

H1 2016

HALF-YEAR FINANCIAL REPORT

JANUARY 1 TO JUNE 30, 2016

August 31, 2016

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GENERAL INTRODUCTORY COMMENTS AND DISCLAIMER

In this interim financial report, unless stated otherwise, the terms “Company”, “Valneva” and “Group” refer to Valneva SE and its subsidiaries.

This interim financial report does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful. The Valneva shares may not be offered or sold in the USA. The offer and sale of the Valneva shares has not been and will not be registered under the US Securities Act.

This interim financial report contains forward-looking statements about the Group's targets and forecasts, especially in chapter 4 – “Operational and strategic outlook FY 2016”. Such statements are based on data, assumptions and estimates that the Company considers reasonable.

They are subject to change or adjustments to factor in uncertainties inherent in all research and development activities, as well as the economic, financial, competitive, regulatory and climatic environment. In addition, the Group's business activities and its ability to meet its targets and forecasts may be affected if some of the risk factors described in chapter 5 – “Risk factors” of this interim financial report arise.

Investors are urged to pay careful attention to the risk factors before making their investment decision. One or more of these risks may have an adverse effect on the Group's activities, condition, the results of its operations or on its targets and forecasts. Furthermore, other risks not yet identified or considered as significant by the Group could have the same adverse effects, and investors may lose all or part of their investment.

Forward-looking statements, targets and forecasts shown in this interim financial report may be affected by risks, either known or unknown uncertainties and other factors that may lead to the Group's future results of operations, performance and achievements differing significantly from the stated or implied targets and forecasts. These factors may include changes in economic or trading conditions and regulations, as well as the factors set forth in chapter 5 – “Risk factors” of this interim report.



1. MANAGEMENT REPORT

1.1 Overview

Valneva is an independent vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to advance vaccines for better lives.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

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, for the prevention of ETEC (Enterotoxigenic *Escherichia coli*). The Company has proprietary vaccines in development including candidates against *Clostridium difficile* and *Lyme borreliosis*. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (the EB66[®] vaccine production cell line and the IC31[®] adjuvant).

Valneva's ordinary shares (ISIN code: FR0004056851) are traded on segment B of Euronext Paris (stock code: VLA.PA) and eligible for the deferred settlement service ("Service de Règlement Différé" or "SRD"). The Group is part of the CAC MID&SMALL 190 index and the CAC PME index. Valneva's shares are also traded on the Prime Market of the Vienna Stock Exchange (stock code: VLA.VI)

1.2 Operational Review

1.2.1 Commercialized vaccines

Valneva's commercialized vaccines are its main sources of revenue. Product sales from the two fully owned and manufactured products IXIARO[®]/JESPECT[®] and DUKORAL[®] are complemented by sales revenues from the distribution of third party products in markets where Valneva maintains its own marketing and sales infrastructure.

Valneva intends to further leverage its sales and marketing presences in Canada, the European Nordic countries and in the UK through the distribution of additional complementary products.

Japanese encephalitis vaccine (IXIARO[®]/JESPECT[®])

Valneva's first marketed product is a next-generation vaccine indicated for active immunization against the Japanese encephalitis (JE) virus which aims to protect travelers, military personnel, and residents in endemic regions. It is licensed in more than thirty-five countries and marketed under the trade names IXIARO[®] in North America, Europe, Hong Kong, and Singapore, and under the trade name JESPECT[®] in Australia and New Zealand.

Since the approval of IXIARO[®]/JESPECT[®] in 2009, the vaccine label has been extended by the European Medical Agency (EMA) and the US Food and Drug Administration (FDA) for use in children from the age of 2 months. In parallel, the Company, together with its marketing & distribution partners, has been focusing on increasing penetration through its sales and marketing activities and global expansion strategy.

In 2012, Valneva's partner Biological E. Ltd. launched the JEEV[®] vaccine to protect small children and adults from JE in India. The product, based on Valneva's technology, is manufactured at Biological



E.'s facility in Hyderabad, India. JEEV[®] was prequalified by the World Health Organization (WHO). Valneva has been receiving royalties on Biological E.'s sales since 2014.

In April 2014, Valneva granted vaccine manufacturer Adimmune Corporation certain exclusive rights to its JE vaccine in Taiwan. Adimmune is entitled to register and commercialize Valneva's JE vaccine under a local trade name and to manufacture and commercialize the vaccine from bulk product delivered by Valneva. At the beginning of 2016, Valneva announced that Adimmune was granted marketing approval for the vaccine by the Taiwanese Food & Drug Administration (TFDA). Adimmune now intends to establish a local fill-and-finish operation and expects to supply the vaccine for the Taiwanese national immunization program within the next two years under the trade name JEVAL[®].

In May 2015, the European Medical Agency (EMA) approved an accelerated IXIARO[®] vaccination schedule that allows adult travelers (18-65 years) to receive full immunization within one week compared to almost four weeks under the conventional vaccination schedule (second dose 28 days after first dose).

In June 2015, Valneva announced its decision to take direct control over the marketing and distribution of IXIARO[®] by terminating the marketing and distribution agreement it had signed with Novartis vaccines in 2006 which had been transferred to GlaxoSmithKline (GSK) in 2015. The decision was taken in support of Valneva's strategy to build a leading, independent and fully integrated vaccine company, and to leverage synergies with the second travel vaccine (DUKORAL[®]) and commercial infrastructure in the Nordic countries which were acquired in 2015. As of today, the Company's own dedicated sales and marketing organization, with offices in the US, Canada, UK and Sweden, manages more than 60% of the expected 2016 product sales.

Valneva now distributes the IXIARO[®] vaccine directly to the US military, its largest client for the product and, in the first quarter of 2016, announced the signing of a \$42 million contract with the US Government's Department of Defense. Under the terms of the agreement, Valneva will supply IXIARO[®] doses to the US military for a total value of \$42 million over a two-year period to protect the nearly 360,000 US military and civilian personnel, and their families, working and living in endemic countries. To complement its distribution of IXIARO[®] to the US public market, Valneva entered into distribution and marketing service agreements with VaxServe Inc, a Sanofi Pasteur company, at the end of 2015. Under the terms of the agreements, VaxServe performs marketing and promotional services and distributes IXIARO[®] exclusively in the US private market.

In the first half of 2016, revenues from IXIARO[®]/JESPECT[®] product sales doubled to €30.1 million compared to €15.3 million in the first half of 2015. The increase was strongly driven by the capturing of additional revenue margins under the new sales and distribution network and also benefited from strong demand from the US military and the US, German, UK and Canadian private markets. Based on first-half sales, Valneva re-affirms its full year 2016 guidance of revenues from IXIARO[®]/JESPECT[®] product sales reaching approximately €50 million.

Cholera / ETEC vaccine (DUKORAL[®])

DUKORAL[®] is an oral vaccine indicated for the prevention of cholera and, in some countries, ETEC (Enterotoxigenic *Escherichia Coli*) or diarrhea caused by LT-ETEC. DUKORAL[®] is indicated for adults and children from 2 years of age who will be visiting endemic areas. DUKORAL[®] was first granted authorization for use in Sweden in 1991. In 2004, DUKORAL[®] was granted a marketing authorization by the European commission for European Union members (including Norway and Iceland) and was prequalified by the World Health Organization.

In February 2015, Valneva completed the acquisition of the DUKORAL[®] vaccine and a distribution business in the Nordic countries to create a critical mass in its travel vaccine portfolio and add a commercial infrastructure to its assets. The business has now been fully integrated.



In support of the Company's objective to directly control the marketing and commercialization of its products in key markets, Valneva created a commercial subsidiary in Canada, DUKORAL[®]'s largest market at the beginning of 2015, and now distributes the vaccine directly to the Canadian market. To complement the Company's own marketing and distribution network, DUKORAL[®] is commercialized through country-specific marketing & distribution arrangements in various other markets. Mid-2015, Valneva notably entered into a commercial agreement with US firm PaxVax for the marketing and distribution of DUKORAL[®] in Italy, Spain and Portugal. In return, Valneva commercializes PaxVax's typhoid vaccine Vivotif[®] in Canada and the Nordic Countries.

At the end of 2015, following a review of the product monograph by Health Canada, Valneva announced an update of the indication and labelling of DUKORAL[®] in Canada. The vaccine is now indicated in Canada for immunization against cholera and the prevention of diarrhea caused by LT-ETEC¹, the most frequent cause of traveler's diarrhea. As compensation for the label change, Valneva was granted a €25 million reduction in the purchase price agreed with the seller which the Company partially used in the first quarter of 2016 to repay a €15 million loan.

Despite the negative transitional impact of the change in the product monograph in Canada which led the Company to suspend promotional efforts at the end of 2015 and at the beginning of 2016, DUKORAL[®] sales in the first half of 2016 reached €9.8 million compared to €8.1 million reported by Valneva in the first half of 2015.

Valneva confirms its expectation to achieve its DUKORAL[®] full year 2016 revenue goal of approximately €23 million (vs €26.3 million on a pro-forma basis in 2015). The Company will continue to invest in growing the DUKORAL[®] vaccine by way of promotional efforts and geographic expansion.

Third-party distribution

Valneva currently distributes third-party products in Canada, the UK and the Nordic countries and intends to leverage its sales and marketing presence in other countries by signing new distribution and marketing agreements. At the end of August 2016, Valneva announced the signing of an agreement with Seqirus, the second largest flu company in the world, for the marketing & distribution of Seqirus' seasonal flu vaccines Sandovac[®] and Fluad[®] in Austria. Seqirus is the global company created in July 2015 from the combined strength and expertise of bioCSL Inc. and the influenza vaccine business formerly owned by Novartis AG. Under the terms of the agreement, Valneva will start distributing the Sandovac[®] and Fluad[®] vaccines to the Austrian market at the beginning of the 2016-2017 flu season.

1.2.2 Technology and services

EB66[®] cell line

Valneva's EB66[®] cell line, which is derived from duck embryonic stem cells, is a highly efficient platform for vaccine production and today represents a compelling alternative to chicken eggs for large scale manufacturing of human and veterinary vaccines. EB66[®] is one of the most extensively studied and characterized cell lines available for use in vaccine development. More than 20 different families of viruses have been shown to be efficiently propagated in EB66[®] cells².

¹ A heat-labile toxin producing *Enterotoxigenic Escherichia coli*

² A clinical Phase I study of an EB66 cell-derived H5N1 pandemic vaccine adjuvanted with AS03. Takeshi Naruse et al. Vaccine 33 (2015) 6078-6084 <http://dx.doi.org/10.1016/j.vaccine.2015.09.22>



To date, Valneva has more than 35 EB66[®]-based research and commercial license agreements with the largest pharmaceutical companies including GlaxoSmithKline, Sanofi-Pasteur and Zoetis. Current licenses have the potential to yield milestone payments totaling approximately €80 million in addition to royalties on sales at rates of 3-6% for human vaccines and 1.5-5% for veterinary vaccines. To date, milestone payments already been received by the Company for the licensing of its EB66[®] technology amount to approximately €34 million. A research license generally has a term of between 12 and 24 months and generates modest payments. If successful it can evolve into a commercial license with upfront payments, clinical milestone payments and royalties.

Five EB66[®]-based vaccines have already been approved worldwide both in human and animal health, and an EB66[®]-based anti-cancer Newcastle Disease Virus (NDV) vaccine candidate is currently available to treat human patients in Europe through the advanced therapy medicinal products (ATMP) pathway³.

An important ongoing EB66[®] clinical development program in the human vaccine field is linked to pandemic and seasonal influenza programs for which Valneva granted an exclusive EB66[®] license to GSK. In the second quarter of 2016, Valneva recorded its first royalties from the sale of EB66[®]-based pandemic influenza vaccines under this partnership. GSK is developing its EB66[®] cell based influenza vaccines in the US in partnership with the Texas A&M University System.

Valneva's EB66[®] cell-line has become increasingly profitable and the Company expects growing cash-contributions from this technology.

During the first six months of 2016, Valneva also signed new agreements for its EB66[®] cell line including several research license agreements with European companies whose names have not been disclosed and a commercial license agreement for its EB66[®] technology with Gallant Custom Laboratories Inc., a Canadian subsidiary of the German animal health firm IDT Biologika GmbH. Under the terms of the Gallant agreement, the licensee is able to use the EB66[®] cell line to develop, manufacture and commercialize vaccines for the prevention of influenza virus in poultries and fowl adenovirus. Gallant is the only Canadian company authorized by the Canadian Food Inspection Agency (CFIA) to manufacture autogenous viral and bacterial vaccines. Financial terms of the agreement were not disclosed but include cash payments for achieved milestones as well as future royalties on net sales.

Valneva expects to continue to sign new license agreements for its EB66[®] cell line.

IC31[®] adjuvant / IC31[®] tuberculosis vaccine

IC31[®] is a synthetic vaccine (T-cell) adjuvant which can be combined easily with target antigens to improve vaccine response. The role of adjuvants in vaccination is to enhance and shape the immune response to specific antigenic components of vaccines through targeted activation of the immune system. IC31[®] demonstrated that it improved the quality of the immune response in various pre-clinical and clinical trials.

The technology has been licensed to a number of parties, including GSK, Statens Serum Institute, and Sanofi Pasteur, who are evaluating IC31[®] in new vaccine formulations.

³ Advanced Therapy Medicinal Product: http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm;
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000296.jsp;
http://www.iozk.de/en/topics/dendritic_cells_oncolytic_virus



An important ongoing IC31[®] based clinical development program is focused on Tuberculosis, which remains one of the world's largest infectious disease threats⁴. In this area, Valneva is collaborating with the Statens Serum Institut (SSI) in Denmark and SSI's partners, Aeras and Sanofi Pasteur. Three clinical vaccine candidates, all formulated with Valneva's IC31[®] adjuvant, are currently being tested in Phase I and II clinical trials. The Statens Serum Institut's novel tuberculosis vaccine candidate H1/IC31[®] showed good safety and immunogenicity in a Phase II clinical trial in HIV-infected adults⁵.

At the beginning of 2015, Valneva announced the signing of an exclusive worldwide commercial license agreement with Immune Targeting Systems (subsequently acquired by Vaxin Inc., now called Altimmune), granting the rights to develop and commercialize Hepatitis B vaccine candidates in combination with Valneva's IC31[®] adjuvant.

In July 2015, Altimmune announced that it had enrolled the first patient in a phase I clinical trial of HepTcell[™], its immunotherapeutic compound to treat people chronically infected with the hepatitis B virus (HBV). The multicenter trial is being conducted at seven sites within the UK with the goal of recruiting 72 patients with chronic HBV infection.

Existing licenses and collaborations represent a significant potential source of revenues from milestone payments to which future royalties on sales could be added.

1.2.3 Vaccine candidates

Valneva's current proprietary clinical pipeline includes vaccine candidates against *Clostridium difficile*, which has completed Phase II development, and Lyme borreliosis, which is expected to enter Phase I in the later part of 2016.

During the second quarter of the year, Valneva announced that the Phase II/III trial results of its *Pseudomonas aeruginosa* vaccine candidate (VLA43) did not confirm prior Phase II and interim analysis findings which had shown a clinically meaningful vaccine effect of all-cause mortality reduction. As a result, the Company decided to discontinue the program.

Beyond its clinical stage product candidates, Valneva is building a growing pipeline of pre-clinical candidates, some of which are now ready for clinical testing. The Company has been able to develop this pipeline with the help of the technological and scientific competence gained in developing viral vaccines, including the bench-to market experience with its Japanese encephalitis vaccine (JEV).

The Company's most advanced pre-clinical projects focus on Zika and Chikungunya.

Clostridium difficile vaccine candidate – VLA 84

Clostridium difficile (*C. difficile*) is the leading cause for nosocomial diarrhea in Europe and the US. There are an estimated 450,000 cases of *C. difficile* in the US annually⁶. Currently, no vaccine against *C. difficile* exists and antibiotic treatment of the established disease has significant limitations with recurrence in ~20% of cases. Valneva estimates that the total market opportunity for prophylactic *C. difficile* vaccines may significantly exceed \$1 billion annually.

At the end of July 2016, Valneva announced that it successfully completed Phase II development of its *C. difficile* vaccine candidate and that the final results confirmed the previously announced positive topline data that it presented at the American Society of Microbiology's annual meeting, ASM Microbe 2016, on June 17, 2016 in Boston. VLA84 was immunogenic at all doses and formulations tested, in

⁴ One-third of the world's population is believed to be infected with TB./ Tuberculosis Fact sheet N°104". WHO. October 2015. Retrieved 11 February 2016

⁵ Reither et al. 2014. PLoS One 9:e114602.

⁶ Lessa et al, Burden of *Clostridium difficile* Infection in the United States. N Engl J Med 2015;372:825-34.



that Immunoglobulin G (IgG) and functional (neutralizing) antibody responses were seen. The study met its primary endpoint in terms of identifying the dose/formulation with the highest seroconversion rate against both toxins A and B and confirmed the favorable safety profile observed in Phase I.

Final Phase II results included the follow-up on the 500 study participants out to Day 210. This long-term data confirmed the optimal vaccine dose and formulation that had been previously identified (high-dose formulation without adjuvant) with an immunogenicity profile at Day 210 in line with expectations.

Valneva's *C. difficile* Phase II trial was a randomized, placebo-controlled, observer-blind multi-center trial designed to further study and confirm the candidate vaccine's safety, immunogenicity and proposed doses of immunizations in two different age groups (50 to 64 years of age and 65 years of age and older). The trial was conducted in Germany and the United States under an Investigational New Drug application (IND) and included 500 volunteers who were randomized in several study groups: low-dose vaccine without adjuvant, high-dose vaccine with or without adjuvant (Aluminiumhydroxid), or placebo.

The Phase II study design had been agreed in advance with regulators with the aim of supporting a subsequent progression into Phase III. Valneva has confirmed Phase III readiness through an independent Scientific Advisory Board (SAB) and is now ready to support an end-of Phase II meeting (EOP2 meeting) once the final Phase III design is agreed with a potential partner. The Company reaffirms its expectation to enter into a partnering agreement for its *C. difficile* program by the end of year.

Lyme borreliosis vaccine candidate – VLA 15

Lyme borreliosis (LB) is a multi-systemic infection caused by *Borrelia* bacteria, transmitted by infected ticks. Delayed or inadequate treatment of a *Borrelia* infection can lead to very serious disease progression, involving the joints, heart, and central nervous system, and can be disabling. Each year, according to the Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans are diagnosed with Lyme disease with a further 180,000 to 200,000 cases in Europe. Currently, there is no licensed vaccine available to protect humans against Lyme disease.

Valneva has developed a multivalent vaccine candidate (VLA15) which is based on the immunogenicity of OspA, one of the most dominant proteins expressed by the bacteria when present in a tick. Pre-clinical data have shown that this vaccine candidate can provide protection against the majority of *Borrelia* species pathogenic for humans⁷.

Valneva plans to commence a Phase I trial towards the end of 2016. The single-blind, partially randomized, dose escalation Phase I study trial will be conducted in the US and Europe. Besides its primary objectives of evaluating safety and tolerability, immunogenicity (measured by observing IgG antibodies specific against six OspA serotypes), various dose groups and formulations at different time-points will be explored.

Pre-clinical vaccine candidates

Zika vaccine candidate – VLA 1601

Valneva recently announced successful generation of a highly-purified vaccine candidate using the same manufacturing platform as its Japanese encephalitis vaccine, a vaccine which has already been approved by the American (FDA, Health Canada), European (EMA) and other regulatory agencies. By working on a vaccine technology that is familiar to the regulatory agencies and has been previously

⁷<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294>



used in approved commercial vaccines, Valneva believes that the regulatory risk can be minimized, resulting in the most efficient path to market. The Zika vaccine candidate, generated on the IXIARO[®] (JESPECT[®]) platform, has demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to the commercially produced JE vaccine. Based on recent scientific publications⁸ showing that in-vivo neutralization correlates with protection of mice in Zika challenge models, the Company believes that its vaccine candidate has shown scientific proof of concept. Valneva has already received a positive feedback from the European Medicines Agency (EMA) and is now seeking a partner to support advancement into clinical testing.

Other vaccine candidates

Other pre-clinical stage projects include vaccines against diseases such as Chikungunya (CHIKV), yellow-fever (YF) or Human metapneumovirus (hMPV):

The Chikungunya virus re-emerged from East Africa in 2014 to cause devastating epidemics of debilitating and often chronic arthralgia that have affected millions of people in the Indian Ocean Basin and other parts of Asia. There is currently no antiviral treatment for CHIKV infection and no licensed vaccine to prevent the disease. Valneva is working on a live attenuated vaccine candidate focusing on single-shot protection.

Although a live attenuated vaccine has been used to prevent yellow fever for more than 70 years, frequent supply problems and potential adverse reactions underline the necessity of a new, modern and well tolerated yellow fever vaccine.

In addition to much-needed new travel vaccine candidates, Valneva is also targeting one of the most significant and common human viral infections, hMPV. Although the virus was primarily known as causative agent of respiratory tract infections in children, hMPV has become an important cause of respiratory infections in adults as well. To date, no vaccine is available and treatment is supportive.

Valneva expects that its research programs will lead to the development of novel vaccine candidates and form part of its clinical portfolio in the coming years.

1.3 Financial Review

Note: First half 2016 and first half 2015 IFRS results are not fully comparable because of the acquisition of the Crucell Sweden AB business in February, 2015. As a result of the acquisition, which included all assets, licenses and privileges related to DUKORAL[®] as well as a vaccine distribution business in the Nordics, the comparator period of 2015 includes specific acquisition-related transaction effects and the results of the acquired business only from the acquisition closing date on February 9, 2015. Furthermore, the Company amended the presentation of its income and cash flow statements compared to the consolidated annual financial statements for the year ended December 31, 2015 with respect to “gain on bargain purchase” (now presented within “operating profit/loss”) and “interest paid” (now presented within the “cash flow from financing activities”). The previous year comparative period was adjusted accordingly.

1.3.1 Second quarter 2016 financial review⁹

Revenues and grants

Valneva's aggregate second quarter 2016 revenues and grants increased to €26.7 million from €19.7 million in the second quarter of 2015. This increase resulted mainly from the strong growth of IXIARO[®]/JESPECT[®] product sales.

⁸ Abbink et al. 2016, Science, epub ahead of print, DOI: 10.1126/science.aah6157

⁹ Second quarter financial results are unaudited while the consolidated half year financial statements are audited



Product sales in the second quarter of 2016 increased to €20.5 million from €12.4 million in the second quarter of 2015. IXIARO[®]/JESPECT[®] product sales contributed €15.6 million to revenues in the second quarter of 2016 and almost tripled compared to the second quarter 2015 product sales of €5.3 million. The strong increase was driven by shipments to the US military and by the capturing of additional revenue margins under the new sales and distribution structure effective since the start of the fiscal year. DUKORAL[®] sales contributed €4.4 million to the second quarter 2016 product sales representing a growth of €0.9 million compared to the second quarter of 2015. Third Party product sales decreased to €0.5 million in the second quarter of 2016 from €3.5 million in the second quarter of 2015 due to the fact that a couple of GSK vaccines are no longer marketed by Valneva.

Revenues from collaborations and licensing decreased from €6.2 million in the second quarter of 2015 to €5.4 million in the second quarter of 2016.

Grant income decreased from €1.1 million in the second quarter of 2015 to €0.8 million in the second quarter of 2016.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €8.8 million in the second quarter of 2016 of which €4.0 million related to IXIARO[®]/JESPECT[®] sales, yielding a product gross margin of 74.3%. €2.6 million of COGS related to DUKORAL[®] sales, yielding a gross margin of 42.2%. Of the remaining COGS for the second quarter of 2016, €0.3 million related to the Third Party product distribution business and €1.9 million related to cost of services. In the comparator period of 2015, COGS were €11.5 million, of which €4.5 million related to IXIARO[®]/JESPECT[®], €5.3 million to DUKORAL[®] and €1.7 million to cost of services.

Research and development (R&D) expenses in the second quarter of 2016 reached €6.7 million compared to €7.0 million in the second quarter of the previous year.

Distribution and marketing expenses in the second quarter of 2016 amounted to €4.1 million, compared to €2.3 million in the second quarter of 2015. Distribution and marketing costs increased as a result of the establishment of the Company's own sales and marketing organization following the termination of its global distribution partnership with GSK in June 2015.

General and administrative (G&A) expenses in the second quarter of 2016 amounted to €3.6 million, compared to €4.3 million in the second quarter of 2015.

Amortization and impairment charges in the second quarter of 2016 amounted to €35.9 million and included €34.1 million non-cash impairment charges related to the *Pseudomonas aeruginosa* project. The final Phase II/III study results for the *Pseudomonas* vaccine candidate published during the second quarter of 2016 did not confirm a positive vaccine effect, resulting in the discontinuation of the program and full impairment of the related intangible assets. Excluding this one-time effect amortization and impairment, charges remained unchanged compared to the second quarter of 2015 and amounted to €1.8 million.

Valneva's operating profit for the second quarter 2016 was also impacted by the €34.1 million impairment charges related to the *Pseudomonas* project and amounted to a loss of €32.3 million. Excluding the one-time impairment charges, Valneva achieved considerably improved profitability and delivered an operating profit amounting to €1.8 million compared to an operating loss of €7.3 million reported for the second quarter of 2015.

Valneva's second quarter 2016 EBITDA continued showing strong improvements and amounted to an EBITDA profit of €4.7 million compared to an EBITDA loss of €4.4 million in the second quarter of 2015. EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €37.0 million from the operating loss of €32.3 million as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase.



Segment overview

The Commercialized Vaccines segment showed an operating profit of €7.0 million in the second quarter of 2016, compared to an operating loss of €1.9 million in the second quarter of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €8.6 million in the second quarter of 2016 which compares to an operating loss of €0.2 million in the second quarter of 2015.

The Technologies and Services segment showed an operating profit of €1.3 million in the second quarter of 2016 compared to €2.4 million operating profit in the second quarter of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €1.4 million in the second quarter of 2016 compared to €2.5 million in the second quarter of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €2.8 million in the second quarter of 2016 (excluding one-time impairment charges of €34.1 million related to the Pseudomonas project) compared to €3.4 million in the second quarter of 2015.

Net result

Valneva's net loss in the second quarter of 2016 was €34.4 million compared to a net loss of €8.8 million in the second quarter of the prior year. Excluding the one-time impairment charges related to the Pseudomonas project, Valneva's net loss significantly improved to €0.3 million driven by increased product sales and improved operating results. Finance expenses increased to €1.9 million in the second quarter of 2016 from €1.4 million in the second quarter of 2015, mainly due to negative exchange rate effects on financial assets held in British Pounds (£). Going forward, the Company's operating expenses, in particular cost of goods for the JE vaccine manufactured in Scotland, are expected to benefit from the weakness of the British Pound versus the Euro.

Cash flow

Net cash generated by operating activities in the second quarter of 2016 amounted to €10.5 million compared to net cash used in operating activities of €1.0 million in the second quarter of 2015, and resulted from the positive operating profit excluding the non-cash impairment charges and from a reduction in working capital primarily driven by reduced accounts receivable at quarter-end.

Cash outflows from investing activities in the second quarter of 2016 amounted to €0.4 million and resulted primarily from purchase of equipment.

Cash outflows from financing activities in the second quarter of 2016 amounted to €4.5 million and primarily consisted of re-payments of loans in connection with grants.

1.3.2 First half 2016 financial review

Revenues and grants

Valneva's aggregate first half 2016 revenues and grants increased to €51.4 million from €39.2 million in the first half of 2015. This increase was mainly a result of strong growth of IXARO[®]/JESPECT[®] product sales.

Product sales increased to €40.9 million in the first half of 2016 from €27.5 million in the first half of 2015. IXARO[®]/JESPECT[®] product sales contributed €30.1 million to revenues in the first half of 2016 compared to €15.3 million in the first half of 2015 representing 97% growth. The strong increase was driven by the capturing of additional revenue margins under the new sales and distribution network and also benefited from strong demand from the US military and from the US and German private



markets. DUKORAL[®] sales contributed €9.8 million to the first half 2016 product sales representing growth of €1.7 million compared to the first half of 2015. Third Party product sales in the first half of 2016 decreased to €0.9 million from €4.0 million in the first half of 2015 due to the fact that a couple of GSK vaccines are no longer marketed by Valneva.

Revenues from collaborations and licensing decreased from €9.7 million in the first half of 2015 to €8.7 million in the first half of 2016.

Grant income slightly decreased from €2.0 million in the first half of 2015 to €1.8 million in the first half of 2016.

Operating result and EBITDA

Cost of goods and services sold (COGS) in the first half of 2016 were €21.7 million of which €10.5 million related to IXIARO[®]/JESPECT[®] sales, yielding a product gross margin of 65.4%. €6.8 million of COGS related to DUKORAL[®] sales, yielding a gross margin of 30.9%. Of the remaining COGS for the first half of 2016, €0.9 million related to the Third Party product distribution business and €3.5 million related to cost of services. In the comparator period of 2015, COGS were €23.7 million, of which €11.4 million related to IXIARO[®]/JESPECT[®], €6.6 million to DUKORAL[®], €3.2 million to Third Party products, and €2.5 million to cost of services.

Research and development (R&D) expenses in the first half of 2016 reached €12.5 million and remained flat compared to the first half of 2015.

Distribution and marketing expenses in the first half of 2016 amounted to €7.4 million compared to €3.5 million in the first half of 2015. Distribution and marketing costs increased as a result of the establishment of the Company's own sales and marketing organization following the termination of its global distribution partnership with GSK in June 2015.

General and administrative (G&A) expenses slightly increased in the first half of 2016 and amounted to €7.3 million compared to €7.1 million in the first half of 2015.

Amortization and impairment charges for the first half of 2016 amounted to €37.7 million and included €34.1 million non-cash impairment charges related to the *Pseudomonas aeruginosa* project. The final Phase II/III study results for the *Pseudomonas* vaccine candidate published during the second quarter of 2016 did not confirm a positive vaccine effect resulting in discontinuation of the program and full impairment of the related intangible assets. Excluding this one-time effect, amortization and impairment charges amounted to €3.5 million compared to €3.6 million in the first half of 2015.

Valneva's operating loss for the first half of 2016 was also impacted by the €34.1 million impairment charges relating to the *Pseudomonas* project and amounted to a loss of €35.1 million. Excluding the one-time impairment charges Valneva's operating performance amounted to a loss of €0.9 million compared to an operating gain of €2.2 million reported for the first half of 2015. The first half of 2015 included a €13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of the Crucell Sweden AB business. Without taking into account the positive one-time effect Valneva's operating loss in the first half of 2015 amounted to €11.0 million.

Valneva's first half 2016 EBITDA showed a strong improvement and amounted to an EBITDA profit of €4.7 million, compared to an EBITDA loss of €5.3 million in the first half of 2015. EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €39.7 million from the operating loss of €35.1 million as recorded in the condensed consolidated income statement under IFRS. EBITDA also excludes the gains from bargain purchase.



Segment overview

The Commercialized Vaccines segment showed an operating profit of €10.1 million in the first half of 2016 compared to an operating loss of €1.2 million in the first half of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €13.4 million in the first half of 2016 and €2.1 million in the first half of 2015.

The Technologies and Services segment showed an operating profit for the first half of 2016 of €1.8 million compared to €3.1 million in the first half of 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €2.1 million in the first half of 2016 compared to €3.4 million in the first 6 months of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €5.4 million in the first half of 2016 (excluding one-time impairment charges of €34.1 million related to the Pseudomonas project) compared to €5.8 million in the first half of 2015.

Net result

Valneva's net loss in the first half of 2016 was €39.5 million. Excluding the one-time impairment charges related to the Pseudomonas project, Valneva's net loss amounted to €5.3 million compared to a net profit of €0.9 million in the first half of the prior year. The first half of 2015 included a €13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of the Crucell Sweden AB business. Without taking into account the positive one-time effect, the net loss of €5.3 million in the first half of 2016 would compare to a net loss of €12.2 million in the first half of 2015, representing significant improvements in product sales and operating results in 2016. Finance expenses increased to €4.3 million in the first half of 2016 from €2.7 million in the first half of 2015, mainly due to exchange rate effects.

Cash flow and liquidity

Net cash generated by operating activities in the first half of 2016 amounted to €3.9 million, compared to net cash used in operating activities of €10.9 million in the first half of 2015. This strong improvement resulted from the positive EBITDA development and was also helped by working capital effects.

Cash inflows from investing activities in the first half of 2016 amounted to €17.4 million and resulted primarily from a re-payment received from Johnson & Johnson in connection with the adjustment of the purchase consideration for the acquisition of Crucell Sweden AB and the DUKORAL[®] business.

Cash outflows from financing activities in the first half of 2016 amounted to €24.3 million and included the re-payment of borrowings to Athyrium LLC as well as re-payments of loans in connection with grants.

Liquid funds on June 30, 2016 stood at €38.7 million, compared to €43.7 million on June 30, 2015 and consisted of €34.0 million in cash and cash equivalents, €4.0 million in short-term bank deposits and €0.6 million in restricted cash.

1.4 Operational and Strategic Outlook FY 2016

Valneva's strategy is to achieve financial returns by focusing R&D investments in promising product candidates and growing financial contributions from commercial products and technologies - striving towards financial self-sustainability. Valneva will execute this strategy by:



- + Maximizing the value of both its Japanese encephalitis vaccine, IXIARO[®] (also known as JESPECT[®] in certain territories) and its cholera/ETEC vaccine DUKORAL[®] by combining the Company's own marketing and sales teams with a network of country-specific distribution partners
- + Expanding its portfolio of marketed products by partnering and/or through mergers and acquisitions
- + Bringing in-house clinical candidates to their next value inflection points and seeking the best product specific partnering opportunities
- + Leveraging the potential of its main technology platforms (EB66[®] cell line, IC31[®] adjuvant)
- + Improving financial performance by growing revenues, leading to improved margins, and focusing R&D investments with the goal of reaching profitability.

For the second half of 2016, the Company expects to deliver on the following major objectives:

- + Improvement of financial performance in line with previously communicated estimates as detailed below
- + Continuous increase in product sales and net margins compared to prior year
- + A partnering agreement to fund the Phase III study of its *C. difficile* vaccine candidate for which the Company recently reported successful final Phase II results
- + Initiation of clinical trials with its Lyme vaccine candidate
- + Additional license agreements for EB66[®]

With respect to financial performance, Valneva estimates that 2016 overall IFRS revenues and grants will reach €90 to €100 million, with product sales between €70 and €80 million, reflecting up to 30% growth over 2015 product sales. The Company estimates that improved revenues due to its new global marketing and distribution network will lead to a gross margin on product sales of approximately 50% in 2016. Valneva will continue to strive towards financial self-sustainability and expects to reduce its EBITDA loss to less than €5 million while continuing to invest around €25 million in R&D.

For its long-term outlook, Valneva's goal is to grow its revenues to approximately €250 million in 2020 through existing and future products while generating positive cumulative cash-flows.

The Group will continue to build on value growth from R&D and invest significant amounts in an innovative and focused R&D pipeline.

1.5 Risk Factors

Pursuing biotech innovation includes the inherent risk of failure and the Company is therefore exposed to significant industry-specific risks. Valneva is subject to additional risks because (a) virtually all of its revenues, excepting grants and third party products, arise from two commercialized vaccines only, namely DUKORAL[®] and IXIARO[®]/JESPECT[®] and (b) it recently created its own distribution network, a combination of in-house sales and marketing entities and independent distributors, and needs to demonstrate that these can reach the expected level of sales. Moreover, the Company has incurred significant losses since its inception, is exposed to liquidity risk and may never reach sustainable profitability. Management has undertaken considerable efforts to establish a risk management system in order to monitor and mitigate the risks associated with its business.

However, the Company remains exposed to significant risks, including in particular the following:

Valneva may **fail to reach its sales goals** for its two commercial vaccines and to develop and commercialize its product candidates as expected or at all. The ability to commercialize product



candidates will depend upon the degree of market acceptance among Valneva's primary customers, the customers of Valneva's strategic partners and the medical community. This degree of market acceptance will depend upon many factors, including recommendations by global and local health organizations, reimbursements by health authorities and health insurers and payers, legislative efforts to control or reduce health care costs or reform government healthcare programs, and the ability of customers to pay or be reimbursed for treatment costs. Demand for Valneva's vaccines may be adversely affected by international, national or local events or economic conditions that affect consumers' willingness to travel, such as security concerns relating to threatened or actual terrorist attacks, armed conflicts or recent crises in the global economy.

The Company expects the **IXIARO[®]/JESPECT[®] sales** to grow very significantly in 2016, from €30.6 million to approximately €50 million. To achieve the planned level of sales, Valneva's new sales and marketing organization and distributors need to gain further market acceptance for this product and to achieve superior sales and marketing performance in full compliance with applicable laws and regulations.

At the end of 2015, following a regulatory process initiated by Health Canada, the **DUKORAL[®] indications in Canada** were narrowed. While Valneva expects a limited decline in the DUKORAL[®] sales in Canada (please see the end of Section 1.2.1 in this report), Valneva might not be able to restrict the impact to its expected size. Because Canada is the largest market for the DUKORAL[®] vaccine, lower sales could adversely affect Valneva's revenues, operations and financial condition.

The Company's **manufacturing facilities** in Livingston, Scotland, and Solna, Sweden, are, and will continue to be, significant factors in growing revenues from product sales and maintaining control over production costs. The manufacturing of biological materials is a complex undertaking and technical problems may occur. Valneva may experience delays, be unsuccessful in manufacturing or face difficulties in the ability to manufacture its products according to market demands or in meeting regulatory requirements. Biological manufacturing is subject to government regulation and regular inspection. It is not possible to predict the changes that regulatory authorities may require during the life cycle of a novel vaccine. Such changes may be costly and may affect the Company's sales and marketing and product revenue expectations. The failure of any of Valneva's product manufacturing facility to comply with regulatory requirements, including current Good Manufacturing Practices, could give rise to regulatory actions or suspension or revocations of manufacturing licenses and result in failure to supply. The risk of suspension or revocation of a manufacturer's license also applies to third party manufacturers and contractors with whom the Company contracts for manufacturing and services.

The Company's manufacturing facility in Livingston, Scotland, is the **sole source of commercial quantities** of the JE vaccine. The Company's manufacturing facility in Solna, Sweden, is the sole source of commercial quantities of the DUKORAL[®] vaccine. The destruction of either of these facilities by fire or other catastrophic events would prevent the Company from manufacturing the relevant product and supplying its customers and therefore would cause considerable losses. Its business requires the use of hazardous materials, which increases the Company's exposure to dangerous and costly accidents that may result in accidental contamination or injury to people or the environment. In addition, the business is subject to stringent environmental health and safety and other laws, regulations and standards, which result in costs related to compliance and remediation efforts that may adversely affect the Company's performance and financial condition.

The Company's sales largely depend upon (i) the maintenance, renewal or transfer of **marketing authorizations** granted by regulatory authorities, (ii) the therapeutic indications approved by such authorities, (iii) recommendations issued by authorities or advisory bodies, and (iv) the regulatory



status of the Company's products, e.g. prescription or over-the-counter (OTC), reimbursable or not, etc... Any difficulty or delay in maintaining, renewing, amending or transferring marketing authorizations, or any changes in the scope or terms of such authorizations or regulatory status, may adversely affect the Company's revenues, profits and financial condition.

The development and success of the Company's commercial vaccines and several of its product candidates are dependent upon the performance of **third-party manufacturers and contractors**. Should these manufacturers and contractors fail to meet requirements, the development and commercialization of the Company's product and product candidates may be limited or delayed, which would have a material adverse effect on the Company's business, financial condition, and results of operations.

The Company's **R&D activities**, and in particular its late-stage clinical trial programs, are expensive and time-consuming. The result of these R&D activities is inherently uncertain and the Company may experience delays or failures. In order to continue to develop and commercialize its product candidates, the Company will require regulatory approvals from the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other relevant regulatory agencies, which may be delayed or denied if the Company cannot establish the safety and efficacy of its product candidates. Adverse events or lack of efficacy in its clinical trials may force the Company to stop development of its product candidates, prevent regulatory approval of its product candidates, or impact its existing products which could materially harm its business.

The vaccine industry is highly competitive, and if the Company's **competitors** commercialize their products more quickly than Valneva or develop alternatives to Valneva's products or sell competing products at lower prices, the Company might lose a significant share of the expected market.

The Company's ability to commercialize its product candidates or to license its technologies partially depends on the ability to obtain and maintain adequate protection of its **intellectual property rights** in the U.S., the EU, and elsewhere. If the Company's efforts to protect its intellectual property rights are not sufficient, competitors may use its technologies to create competing products, erode the Company's competitive advantage, and capture all or part of its expected market share. The Company's efforts to avoid infringing, or to defend itself against any claims of infringement of the intellectual property rights of third parties may be costly and, if unsuccessful, may result in limited or prohibited commercialization of its product candidates or licensing of its technologies, subject to royalties or other fees, or force it to redesign its product candidates.

The Company may be unsuccessful in establishing additional or maintaining existing, **strategic partnerships** and collaborations, which could significantly limit or delay its ability to develop and commercialize discoveries and inventions and realize results from its R&D programs and technologies. The success of strategic partnerships depends, in part, on the performance of the strategic partners, over which the Company has little or no control. Partners may elect to delay or terminate one or more of these strategic partnerships, develop products independently or in collaboration with a third party that could compete with the Company's product candidates, fail to commit sufficient resources to the development or commercialization of the product candidates which are subject to these partnerships or collaborations, or otherwise fail to perform as Valneva expects. If any of these risks materialize, Valneva's revenues from up-front license payments, milestone payments, and royalties generated from product candidates that are subject to these partnerships and collaborations may be substantially reduced, which would have a material adverse effect on Valneva's business, financial condition, and results of operations.

Future business opportunities or a delay or failure in the development or commercialization of one or more of the Company's product candidates may result in **requirements for additional funding**, which may only be available, if at all, with unfavorable consequences or on unfavorable terms. If the



Company is not able to fulfill investor or analyst expectations, its ability to raise financing may be adversely affected.

Any failure to appropriately **monitor and manage the Company's development**, including any wrong investment decision, as well as any failure to successfully integrate businesses acquired in the future may have a material adverse effect on the Company's business, financial condition, and results of operations. If Valneva undertakes a merger or acquisition, the process of integrating its existing operations with any newly acquired or merger partner business, technology, service or product could be expensive and time consuming and may result in unforeseen operating difficulties and expenditures. The development and commercialization of the Company's product candidates may be delayed if Valneva is unable to recruit and retain top managers and qualified scientific and commercial personnel or if any of the key members of the Management or scientific or commercial staff discontinues his or her employment or consulting relationship with the Company.

Some of the Company's research programs, namely C. difficile and Zika, require that the Company finds a **new development and licensing partner**. The Company may not be able to enter into a development or licensing agreement with any partner for either or both of these product candidates, thus adversely affecting the Company's prospects and, in the case of C. difficile, potentially resulting in an impairment of the relevant assets.

Impairment of intangible assets may lead to substantial losses in Valneva's profit and loss statement. The Company's balance sheet includes substantial intangible assets from development stage projects and technologies, which have been gained through business combinations. If the Company is not able to successfully develop these products and technologies and generate future cash flows from such products and technologies, it may never be able to recover the consideration paid to acquire such intangible assets and, as a consequence, will have to impair the corresponding intangible asset. Such impairment of intangible assets would result in substantial losses in the profit and loss statement.

The use of any of Valneva's product candidates in clinical trials and the sale of any of Valneva's current or future products will subject the Company to potential **liability** or product liability claims. The Company's clinical trial liability and product liability insurance coverage may not be sufficient to cover liability or product liability claims, which Valneva may incur as a result of the use of its product candidates in clinical trials or the sale of current and future products, or may cease to be available at a reasonable cost in the future.

As mentioned in note 11 to the H1 financial statements (section 3 of this report), a claim for additional payment has been raised, and **litigation** has been threatened, in connection with the 2009 sale of the Humalys company, by which Vivalis (now Valneva) acquired a technology which was later combined with other antibody discovery technologies and spun off to Blink Biomedical. Valneva believes that this claim is without merit. Consequently, no litigation reserves have been set. Valneva cannot rule out the possibility that the claimants may want to litigate in the near future.

The Company's success largely depends on the work and expertise of **its management and commercial and scientific personnel**. The loss of their skills could affect the Company's ability to achieve its goals.

Poor development in the **credit markets** and financial services industries, and the general deterioration in **global economic conditions** could decrease consumer discretionary spending and global growth rates, impair Valneva's ability to raise money to fund the expansion of its operations, adversely affect Valneva partners' ability or willingness to further develop and commercialize partnered products or impair the value of, or returns on, Valneva's investments. The Company is exposed to market risk, including price risk and cash flow and fair-value interest rate risk and it is exposed to credit risks.



In addition, operating results may be negatively affected by exposure to **foreign exchange** and other economic risk factors. Valneva may not be able to use **tax loss carry-forwards** to offset future taxable income and as a consequence may face higher future tax obligations than expected and/or may have to repay tax credits.

Further risk factors are set out in detail in the registration document of Valneva filed with the AMF on May 11, 2016 under number D.16-0473.

1.6 Related Parties' transactions

In the first six months of 2016 and 2015, there was no transaction or change in transactions between related parties which materially affected Valneva's financial position or performance.



2. AUDITOR'S REPORT ON THE CONDENSED CONSOLIDATED HALF YEAR FINANCIAL REPORT

This is a free translation into English of the statutory auditors' review report on the half-yearly financial information issued in French and is provided solely for the convenience of English-speaking users. This report includes information relating to the specific verification of information given in the Group's half-yearly management report. This report should be read in conjunction with, and construed in accordance with, French law and professional standards applicable in France.

To the Shareholders

In compliance with the assignment entrusted to us by your Annual General Meeting and in accordance with the requirements of article L. 451-1-2 of the French Monetary and Financial Code ("Code monétaire et financier"), we hereby report to you on:

- the review of the accompanying condensed half-yearly consolidated financial statements of Valneva SE, for the period from January 1 to June 30, 2016;
- the verification of the information presented in the half-yearly management report.

These condensed half-yearly consolidated financial statements are the responsibility of the Board of Directors. Our role is to express a conclusion on these financial statements based on our review.

1. Conclusion on the financial statements

We conducted our review in accordance with professional standards applicable in France. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with professional standards applicable in France and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed half-yearly consolidated financial statements are not prepared, in all material respects, in accordance with IAS 34 - standard of the IFRSs as adopted by the European Union applicable to interim financial information.

Without qualifying our conclusion, we draw your attention to the matter set out in Note 1 « Basis of preparation » to the interim condensed consolidated financial statements, which discloses the changes operated in the income statement as of June 30, 2015 from the previous version of the half-year consolidated financials issued in the prior year and to the matter set out in Note 5 "Intangible Assets" to the interim condensed consolidated financial statements regarding the €34.1 million impairment charges related to the Pseudomonas development project.

2. Specific verification

We have also verified the information presented in the half-yearly management report on the condensed half-yearly consolidated financial statements subject to our review.

We have no matters to report as to its fair presentation and consistency with the condensed half-yearly consolidated financial statements.

Marseille and Neuilly Sur Seine, August 30, 2016

The Statutory Auditors

Deloitte & Associés

Vincent Gros

PricewaterhouseCoopers Audit

Thierry Charron



3. CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT AS OF JUNE 30, 2016

CONDENSED CONSOLIDATED INTERIM INCOME STATEMENT

€ in thousand (except per share amounts)	Three months ended June 30,		Six months ended June 30,	
	2016	2015 ¹⁰	2016	2015 ¹⁰
Product sales	20,459	12,360	40,908	27,497
Revenues from collaboration, licensing and services	5,431	6,232	8,729	9,708
Revenues	25,890	18,592	49,636	37,205
Grant income	811	1,121	1,751	2,009
Revenues and grants	26,700	19,713	51,387	39,214
Cost of goods and services	(8,770)	(11,547)	(21,691)	(23,658)
Research and development expenses	(6,658)	(6,985)	(12,457)	(12,489)
Distribution and marketing expenses	(4,061)	(2,274)	(7,356)	(3,492)
General and administrative expenses	(3,558)	(4,316)	(7,323)	(7,083)
Other income and expenses, net	(48)	(6)	43	146
Amortization and impairment of fixed assets/intangibles	(35,939)	(1,844)	(37,658)	(3,638)
Gain on bargain purchase	-	-	-	13,183
OPERATING PROFIT/LOSS	(32,334)	(7,259)	(35,054)	2,183
Finance income	162	101	189	2,157
Finance expenses	(1,926)	(1,365)	(4,270)	(2,706)
Result from investments in affiliates	-	(167)	-	(264)
PROFIT/LOSS BEFORE INCOME TAX	(34,098)	(8,690)	(39,135)	1,369
Income tax	(325)	(156)	(325)	(423)
PROFIT/LOSS FOR THE PERIOD	(34,422)	(8,846)	(39,460)	946
Profit/losses per share for profit/loss for the period attributable to the equity holders of the Company, expressed in € per share				
- basic	(0.46)	(0.12)	(0.53)	0.1
- diluted	(0.46)	(0.12)	(0.53)	0.1

¹⁰ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10) as well as the presentation of the gain on bargain purchase within the operating result.

**CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE INCOME**

€ in thousand	Three months ended June 30,		Six months ended June 30,	
	2016	2015 ¹¹	2016	2015 ¹¹
Profit/Loss for the period	(34,422)	(8,846)	(39,460)	946
Other comprehensive income/(loss) Items that are or may be reclassified subsequently to profit or loss				
Currency translation differences	(1,353)	1,415	(1,120)	(1,576)
Total items that are or may be reclassified subsequently to profit or loss	(1,353)	1,415	(1,120)	(1,576)
Other comprehensive income/(loss) for the period, net of tax	(1,353)	1,415	(1,120)	(1,576)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD ATTRIBUTABLE TO THE OWNERS OF THE COMPANY	(35,775)	(7,432)	(40,580)	(630)

¹¹ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).

**CONDENSED CONSOLIDATED INTERIM BALANCE SHEET**

€ in thousand	June 30, 2016	December 31, 2015
ASSETS		
Non-current assets	117,763	158,804
Intangible assets and goodwill	61,092	98,567
Property, plant and equipment	40,177	42,439
Other non-current assets	16,495	17,797
Current assets	92,022	116,383
Inventories	24,013	26,687
Trade receivables	21,655	15,754
Other current assets	7,696	31,374
Cash, cash equivalents, short-term deposits and current financial assets	38,657	42,567
TOTAL ASSETS	209,785	275,187
EQUITY		
Capital and reserves attributable to the Company's equity holders	104,268	144,335
Share capital	11,205	11,205
Share premium and other regulated reserves	245,965	245,965
Retained earnings and other reserves	(113,442)	(92,219)
Net result for the period	(39,460)	(20,617)
LIABILITIES		
Non-current liabilities	71,807	84,489
Borrowings	64,817	76,568
Deferred tax liability	93	112
Other non-current liabilities and provisions	6,897	7,810
Current liabilities	33,710	46,363
Borrowings	15,650	25,687
Trade payables and accruals	10,062	10,698
Current tax liability	657	425
Tax and employee-related liabilities	5,569	6,889
Other current liabilities and provisions	1,772	2,664
TOTAL LIABILITIES	105,517	130,852
TOTAL EQUITY AND LIABILITIES	209,785	275,187

**CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENT**

€ in thousand	Six months ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Profit/Loss for the period	(39,460)	946 ¹²
Depreciation and amortization	5,617	5,654
Impairment	34,109	-
Share-based payments	699	262
Income tax	326	436
Other adjustments for reconciliation to cash used in operations	4,821	(8,804)
Changes in working capital	(2,141)	(9,233)
Cash generated from/(used in) operations	3,971	(10,739)
Income tax paid	(83)	(146)
Net cash generated from/(used in) operating activities¹³	3,888	(10,886)
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of other businesses, net of acquired cash	15,279	(22,181)
Purchases of property, plant and equipment	(817)	(935)
Proceeds from sale of property, plant and equipment	1	173
Purchases of intangible assets	(226)	(502)
Investments in associated companies	-	(1,999)
Interest received	3,189	53
Net cash generated from/(used in) investing activities	17,427	(25,390)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of costs of equity transactions	-	41,838
Disposal/(Purchase) of treasury shares	(185)	(2)
Proceeds from borrowings, net of transaction costs	-	14,719
Repayment of borrowings	(18,803)	(2,993)
Interest paid ¹³	(5,340)	(2,093)
Net cash generated from financing activities	(24,328)	51,469
Net change in cash and cash equivalents	(3,013)	15,193
Cash at beginning of the period	41,907	28,857
Exchange gains/(losses) on cash	(877)	(1,012)
Cash at end of the period	38,017	43,038
Cash, cash equivalents, short-term deposits and financial assets at end of the period	38,657	43,673

¹² The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).

¹³ Presentation revised – see note 1

**CONDENSED CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY**

€ in thousand	Share capital	Share premium and other regulated reserves	Retained earnings and other reserves	Net result	Total equity
Balance as of January 1, 2015	8,453	206,707	(64,444)	(26,272)	124,444
Total comprehensive loss	-	-	(1,576)	946 ¹⁴	(630)
Income appropriation	-	-	(26,272)	26,272	-
Employee share option plan					
- value of employee services	-	-	262	-	262
- exercise of share options	12	132	-	-	144
Treasury shares	-	-	(2)	-	(2)
Issuance of common stock, February 2015	2,735	42,297	-	-	45,032
Cost of equity transactions, net of tax	-	(3,338)	-	-	(3,338)
	2,747	39,091	(27,588)	27,217	41,467
Balance as of June 30, 2015	11,199	245,798	(92,032)	946	165,911
Balance as of January 1, 2016	11,205	245,965	(92,219)	(20,617)	144,335
Total comprehensive loss	-	-	(1,120)	(39,460)	(40,580)
Income appropriation	-	-	(20,617)	20,617	-
Employee share option plan					
- value of employee services	-	-	699	-	699
- exercise of share options	-	-	-	-	-
Treasury shares	-	-	(185)	-	(185)
Cost of equity transactions, net of tax	-	-	-	-	-
	-	-	(21,223)	(18,843)	(40,067)
Balance as of June 30, 2016	11,205	245,965	(113,442)	(39,460)	104,268

¹⁴ The results differ from previously released results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10).



SELECTED NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL REPORT

1. Basis of preparation

This condensed consolidated interim financial report of Valneva SE (hereafter referred to as the “Group” or “Company”) for the first six months ended June 30, 2016 has been prepared in accordance with International Financial Reporting Standards as adopted by the EU applicable to interim financial reporting (IAS 34) authorizing the presentation of selected explanatory notes. In consequence, these condensed consolidated financial statements must be read in conjunction with the consolidated annual financial statements for the year ended December 31, 2015 available in French and in English at the company’s website: www.valneva.com.

In this interim financial reporting the same accounting policies and methods of computation as in the most recent annual financial statements for the year ended December 31, 2015, have been applied.

No standards or interpretations were early adopted, if they are not mandatorily applicable in 2016.

The following standards may in future have an effect on the Group’s financial statements, but are not yet applicable or adopted by the European Union:

- IFRS 15 “Revenue from Contracts with Customers” applicable as of January 1, 2018
- IFRS 9 “Financial Instruments” applicable as of January 1, 2018
- IFRS 16 “Leases” applicable as of January 1, 2019

Standards and amendments to standards published and effective as of January 1, 2016 have no effect on the financial statements of the Group.

Taking into consideration the increased importance of the group’s financing structure on the cash flow statement in the first half of 2016 and going forward, and to provide more relevant information, interest payments are being presented within the cash flow from financing activities instead of the cash flow from operating activities in the condensed consolidated interim cash flow statement for the first half of the financial year 2016. The previous year comparative period was adjusted accordingly.

The 2015 income statement amounts differ from previously released interim results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business (see note 10). Furthermore, upon the request of the French Financial Market Authority (“AMF”), the Company amended the presentation of the “gain on bargain purchase” compared to the consolidated annual financial statements for the year ended December 31, 2015 and presents such gain within “operating profit/loss”.

EBITDA, as calculated by the Company, has been removed from the face of the income statement and a detailed reconciliation of EBITDA to operating profit/(loss) is presented in note 6.

For presentation clarity, figures herein have been rounded and, where indicated, are presented in thousands of euros. However, calculations are based on exact figures. For this reason, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

The “Brexit” vote had no significant impact on our financial statements as of June 30, 2016. Future events following the vote and their implications on our business are monitored by the management.



2. Group structure

List of direct or indirect interests:

Name	Country of incorporation	Consolidation method	June 30, 2016	December 31, 2015
BliNK Biomedical SAS	FR	at equity	43.29%	48.22%
Intercell USA, Inc.	US	full	100%	100%
Vaccines Holdings Sweden AB	SE	full	100%	100%
Valneva Austria GmbH	AT	full	100%	100%
Valneva Canada Inc.	CA	full	100%	100%
Valneva Scotland Ltd.	UK	full	100%	100%
Valneva Sweden AB	SE	full	100%	100%
Valneva Toyama Japan KK	JP	full	100%	100%
Valneva UK Ltd.	UK	full	100%	100%

3. Revenues

Revenues comprise grant income, revenues from collaborations and licensing and product sales. The main part relates to product sales from commercialized vaccines as broken down in the following table:

€ in thousand	Six months ended June 30,	
	2016	2015
JEV	30,142	15,320
DUKORAL	9,845	8,107
Third-party products	921	4,070
Product sales	40,908	27,497

In general, revenues have fluctuated in the past and the Company expects that they will continue to do so over different reporting periods in the future.

4. Segment reporting

The segments consist of the following:

- + “Commercialized vaccines” (marketed vaccines, currently the Group’s vaccines IXIARO[®]/JESPECT[®], DUKORAL[®], as well as Third-party products)
- + “Vaccine candidates” (proprietary research and development programs aiming to generate new approvable products in order to generate future cash flows from product sales or from commercialization through partnering with pharmaceutical companies)
- + “Technologies and services” (services and inventions at a commercialization stage, i.e. revenue generating through collaborations, service and licensing agreements, including EB66[®] and IC31[®])



Income statement aggregates by segment for the six months ended June 30, 2016:

€ in thousand	Commer- cialized vaccines	Vaccine candi- dates	Techno- logies and services	Un- allocated	Total
Revenues and grants	41,019	3,863	6,505	-	51,387
Cost of goods and services	(18,191)	-	(3,500)	-	(21,691)
Research and development expenses	(2,493)	(9,229)	(542)	(193)	(12,457)
Distribution and marketing expenses	(6,932)	-	(412)	(12)	(7,356)
General and administrative expenses	(1)	-	-	(7,322)	(7,323)
Other income and expenses, net	-	-	-	43	43
Amortization and impairment of fixed assets/intangibles	(3,348)	(34,132)	(201)	23	(37,658)
Operating profit/(loss)	10,054	(39,498)	1,850	(7,461)	(35,054)
Finance income/loss, result from investments in affiliates, gain on bargain purchase, and income tax	-	-	-	(4,406)	(4,406)
Income/(Loss) for the period	10,054	(39,498)	1,850	(11,867)	(39,460)

Income statement aggregates by segment for the six months ended June 30, 2015:

€ in thousand	Commer- cialized vaccines	Vaccine candi- dates	Techno- logies and services	Un- allocated	Total
Revenues and grants	27,791	3,828	7,595	-	39,214
Cost of goods and services	(21,189)	-	(2,469)	-	(23,658)
Research and development expenses	(1,374)	(9,629)	(1,329)	(156)	(12,489)
Distribution and marketing expenses	(3,091)	-	(396)	(5)	(3,492)
General and administrative expenses	-	-	-	(7,083)	(7,083)
Other income and expenses, net	-	-	-	146	146
Amortization and impairment of fixed assets/intangibles	(3,346)	-	(292)	-	(3,638)
Operating profit/(loss)	(1,209)	(5,801)	3,087	(7,077)	(11,000)
Finance income/loss, result from investments in affiliates, gain on bargain purchase, and income tax	-	-	-	11,946	11,946
Income/(Loss) for the period	(1,209)	(5,801)	3,087	4,869	946



5. Intangible Assets

Impairment testing

In case of triggering events, the book values of capitalized in-process research & development projects have been assessed for impairment testing purposes using the risk-adjusted discounted cash flow method. Management reviews the business performance based on in-process Research & Development projects. The recoverable amounts of these projects are determined based on value-in-use calculations.

The calculations use post tax risk-adjusted cash flow projections based on the Group's long-range business model including the Management's best estimate on probability of success of the respective projects (risk-adjustment) and a discount rate.

Triggering events have been identified for two development projects during H1 2016:

1) *Pseudomonas aeruginosa*

During the second quarter of the 2016, Valneva announced that the Phase II/III trial results of its *Pseudomonas aeruginosa* vaccine candidate did not confirm the all-cause mortality reduction observed in previous studies. While the trial confirmed good immunogenicity and an acceptable safety profile, all-cause mortality (primary endpoint) and overall survival (secondary endpoint) did not differ between the VLA43 treatment group and the placebo group. The Company has now discontinued the program.

Consequently the decision has been taken to fully impair the book-value of the intangible asset amounting to €34.1 million in June 2016 as it is highly unlikely that the asset will generate any future cash flows.

2) *Clostridium difficile*

In May 2016, GSK communicated its decision to Valneva to not exercise the opt-in rights granted to GSK through the Strategic Alliance Agreement signed in 2007. Valneva has started to identify alternative partners to finance the upcoming Phase III-studies and final market approval steps necessary to bring the asset to the market.

The existing business model has been revised resulting in a reduction of future cash-flows, however, the value-in-use still significantly exceeds the current book value of the intangible asset and therefore no adjustment has been made in our financial statements related to *C.difficile*

The result of the acquired research & development projects is inherently uncertain and the Group may experience delays or failures in clinical trials. A failure to demonstrate safety and efficacy in clinical product development of one of the acquired research & development projects would result in an impairment loss. The net present value calculation uses a probability of success rate of 10% to 50% for acquired products in the stage of Research & Development. Applying the Industry standard for the likelihood of successfully passing clinical Phase II, Phase III or final filing stages, results in no additional impairment. Assumptions used were a 10% likelihood of failure to gain regulatory approval following a positive Phase II result (2.5% weighted risk), a 50% chance to fail in Phase III after having successfully passed Phase II (22.5% weighted risk) and a risk of 50% for failing in Phase II after successful finalization of Phase I (50% weighted risk).

The discount rate of 11.22% per annum is based on 0.49% risk-free rate, 7.00% market risk premium, 1.10% country risk premium, 0.47% currency risk, a beta of 1.49, and a peer group related equity-capital ratio.



The long range business model covers a period of 20 years and therefore accounts for all project related cash flows from the development stage over the market entry until the market phase-out (project life cycle) of the relevant projects.

Sensitivity to changes in assumptions (C.difficile only)

The net present value calculations are most sensitive to changes in the following assumptions:

- Discount rate
- Probability of project success
- Reduction in expected revenues / royalties

The net present value calculation uses a discount rate of 11.22%. An increase in the discount rate of 22.23% points to 33.45% would trigger an impairment loss. Furthermore, an increase in the discount rate of one percentage point would result in no additional impairment loss.

The net present value calculations are based upon assumptions regarding market size, expected sales volumes resulting in sales value expectations, or expected royalty income. A reduction in revenues or royalty income of 10% would result in no additional impairment loss. A reduction of expected revenues / royalties of 95.43% would trigger an impairment loss.

6. EBITDA

EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets as well as gains from bargain purchase ("negative goodwill") from the operating loss.

€ in thousand	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Operating profit/(loss)	(32,334)	(7,259)	(35,054)	2,183
Depreciation	1,159	1,161	2,315	2,132
Amortization	1,701	1,713	3,302	3,522
Impairment on intangibles and fixed assets	34,132	-	34,109	-
Gains from bargain purchase ("negative goodwill")				(13,183)
EBITDA	4,658	(4,384)	4,672	(5,346)

7. Financial instruments

The Company's only derivatives measured at fair market value are interest rate SWAPs with a negative fair market value of €2 thousands as of June 30, 2016.

Other financial assets and financial liabilities accounted at their carrying amount which corresponds to their approximate fair value.



8. Cash, cash equivalents and short-term deposits

Cash, cash equivalents and short-term deposits include the following:

€ in thousand	June 30, 2016	December 31, 2015
Cash at bank and in hand	34,631	38,841
Other short-term deposits	4,025	3,726
Cash, cash equivalents and short-term deposits	38,657	42,567

As of June 30, 2016, cash and cash equivalents include €640 thousand (December 31, 2015: €660 thousand) with restrictions on remittances.

9. Share capital, share premium and other regulated reserves

€ in thousand (except numbers of shares)	Number of shares	Share capital	Share premium	Other regulated reserves	Total share capital, share premium and other regulated reserves
Balance at January 1, 2015	56,351,833	8,453	153,887	52,820	215,160
Employee share option plan:					
- exercise of share options	79,800	12	132	-	144
Issuance of common stock, February 2015	18,231,466	2,735	42,297	-	45,032
Cost of equity transactions, net of tax	-	-	(3,338)	-	(3,338)
Balance at June 30, 2015	74,663,099	11,199	192,978	52,820	256,997
Balance at January 1, 2016	74,699,173	11,205	193,145	52,820	257,170
Employee share option plan:					
- exercise of share options	-	-	-	-	-
Issuance of common stock	-	-	-	-	-
Cost of equity transactions, net of tax	-	-	-	-	-
Balance at June 30, 2016	74,699,173	11,205	193,145	52,820	257,170

The acquisition of the Crucell Vaccine Assets in 2015 was financed in part through a public rights issue with shareholders' preferential subscription rights, which was launched on January 12, 2015 and closed on February 4, 2015. The final gross proceeds of the rights issue amounted to €45.0 million, corresponding to the issuance of 18,231,466 new ordinary shares, at a subscription price of €2.47 per new ordinary share.

10. Business combination

On February 9, 2015, the Group completed the acquisition of Crucell Sweden AB, (subsequently renamed Valneva Sweden AB), and all assets, licenses and privileges related to DUKORAL[®], a vaccine against cholera and diarrhea caused by LT-EPEC (including a manufacturing site in Solna, Sweden) as well as a vaccine distribution business in the Nordic countries (together "Crucell



Sweden"). After completion of the acquisition, Valneva holds 100% of the voting rights of the acquired company.

The acquisition was financed through a combination of debt and equity. The latter was raised through a public rights issue with final gross proceeds of €45.0 million. The debt part of the acquisition financing was raised through a loan facility put in place with Athyrium in an amount of €15.0 million, which was repaid in January 2016.

The comparative results of the 2015 income statement in this document differ from previously released quarterly results to reflect the retrospective adjustments to the purchase accounting for the ex-Crucell business.

In December 2015, changes to the Canadian DUKORAL[®] product monograph that Health Canada had requested became effective. The updated product monograph and subsequent labelling may negatively impact DUKORAL[®] sales in Canada going forward. In order to reflect these business changes Valneva and the seller agreed on amendments to the purchase agreement which led to a €25 million reduction of the purchase consideration, bringing it from originally €45 million down to €20 million.

Therefore, the Company adjusted the preliminary purchase price accounting retrospectively in December 2015 in accordance with IFRS 3.45. The purchase price, intangible assets, fixed assets, inventories, and deferred taxes were adjusted accordingly. The resulting €13.2 million gain on bargain purchase related to the acquisition was retrospectively included in the income statement of the first quarter of 2015. Adjustments to asset values also led to changes in the income statements of the subsequent quarters, in particular affecting costs of goods sold through changes in depreciation and amortization relating to the re-valued assets.

The final allocation of the purchase price was presented in the consolidated annual financial statements for the year ended December 31, 2015.

The cash consideration paid, net of cash acquired through the acquisition includes the final payment from J&J of €15 million in January 2016 due to the label-change in Canada and is as follows:

€ in thousand

Cash consideration paid	35,000
Cash and cash equivalents in acquired business	(2,795)
Payments received from J&J (WC adjustment, label-change Canada, other liabilities)	(25,303)
Cash outflow through acquisition	6,602

11. Events after the reporting period

Subsequent to the balance sheet date, a claim for additional payment was raised by former owners of parts of the Company's antibody technology which was spun off into Blink Biomedical in early 2015. The Company believes that the claim is unsubstantiated and unlikely to succeed in case of litigation.



4. RESPONSIBILITY STATEMENT

We hereby declare that to the best of our knowledge, the condensed consolidated financial statements for the half year ended June 30, 2016 have been prepared in accordance with applicable accounting standards and present a fair view of the assets, financial position and results of the company and all companies included in the scope of consolidation and that the management report fairly presents all major events during the first six months of the year, their impact on the accounts and the main transactions between related parties and provides a description of the main risks and uncertainties the company faces in the remaining six months of the year.

Thomas Lingelbach,
Chairman of the Management Board and CEO

Franck Grimaud
Managing Director and Deputy CEO

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