H4+ IC31®, and one-third will receive a placebo. Infection will be determined with the use of commercially available interferon gamma release assays. Models indicate that an effective vaccine given to adolescents and adults, who bear the brunt of the TB burden, could have a dramatic impact on the global TB epidemic, preventing tens of millions of cases and millions of deaths from the disease.

Preliminary results are expected at the end of 2015. If this initial study in adolescents shows that revaccination with BCG or vaccination with H4+ IC31® prevents infection with Mtb, then additional larger scale efficacy studies looking at the impact on TB disease in more diverse populations would be warranted.

1.2.2. Approval and launch in South America of a second veterinary vaccine produced in the EB66® cell line

On March 13, 2014 the Company announced the approval and launch of a second veterinary vaccine produced in the EB66® cell line. The vaccine for the prevention of inclusion body hepatitis virus (IBH) was developed by Lima (Peru) based biopharmaceutical company FARVET SAC (FARVET), and will be available for sale in Peru and several other South American countries.

Inclusion body hepatitis is an acute disease of young chickens associated with anemia and hemorrhagic disorders. The vaccine is routinely used in many Central and South American countries. FARVET, which licensed the EB66® cell line in June 2012, developed and launched the IBH vaccine into the market in only 20 months.

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1.2.3. Continuation of the Phase II/III clinical trial for its pseudomonas aeruginosa vaccine candidate

On March 24, 2014 the Company announced the continuation of the current phase II/III clinical trial of its Pseudomonas aeruginosa vaccine candidate IC43.

Valneva's Pseudomonas aeruginosa vaccine candidate is targeted for ventilated intensive care patients, who are vaccinated after ICU admission and are at particular risk of life threatening Pseudomonas infections. Targeted patients include more than 700,000 patients in Europe and US.

Valneva and its co-development partner decided to continue the trial following different assessments including analyses conducted by a Data Monitoring Committee (DMC) and after consultation with two European regulatory agencies and experts.

The continuation decision was also taken since the interim analysis showed a clinically meaningful reduction in all-cause mortality rates for the vaccine group as compared to placebo, and no safety concerns were observed. These findings were in-line with previous Phase II results.

Valneva expects to resume recruitment for the trial in progress in the second quarter of 2014. In addition to the 394 patients already enrolled, another 400 ventilated intensive care patients are planned initially to be enrolled in this second phase of the study in 40 different sites. Preliminary results are expected at the end of 2015 / early 2016.

Although the difference on all-cause mortality between vaccine and placebo groups on day 28 (primary endpoint) at interim analysis was smaller than initially pre-specified, the development partners concurred to progress with the original sample size, to potentially achieve statistical significance in this pivotal trial earlier on a potential route to licensure. The company is however also considering the option to extend the study further if needed and justified.

1.2.4. First-ever marketing authorization for a human vaccine produced in the EB66® cell line

On March 24, 2014, the Company announced that the Chemo-Sero Therapeutic Research Institute (Kaketsuken), a co-development partner to GlaxoSmithKline (GSK), received the marketing authorization in Japan for a pandemic H5N1 influenza vaccine produced in Valneva's EB66® cell line.

The preventative vaccine is the first human vaccine produced in EB66® cells to be approved by any regulatory authority in the world. The vaccine has been developed in accordance to the Japanese government's plan to rapidly respond to an influenza pandemic both before and during an outbreak, and has been approved for prophylaxis of pandemic H5N1 influenza.

Kaketsuken has recently completed the construction of a state-of-the-art manufacturing facility in Kumamoto. Following a Japanese national directive, Kaketsuken will produce pandemic H5N1 vaccine for more than 40 million people within six months after the virus strain for vaccine production is decided.

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1.2.5. Valneva and Adimmune partner to commercialize Japanese encephalitis vaccine in Taiwan

On April 10, 2014, the Company announced that it had granted vaccine manufacturer Adimmune Corporation certain exclusive rights to its Japanese encephalitis (JE) vaccine in Taiwan. Adimmune will be entitled to register and commercialize Valneva´s JE vaccine under a local trade name and to develop, manufacture and commercialize such a vaccine from bulk product delivered by Valneva.

Japanese encephalitis is recognized as a major public health issue in Asia, as evidenced by its inclusion into the national vaccination schedules of many endemic countries in Asia including Taiwan. Adimmune has worked with the Taiwanese Center for Disease Control and Prevention for decades to ensure supply of its mouse-brain derived JE vaccine, for which public tenders have historically reached a level of 600,000 doses per year. The Taiwanese Advisory Committee on Immunization Practices (ACIP) has recently recommended the introduction of a more modern, cell culture-derived vaccine.

1.2.6. First ever marketing approval in Europe for a vaccine produced in the EB66® cell line

On May 19, 2014, the Company announced the first ever marketing approval in Europe for a vaccine produced in the EB66® cell line. The marketing authorization was granted by the European Medicines Agency (EMA) for the prevention of Muscovy Duck Parvovirus (MDPV).

MDPV is a contagious disease which causes high morbidity and mortality in one to three weeks-old ducklings and is a well-recognized hazard of commercial duck production. The disease, which has been reported from all major duck farming countries in Europe and other countries including the former Soviet Union, Israel, China, Vietnam and Japan, remains a serious problem in countries where Muscovy ducks are farmed intensively.

1.2.7. Texas A&M inauguration of EB66®-based influenza vaccine facility in Texas

The Company joined GlaxoSmithKline (GSK) in celebrating the site dedication of the Texas A&M Pandemic Influenza Vaccine Facility in Texas, which is on track for completion of construction by the end of 2015, to be followed by start-up phase in 2016. This new facility will provide the capabilities to manufacture bulk antigen for GSK's next generation pandemic influenza vaccine, based on Valneva's proprietary EB66® cell line, to help protect the United States against global influenza pandemics.

After completion of construction and subsequent validation of the facility to manufacture pandemic bulk antigen, the facility is expected to have the capacity to produce, within four months of a declared influenza pandemic and availability of acceptable virus seeds, the bulk antigen needed for up to 50 million doses of EB66®-based adjuvanted pandemic influenza vaccine for use by the US government in the event of an influenza pandemic.

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1.2.8. Publication of pre-clinical data for its Lyme/ Borrelia Vaccine Candidate in international scientific journal PLOS ONE showing good safety and immunogenicity;

On November 25, 2014, the Company announced that an article, presenting for the first time the pre- clinical data of its novel vaccine candidate for prevention of Lyme borreliosis, was published in PLOS ONE, the largest scientific journal in the world by volume.
The article, entitled "Design and development of a novel vaccine for protection against Lyme borreliosis", details for the first time Valneva´s Borrelia/Lyme borreliosis vaccine approach, with design, proof-of-concept studies and preclinical data on protection.

The publication reveals that Valneva's vaccine candidate, a multivalent, protein subunit based vaccine, has the potential to provide protection against the majority of Borrelia species pathogenic for humans. Lyme borreliosis is caused by at least four species of Borrelia and is transmitted via the bite of an infected tick. Delayed or inadequate treatment can lead to very serious symptoms, involving the joints, heart, and central nervous system, which can be disabling. There is currently no vaccine available to protect humans against Lyme borreliosis, the most common vector-borne infection in the Northern hemisphere.

1.2.9. Publication of first Phase II data of tuberculosis vaccine candidate formulated with IC31® adjuvant showing good safety and immunogenicity

On December 10, 2014 Valneva announced that the Statens Serum Institut's (SSI) novel Tuberculosis (TB) vaccine candidate H1/IC31® formulated with Valneva's proprietary adjuvant IC31® showed good safety and immunogenicity in Phase II clinical trial in HIV-infected adults.

H1/IC31® is a recombinant subunit vaccine based on two important TB antigens (Ag85B and ESAT-6) developed by SSI and formulated with Valneva's proprietary adjuvant IC31®, ultimately targeted toward adults and adolescents.

The results of the randomized, double-blind, clinical phase II trial initiated and led by Prof Churchyard from the Aurum Institute NPC, South Africa, were published in an article written by Dr. Reither of the Swiss Tropical and Public Health Institute (TPH), in the scientific publication PLOS ONE*. The aim of the trial, which was conducted in South Africa and Tanzania, was to evaluate the immunogenicity and safety of two doses of the TB vaccine candidate H1/IC31® in 48 HIV-positive adults (between 18 and 55 years of age).

According to the article, the vaccine candidate H1/IC31® was well tolerated and safe in HIV-infected adults with a CD4+ Lymphocyte count greater than 350 cells/mm^3. It did not affect HIV viral load and induced a specific and durable immune response against TB.

SSI is also conducting a second Phase II clinical study to assess the safety and immunogenicity of the H1/IC31® vaccine candidate in 240 adolescents.

1.2.10. Launch with BliNK Therapeutics Ltd. of a new biotech company specialized in the discovery of innovative monoclonal antibodies

On December 11, 2014 the Company and UK company BliNK Therapeutics Ltd ("**BliNK Therapeutics**") announced the creation of a private company specialized in the discovery of innovative monoclonal antibodies to be headquartered in Lyon, France and to be named BliNK Biomedical SAS.

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The creation of BliNK Biomedical SAS will give Valneva's antibody business the necessary structure and prospects to expand into novel antibody discovery fields outside of infectious diseases while offering a new investment opportunity for future additional shareholders. BliNK Biomedical SAS' powerful B cell technology will enable the isolation of antibody- producing cells for difficult targets for which other platforms have failed to deliver. This cutting-edge technology will be based on the combination of two validated platforms, BliNK Therapeutics' IVV and Valneva's VIVA|Screen®, which have already both succeeded in delivering high quality human antibodies. With the combined highly efficient process, an unprecedented capability to screen and identify extremely rare antibody-secreting cells will be achieved. This unique capability represents a major competitive advantage compared to other technologies.

Update: the closing of the transaction for the creation of BliNK Biomedical SAS was announced on January 20, 2015 (with retroactive effect on January 1, 2015) with all conditions precedent having been met, including the absence of material adverse events and the consent of certain third parties. BliNK Biomedical SAS is today held by Valneva (by approximately 48.2%), Kurma Biofund I (by approximately 30.6% - the historic investor of BliNK Therapeutics), different funds managed by Idinvest (for approximately 6.8%), the Cancer Research Technology (approximately 10.5%) et and the founders of BliNK Therapeutics Ltd (with approximately 3.7%).

1.2.11. Start of Phase II clinical trial of its Clostridium difficile vaccine candidate

On December 18, 2014, Valneva announced the initiation of the Phase II clinical trial of its VLA84 prophylactic vaccine candidate against Clostridium difficile (C. difficile), the main cause of nosocomial diarrhea. Data from the Phase I study in healthy elderly and adults showed good safety and immunogenicity of the vaccine candidate, and indicated functionality of induced antibodies, supporting the Company's decision to progress the vaccine candidate into Phase II.

The Phase II study (VLA84-201) will enroll 500 healthy subjects aged 50 years and older. This age group represents the target population for a prophylactic C. difficile vaccine as the risk to contract the infection-associated disease increases with age. The randomized, placebo-controlled, observer-blind study will be conducted in Germany as well as in the United States under an Investigational New Drug application (IND). It aims to confirm the optimal dose and formulation of the vaccine in two different age groups and to generate sufficient additional clinical data to advance the program into Phase III.

Valneva expects to announce the first results of the Phase II study at the end of 2015.

Valneva's C. difficile vaccine is part of the Strategic Alliance Agreement (SAA) which was signed between Valneva Austria GmbH and Novartis in 2007. Following completion of Phase II clinical development and if Novartis opts-in, Valneva will have the right, at its option, to either co-develop and profit-share with Novartis or to receive potential milestones for the remaining development period along with royalties tied to sales performance.

2. BUSINESS DEVELOPMENT, RESULTS AND FINANCIAL POSITION

Please, refer to Section 1 of the excerpt to the Management Board Report 2014 of the Company, such as published in the 2014 Annual Financial Report:
http://www.valneva.com/?page=80