

**VALNEVA SE**

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## Valneva Reports Best Financial Results in the Company's History with its First Year of Positive EBITDA in 2016

### The Company expects to continue showing a strong financial performance in 2017

- + Total revenues and grants of €97.9 million in 2016 (vs €83.3 million in 2015) driven mainly by a 73.1% increase in IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenues;
- + Valneva reported a positive EBITDA of €2.8 million in 2016 (vs. an EBITDA loss of €8.5 million in 2015);
- + Net loss of €49.2 million in 2016, impacted by the impairment charges related to the Pseudomonas program termination. Excluding these charges and the exceptional gain related to the DUKORAL<sup>®</sup> acquisition in 2015, net loss was cut by more than half compared to 2015 to €15.1 million;
- + Positive operating cash flow of €6.5 million in 2016 and equity financing proceeds of €7.5 million brought cash position to €42.2 million at the end of 2016;
- + Under the €25 million loan agreement announced in July 2016 with the European Investment Bank, Valneva expects to receive a first installment of €5 million at the beginning of April 2017.

### 2017 Outlook

- + Valneva expects 2017 overall IFRS revenues to reach €105 to €115 million, reflecting up to 17% total revenue growth compared to 2016;
- + The Company anticipates product sales this year to grow by 10-15% over the €80.4 million reported in 2016, driven mainly by IXIARO<sup>®</sup>/JESPECT<sup>®</sup> and DUKORAL<sup>®</sup>;
- + After reaching operational profitability in 2016 with a positive EBITDA of €2.8 million for the full year, the Group expects to further grow its operational performance to an EBITDA of €5 to €10 million in 2017
- + Valneva intends to invest between €21 million and €23 million in R&D, corresponding to approximately 20% of annual revenues.

### 2017 R&D catalysts

- + In 2017, the Company will advance the Phase I trial of its Lyme vaccine candidate and expects to accelerate the program's progression towards Phase II;
- + Valneva plans to advance at least one additional vaccine candidate into Phase I in the second half of 2017. The preclinical portfolio includes vaccine candidates against Chikungunya and Zika.
- + Valneva also seeks to partner its Phase III-ready *Clostridium difficile* vaccine candidate in 2017 following the publication of positive final Phase II results in 2016;



**Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented,** *“2016 has been a successful and transformational year for Valneva as we have mastered the transformation of Valneva into a fully integrated (from Research to Sales), commercial stage biotech company and reported the best results in the Company’s history while still making significant investments in the development of life-saving vaccines. We have also largely exceeded our operational goals across almost every area of our business, leading to strong financial performance. In 2017, we will focus on pursuing this operational performance while at the same time trying to create R&D value through both the advancement and, when appropriate, the partnering of our product candidates.”*

## Key Financial Information

€ in thousand	3 months ending December 31 (unaudited)		12 months ending December 31	
	2016	2015	2016	2015
Revenues & grants	27,151	22,652	97,892	83,335
Net profit/(loss)	(2,717)	(16,398)	(49,184)	(20,617)
EBITDA <sup>1</sup>	(653)	(4,185)	2,810	(8,492)
Net operating cash flow	(1,469)	(4,063)	6,505	(19,828)
Cash, short-term deposits and marketable securities, end of period	42,180	42,567	42,180	42,567

**Lyon (France), March 23, 2017** – Valneva SE (“Valneva” or “the Company”), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, reported today its fourth quarter and full year financial results ending December 31, 2016. The annual financial report including the consolidated financial statements 2016 are available on the Company’s website [www.valneva.com](http://www.valneva.com).

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00 pm (CET). A replay will be available on the Company’s website. Please refer to this link: <http://edge.media-server.com/m/p/7iddifyq>.

<sup>1</sup> 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.

## Commercialized vaccines

### **JAPANESE ENCEPHALITIS VACCINE (IXIARO<sup>®</sup>/JESPECT<sup>®</sup>)**

#### **Significant sales growth following establishment of new commercial network**

In 2016, IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenues increased to €53.2 million compared to €30.7 million in 2015, representing a 73.1% year-on-year growth which was supported by robust fourth quarter revenues of €13.1 million. The increase in revenue was largely the result of Valneva taking over marketing and distribution responsibilities for the product in several geographic territories. Valneva expects IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenues to continue to grow in 2017, reaching €58 to €62 million, through continued marketing and sales efforts and an increase in product adoption by travelers.

### **CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL<sup>®</sup>)**

#### **Strong sales performance**

DUKORAL<sup>®</sup> revenues grew to €24.7 million in 2016 compared to €21.2 million reported in 2015. In the fourth quarter of 2016, DUKORAL<sup>®</sup> revenues were €9.8 million compared to €8.5 million in the fourth quarter of 2015 primarily due to increased sales in Canada, a country which accounts for more than 50% of global revenue. Valneva will continue to invest in growing the DUKORAL<sup>®</sup> vaccine by way of promotional efforts and geographic expansion and expects DUKORAL<sup>®</sup> sales to grow by 10% in 2017 to approximately €27 million.

## Technologies and services

### **EB66<sup>®</sup> CELL LINE**

In 2016, Valneva signed 10 new agreements (9 research agreements and 1 commercial agreement) for the development of human and veterinary vaccines on its EB66<sup>®</sup> platform. The Company received the first royalties for an EB66<sup>®</sup>-based human vaccine under the exclusive agreement it signed in 2007 with GlaxoSmithKline for the development of pandemic and influenza vaccines on the EB66<sup>®</sup> cell line.

GE Healthcare and Valneva also announced the launch of a new cell culture medium, CDM4Avian, to optimize virus productivity in the EB66<sup>®</sup> cell-line.

Valneva also expects that the European Medical Agency's decision in 2016 to issue new guidelines allowing the production of live attenuated vaccines in immortal cell-lines such as EB66<sup>®</sup> will open new markets for the technology.

Valneva will continue to licence its vaccine platform in 2017 and has already signed three new research agreements since the beginning of the year.

## Vaccine Candidates

### **CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE– VLA 84**

#### **Partnering agreement sought in 2017**

*Clostridium difficile* (*C. difficile*) is the most common infectious cause for nosocomial diarrhea in Europe and the US. There are an estimated 450,000 cases of *C. difficile* in the US annually<sup>2</sup> and no vaccine against the disease is commercially available.

Valneva seeks to partner its *Clostridium difficile* vaccine candidate and has ongoing discussions with interested parties. Published Phase II data<sup>3</sup> from the most advanced vaccine program targeting primary prevention of *Clostridium Difficile Infections* (CDI) indicates that Valneva's VLA84 provides a comparable immunological profile to that other product.

### **LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15**

#### **First subject vaccinated**

Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection affecting 300,000 Americans each year.

Following clearance from the Food & Drug Administration (FDA) and the Belgian authorities at the end of December 2016, Valneva has initiated a Phase I clinical trial in the US and Europe, and vaccinated the first subject at the end of January.

In 2017, the company will advance the Phase I trial of its Lyme vaccine candidate and expects to accelerate the program's progression towards Phase II.

The global market for a vaccine against Lyme disease is estimated at approximately €700-€800 million annually<sup>4</sup>.

### **CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553**

#### **Expected to Enter Phase I in 2017**

Valneva is also working actively on the development of a Chikungunya vaccine and expects to enter Phase I clinical development in 2017. Pre-clinical data showed that Valneva's live attenuated vaccine candidate was safe and has the potential to provide long term protection against Chikungunya after a single immunization. The Chikungunya virus (CHIKV) re-emerged from East Africa in 2014 to cause devastating epidemics of debilitating and often chronic arthralgia and is now considered as a major health threat with 180,000 reported cases in the Americas in 2016<sup>5</sup>. There is currently no antiviral treatment for CHIKV infection and no licensed vaccine to prevent the disease. The global market for a Chikungunya vaccine is estimated at approximately €500 million annually<sup>6</sup>.

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<sup>2</sup> Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34

<sup>3</sup> G. de Bruyn et al. *Vaccine* 34 (2016) 2170-2178

<sup>4</sup> Company estimate supported by independent market studies

<sup>5</sup> PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016)

<sup>6</sup> Company estimate supported by independent market studies

## Financial Review<sup>7</sup>

### FOURTH QUARTER 2016 FINANCIAL REVIEW (unaudited)

#### Revenues and grants

Valneva's aggregate fourth quarter 2016 revenues and grants were €27.2 million compared to €22.7 million in the fourth quarter of 2015.

Product sales in the fourth quarter of 2016 increased to €23.8 million from €17.4 million in the same period of the previous year.

Revenues from collaborations and licensing in the fourth quarter of 2016 decreased to €2.2 million compared to €3.6 million in the fourth quarter of 2015. Grant income in the fourth quarter of 2016 decreased to €1.1 million from €1.7 million in the fourth quarter of 2015.

#### Operating result and EBITDA

Cost of goods and services sold (COGS) were €13.1 million in the fourth quarter of 2016 of which €6.7 million were related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 49.0%. €4.3 million of COGS were related to DUKORAL<sup>®</sup> sales, yielding a product gross margin of 56.0%. Of the remaining COGS for the fourth quarter of 2016, €0.6 million were related to the Third Party product distribution business and €1.5 million related to cost of services. In the comparative period of 2015, COGS were €13.3 million, of which €12.0 million were related to cost of goods and €1.3 million to cost of services.

Research and development expenses in the fourth quarter of 2016 decreased to €5.9 million from €6.6 million in the fourth quarter of the previous year. Distribution and marketing expenses in the fourth quarter of 2016 amounted to €5.3 million, compared to €3.3 million in the fourth quarter of 2015. General and administrative expenses amounted to €4.0 million compared to €4.2 million in the fourth quarter of 2015. Amortization and impairment charges in the fourth quarter of 2016 were flat to the fourth quarter of 2015 at €1.8 million.

As a result of the increased revenues, Valneva's operating loss for the fourth quarter 2016 decreased to €3.5 million compared to an operating loss of €7.1 million reported for the fourth quarter of 2015. Valneva's fourth quarter 2016 showed an EBITDA loss of €0.7 million which compares to an EBITDA loss of €4.2 million in the fourth quarter of 2015. Q4 2016 EBITDA was

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<sup>7</sup>Note: FY 2016 and FY 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<sup>®</sup> 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 are only included 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.

calculated by excluding depreciation, amortization and impairment charges amounting to €2.8 million from the operating loss of €3.5 million as recorded in the condensed consolidated income statement under IFRS.

### **Segment overview**

The Commercialized Vaccines segment showed an operating profit of €4.0 million in the fourth quarter of 2016, which compares to an operating loss of €0.4 million in the fourth quarter of 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €5.7 million in the fourth quarter of 2016 and €1.3 million in the fourth quarter of 2015.

The Technologies and Services segment showed an operating loss of €0.7 million in the fourth quarter of 2016 compared to an operating profit of €0.6 million in the fourth quarter of 2015. Excluding amortization and impairment, the operating loss of the Technologies and Services segment amounted to €0.5 million in the fourth quarter of 2016 compared to an operating profit of €0.8 million in the fourth quarter of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €3.0 million in the fourth quarter of 2016 compared to a €2.7 million operating loss in the fourth quarter of 2015.

### **Net result**

Valneva's net loss in the fourth quarter of 2016 was €2.7 million compared to a net loss of €16.4 million in the fourth quarter of the prior year. The fourth quarter 2015 net loss included an impairment charge of €8.4 million related to Valneva's 43.3% shareholding in BliNK Biomedical SAS.

The finance result for the fourth quarter of 2016 was positive, amounting to a net finance income of €0.7 million compared to a net loss of €1.0 million in the fourth quarter of 2015.

## **FULL-YEAR 2016 FINANCIAL REVIEW**

### **Revenues and grants**

Valneva's aggregate revenues and grants in the full year 2016 increased to €97.9 million from €83.3 million in 2015. This increase was mainly a result of strong growth of IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales.

Total product sales increased to €80.4 million in the full year 2016 from €61.5 million in the year 2015. IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales contributed €53.0 million to revenues in 2016 compared to €30.6 million in 2015 representing 73.1% 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 private markets in Germany and the

UK. DUKORAL<sup>®</sup> sales contributed €24.6 million to 2016 product sales representing growth of €3.5 million, or 16.8% compared the year 2015. Third Party product sales for the year 2016 decreased to €2.9 million from €9.9 million in the year 2015, due to the fact that several GSK vaccines were no longer marketed by Valneva in the Nordic countries.

Revenues from collaborations and licensing decreased from €16.8 million in 2015 to €13.6 million in the year 2016. Grant income decreased to €3.8 million in 2016 compared to €5.0 million in 2015.

### **Operating result and EBITDA**

Cost of goods and services sold (COGS) in 2016 were €43.1 million, leading to an overall gross margin of 56%. €21.5 million in COGS were related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales, yielding a product gross margin of 59.6%, and €13.5 million were related to DUKORAL<sup>®</sup> sales, yielding a product gross margin of 45.5%. Of the remaining COGS for full year 2016, €2.0 million were related to the Third Party product distribution business and €6.2 million were related to cost of services. In the comparative period of 2015, COGS were €47.0 million, of which €16.4 million were related to IXIARO<sup>®</sup>/JESPECT<sup>®</sup>, €18.2 million to DUKORAL<sup>®</sup>, €7.3 million to Third Party products, and €5.0 million to cost of services.

Research and development expenses for the year 2016 reached €24.6 million, representing a slight decrease compared to 2015 R&D expenses of €25.4 million.

Distribution and marketing expenses in 2016 amounted to €16.6 million compared to €9.1 million in 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 expenses were flat year on year, with 2016 and 2015 expenses, both amounting to €14.4 million.

Amortization and impairment charges for full year 2016 amounted to €41.2 million and included €34.1 million of non-cash impairment charges which were recognized in the second quarter following negative Phase II/III study results for the *Pseudomonas* vaccine candidate and discontinuation of the program.

Valneva's operating loss for the year 2016 was also impacted by the impairment charges relating to the *Pseudomonas* project and amounted to €42.6 million, compared to an operating loss of €6.8 million reported for the year 2015.

Valneva's full year 2016 EBITDA showed a strong improvement and amounted to an EBITDA profit of €2.8 million compared to an EBITDA loss of €8.5 million in the year 2015. 2016 EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €45.4 million from the operating loss of €42.6 million as recorded in the condensed consolidated

income statement under IFRS. EBITDA also excludes the gains from bargain purchase in the calculation for the comparator period of the previous year.

### **Segment overview**

The Commercialized Vaccines segment showed an operating profit of €16.7 million for full year 2016 compared to an operating profit of €1.7 million in full year 2015. Excluding amortization expenses for acquired intangible assets, the operating profit of that segment was €23.4 million in 2016 and €8.4 million in 2015.

The Technologies and Services segment showed an operating profit for the year 2016 of €1.7 million compared to €4.1 million in the year 2015. Excluding amortization and impairment, the operating profit of the Technologies and Services segment amounted to €2.1 million in 2016 compared to €4.6 million in 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €11.9 million in the year 2016 (excluding one-time impairment charges of €34.1 million related to the *Pseudomonas* project) compared to €11.2 million in full year 2015.

### **Net result**

Valneva's net loss for the year 2016 was €49.2 million. Excluding the one-time impairment charges related to the *Pseudomonas* project, Valneva's net loss amounted to €15.1 million compared to a net loss of €20.6 million for the year 2015. The 2015 result 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 one-time effects in both periods, the net loss significantly improved to €15.1 million in 2016 compared to €33.8 million in 2015.

The net finance result amounted to minus €6.3 million for the year 2016 compared to minus €4.6 million in the year 2015. This increase in net finance expenses was mainly due to negative exchange rate effects in 2016 as opposed to positive effects in the previous year. In 2015 net loss included an impairment charge of €8.4 million related to Valneva's shareholding to the BliNK Biomedical SAS.

### **Cash flow and liquidity**

Net cash generated by operating activities in 2016 was €6.5 million compared to a negative cash-flow from operating activities of €19.8 million in 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 year 2016 amounted to €14.9 million and resulted primarily from a payment received from Johnson & Johnson in connection with the adjustment of

the purchase consideration for the acquisition of Crucell Sweden AB and the DUKORAL<sup>®</sup> business.

Cash out-flows from financing activities in 2016 amounted to €26.8 million and included the re-payment of borrowings to Athyrium LLC as well as interest payments and re-payments of other loans. Cash outflows in connection with debt financing, were partly offset by the net proceeds from a capital increase of €7.5 million performed in December 2016 in connection with an investment by MVM Life Science Partners LLP.

Liquid funds on December 31, 2016 stood at €42.2 million compared to €42.6 million on December 31, 2015 and consisted of €35.3 million in cash and cash equivalents and €6.9 million in restricted cash.

## 2017 Financial Outlook

in million €	2016 Actual	2017 Estimates	Growth
<b>Total revenues &amp; grants</b>	97.9	<b>105 - 115</b>	up to 17%
<b>Product sales</b>	80.4	<b>88 - 92</b>	10 - 15%
IXIARO <sup>®</sup> /JESPECT <sup>®</sup> sales	53.0	58 - 62	10 - 15%
DUKORAL <sup>®</sup> sales	24.6	27	10%
<b>EBITDA</b>	2.8	<b>5 - 10</b>	80 – 250%
<b>R&amp;D expenses (20% of revenues)</b>	(24.6)	<b>(21) – (23)</b>	-

## Valneva to receive a €5 million installment from the European Investment Bank loan

Under the €25 million loan agreement concluded in July 2016 with the European Investment Bank (EIB), Valneva expects to receive a first installment of €5 million at the beginning of April 2017. The Company submitted a drawdown request under this loan following the satisfaction of all material conditions precedent. The EIB granted the €25 million loan facility to support Valneva's R&D activities. The loan may be utilized by Valneva in several installments within a 24-month period following the signing of the loan agreement. Each installment is repayable at the end of a five-year period, starting from the drawing date.

## Valneva's CFO Reinhard Kandra to depart by end of March

As previously announced, Valneva's Chief Financial Officer, Reinhard Kandra, has decided to resign his position as Management Board member and CFO to pursue other interests. After 15 years with Valneva (Intercell) Mr. Kandra will leave at the end of March. After his decision in

February, Mr. Kanderer has worked through a handover process with the Company to ensure a smooth transition of his responsibilities.

*“Reinhard has made great contributions to the creation of Valneva and its development into one of the few financially sustainable biotech companies, now covering its R&D investments by product cash-flows. He has set the finance, IT and investor relations functions up to operate efficiently and has built a great team in these areas. Reinhard is handing over the CFO role with the best financial results in the Company’s history and we want to thank him for the time he spent with us on the management board”* commented **Thomas Lingelbach, CEO, and Franck Grimaud, Deputy CEO of Valneva.**

**Reinhard Kanderer, departing CFO** said, *“Leaving Valneva has been a difficult decision because it is a great company with a lot of future potential, but after 15 years at Valneva and its predecessor company Intercell, I feel it is time for me to do something new. It has been a privilege to be part of such a great management team which I am convinced will lead Valneva to continued success.”*

Valneva has initiated a process with Korn-Ferry to recruit a new CFO. In the interim, Manfred Tiefenbacher, VP Finance will manage operational finance matters. In addition, the Company’s Supervisory Board has decided to appoint Mr. Frédéric Jacotot, General Counsel, to the Management Board, taking effect on April 1, 2017.

### **About Valneva SE**

Valneva is a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines.

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, prevention of diarrhea caused by ETEC. 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 (EB66® vaccine production cell line, IC31® adjuvant).

Valneva is listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Great Britain, Sweden, Canada and the US with over 400 employees. More information is available at [www.valneva.com](http://www.valneva.com).

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### **Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.