VALNEVA

A European company (*Societas Europaea* or SE) with a Management and a Supervisory Board
Share capital: €13,816,511.49
Registered office: 6 rue Alain Bombard, 44800 Saint-Herblain (France)
Nantes Companies Register (RCS) No. 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

Valneva is a biotech company developing, manufacturing and commercializing vaccines for infectious diseases with major unmet needs.

Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by *Enterotoxigenic escherichia coli*. The Group has various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with approximately 480 employees. More information is available at www.valneva.com.

Valneva's Vision

Valneva's vision is to contribute to a world in which no one dies or suffers from a vaccine-preventable disease.

1.2 Activities of the Group: 2018 Annual operating highlights

Operating highlights for the Group in 2018 included:

+ the completion of a €50.0 million oversubscribed placement led by blue-chip US healthcare investors and supported by the Company's existing major shareholders;
+ the publication of positive Phase 1 interim results for the Group's Lyme disease vaccine candidate and the initiation of Phase 2 clinical development;
+ the initiation of a Phase 1 clinical study to evaluate the Group's single-shot vaccine candidate against chikungunya, the reporting of progress in the program and the granting of an FDA fast track designation;
+ the initiation of a Phase 1 Clinical Study to evaluate Emergent BioSolutions and Valneva's vaccine candidate against the Zika virus and the publication of Phase 1 interim data
+ the FDA approval of an accelerated vaccination schedule for the Group's Japanese encephalitis vaccine IXIARO®;
+ the signing of a collaboration and manufacturing agreement with Hookipa;
+ the extension of a drawdown period for the European Investment Bank Loan;
+ the transfer of Valneva's liquidity providing contract from Natixis to Oddo BHF.

(a) Completion of a €50.0 million oversubscribed placement led by blue-chip US healthcare investors and supported by the Company's existing shareholders

On September 27, 2018, Valneva SE announced that it has raised €50.0 million of gross proceeds in a private placement of its ordinary shares. The transaction, led by blue-chip US healthcare investors and supported by the Company's existing major shareholders, was heavily oversubscribed.

The capital raise was conducted by means of a private placement reserved for qualified investors. Approximately 81% of the shares were allocated to US investors. Two of the Company's major shareholders, Groupe Grimaud and MVM Life Science Partners, also participated in the placement. Groupe Grimaud and MVM Life Science Partners have subscribed 12% and 6% of the new shares respectively. On this basis, after completion of the capital increase, Groupe Grimaud and MVM Life Science Partners hold 15.1% and 7.3% of the Company's ordinary shares respectively.

Key characteristics of the offering

A total of 13,333,334 new shares, par value €0.15 each, were placed with new and existing investors. The closing date of the offering was October 1, 2018.

The issue price of the new shares was set at €3.75 per share, representing a 2.6% discount to the volume weighted average price of the Company's shares on the regulated market of Euronext Paris over the 3 last trading days before pricing (*i.e.* from September 24, 2018 to September 26, 2018 inclusive), which was €3.85.

Use of proceeds

The offering proceeds raised will be used to pursue the clinical development of the Group's pipeline candidates, notably its vaccine candidates against Lyme and chikungunya, as well as for working capital and general corporate purposes. Net proceeds will reinforce the cash position of the Group, which amounted to €37.7 million at the end of June 2018.

(b) Publication of positive Phase 1 interim results for the Group's Lyme disease vaccine candidate and initiation of Phase 2 clinical development

On March 19, 2018, Valneva SE announced positive Phase 1 interim results for its Lyme vaccine candidate, VLA15. The primary objective of the Phase 1 study VLA15-101 was to evaluate the vaccine candidate's safety and tolerability profile at different dose levels and formulations. Immunogenicity, measured by determining IgG antibodies against the six most prevalent serotypes of *Lyme borreliosis* in the U.S. (ST1) and Europe (ST1 to ST6) present in the vaccine, was also monitored for different dose groups and formulations at various time-points. This interim analysis for the primary and secondary endpoints includes safety and immunogenicity data up to Day 84 (month 3).

The study met its primary endpoint: the vaccine candidate showed a favourable safety profile. There were very few severe, related AEs in all treatment groups and no associated safety concerns. No differences in the safety profile were observed for the adjuvanted groups compared to the non-adjuvanted treatment groups. The safety profile of all tested doses and formulations is considered comparable to other licensed lipidated recombinant vaccines or lipid-containing vaccine formulations, and supports further clinical development for all doses and formulations.

VLA15 was also immunogenic in all doses and formulations tested. OspA-specific IgG antibody responses were induced in all treatment groups and against all OspA serotypes, with significant dose responses seen between the lowest and the highest dose groups. VLA15 was more immunogenic in adjuvanted treatment groups compared to non-adjuvanted treatment groups of the same dose level. For all six OspA serotypes, IgG levels were substantially higher after three immunizations (Day 84) compared to after two (Day 56).

Seroconversion Rates (SCR) for the highest, adjuvanted dose group, which is considered preferred for further development, ranged from 71.4% to 96.4% for the different OspA serotypes.

On July 2, 2018, Valneva SE announced that it had successfully concluded the end of Phase 1 process for this candidate with the U.S. Food and Drug Administration ("**FDA**") and had obtained alignment with regard to its Phase 2 strategy.

On October 25, 2018, the Company announced that the European Medicines Agency ("**EMA**") also provided positive feedback on its general development approach for its Lyme disease vaccine candidate. EMA's comprehensive scientific advice was largely aligned with previous discussions with the FDA on the strategy for the VLA15 development and reaffirmed the Group's key development assumptions.

On December 17, 2018, Valneva SE announced the initiation of the Phase 2 Clinical Development for its Lyme disease vaccine candidate. The overall Phase 2 objective for VLA15 is to determine the optimal dosage level and schedule for use in Phase 3 pivotal field efficacy studies, based on immunogenicity and safety data. The Phase 2 development for the Lyme disease vaccine candidate will include the evaluation of the highest dose of VLA15 tested in Phase 1 in addition to two higher doses. Furthermore, the Group plans to include the evaluation of an additional, alternative three-dose schedule. The Phase 2 duration is expected to be approximately two years with interim data (primary endpoint) expected mid-2020.

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For more information on the progress of the program since the end of the fiscal year 2018, please refer to Section 3.4 of this Annual Management Report.

(c) Initiation of a Phase 1 clinical study to evaluate the Group's single-shot vaccine candidate against chikungunya, the reporting of progress in the program and the granting of an FDA fast track designation

On March 13, 2018, Valneva SE announced the initiation of a Phase 1 clinical trial in the U.S. to evaluate the safety and immunogenicity of VLA1553, its live-attenuated vaccine candidate against chikungunya. The Phase 1 clinical trial is a randomized, observer-blinded, dose-escalation, multi-center study. It will investigate three different dose levels of VLA1553 in approximately 120 healthy adults vaccinated with a single-shot immunization.

On October 16, 2018, the Company announced that the Group had commenced the second stage of its Phase 1 study. A first group of study participants has then being re-vaccinated. This re-vaccination will act as an intrinsic human challenge, with the goal of demonstrating that subjects are protected from vaccine-induced viremia early in the VLA1553 clinical development.

In addition, on December 21, 2018, Valneva SE announced that the U.S. Food and Drug Administration had granted Fast Track designation for its chikungunya vaccine candidate. Fast Track designation is granted by the FDA to products under development for serious conditions that have the potential to fulfill an unmet medical need. Fast Track is designed to facilitate the clinical development and expedite the review of new drugs and vaccines with the intention of accelerating the availability of promising products on the market.

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For more information on the progress of the program since the end of the fiscal year 2018, please refer to Section 3.2 of this Annual Management Report.

(d) Initiation of a Phase 1 Clinical Study to evaluate Emergent BioSolutions and Valneva's vaccine candidate against the Zika virus and the publication of Phase 1 interim data

On February 26, 2018, Emergent BioSolutions Inc. (NYSE: EBS) and Valneva SE announced the initiation of a Phase 1 clinical trial in the U.S. to evaluate the safety and immunogenicity of VLA1601, their vaccine candidate against Zika virus. The Phase 1 clinical trial is a randomized, observer-blinded, placebo-controlled, single center study. This study, in approximately 65 healthy adults, investigates two dose levels of VLA1601 when administered using two different vaccination schedules.

On November 19, 2018, the two companies announced positive interim results for this Phase 1 study. The highly purified inactivated vaccine candidate met the study's primary endpoint showing a favorable safety profile in all doses and schedules tested. VLA1601 was also immunogenic in all treatment groups and induced both dose- and schedule-dependent neutralizing antibodies against the Zika virus with the kinetics expected for an inactivated, alum-adjuvanted whole-virus vaccine. Seroconversion Rates (SCR) reached up to 85.7% on Day 35 (Interim Analysis of Data up to Day 56). The Phase 1 clinical trial is being co-financed by Emergent BioSolutions Inc. and Valneva SE as part of an exclusive, worldwide license agreement signed in July 2017. The agreement includes pre-defined post-Phase 1 opt-in rights for Emergent BioSolutions Inc.

(e) FDA approval of an accelerated vaccination schedule for the Group's Japanese encephalitis vaccine IXIARO®

On October 5, 2018, Valneva SE announced that the FDA had approved an alternate IXIARO® immunization schedule of two doses administered seven days apart for adult travelers aged 18-65 years old. This accelerated schedule comes in addition to the previously approved schedule. IXIARO® is the only *Japanese encephalitis* vaccine licensed and available in the U.S. The vaccine was approved with a two-dose primary immunization with the two vaccinations administered 28 days apart. The newly-approved accelerated vaccination schedule allows rapid immunization in adults with the two doses given seven days apart. This rapid schedule has already been approved and is used in Europe and Canada. The FDA's revised schedule follows previous approvals by Health Canada and the European Medicines Agency, who authorized accelerated IXIARO® vaccination schedules for adult travelers in March 2018 and April 2015, respectively.

(f) Signing of a collaboration and manufacturing agreement with Hookipa

On December 6, 2018, Valneva Sweden AB, the Swedish subsidiary of Valneva SE, and Hookipa Pharma Inc., announced that they had entered into a three-year collaboration and manufacturing agreement.

Under the terms of the agreement, Valneva Sweden AB will provide analytical services, develop process scale-up and produce Good Manufacturing Practices clinical trial material to support the development of new immunotherapies based on Hookipa's Vaxwave® and TheraT® arenavirus vector-technologies. In return, Valneva Sweden AB will receive fixed and success-based service fees. The agreement may be extended beyond three years.

(g) Extension of drawdown period for the European Investment Bank Loan

On September 20, 2018, Valneva SE announced that it had agreed, with the European Investment Bank ("**EIB**"), a one-year extension to its loan facility. The €25.0 million loan was granted to the Company by the EIB in July 2016. Valneva has drawn down €10.0 million of the €25.0 million facility[1] and can now draw down a further €15.0 million before the end of July 2019. Under the terms of the

[1] Two tranches of €5.0 million each, in April and December 2017 respectively.

agreement signed with the EIB, each credit tranche is repayable at the end of a five-year period commencing from the drawdown date.

Valneva plans to use the funds to advance its research and development ("**R&D**") programs, including its Lyme disease vaccine candidate.

(h) Transfer of Valneva Liquidity Providing Contract from Natixis to Oddo BHF

On July 18, 2018, Valneva SE announced that its Liquidity Providing Agreement was transferred from Natixis to Oddo BHF. By agreement dated June 25 2018, Valneva has entrusted Oddo BHF and Natixis with the implementation of a liquidity and market supervision contract. Consistent in particular with the AMF Decision 2018-01 establishing liquidity contracts on equity securities as an accepted market practice, this agreement is effective for a period of one year starting July 2, 2018 and tacitly renewable.

2. BUSINESS DEVELOPMENT, RESULTS AND FINANCIAL POSITION

Please, refer to Section A.4.1 of the Company's Registration Document 2018, as published on Valneva SE website: http://www.valneva.com/en/investors-media/registration-document