# Valneva presents its FY 2018 financial results

Analyst Presentation
February 21, 2019

valneva

# Disclaimer

This presentation does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva SE 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 1933 US Securities Act, as amended.

Valneva is a European company. Information distributed is subject to European disclosure requirements that are different from those of the United States. Financial statements and information may be prepared according to accounting standards which may not be comparable to those used generally by companies in the United States.

This presentation includes only summary information and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of their affiliates, directors, officers, advisors and employees shall bear any liability for any loss arising from any use of this presentation.

Certain information and statements included in this presentation are not historical facts but are forward-looking statements. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.

# Agenda

- Introduction
- Financial Report FY 2018
- R&D Portfolio Update
- Outlook
- Q&A

# Key Business and R&D Milestones Completed in 2018

| | |
|---|---|
| ✓ **Strong financial results** | + Product Sales +16% CER vs. 2017, according to guidance<br>+ 2018 Gross Margin 60.7% vs. 56.3% in 2017<br>+ EBITDA €13.1m vs. €10.8m in 2017<br>+ Net profit €3.3m; first ever profitable annual result for Valneva |
| ✓ **Major R&D milestones** | + Nine key R&D milestones achieved in 2019 including Lyme Phase 1 results and Phase 2 initiation, Phase 1 trials for chikungunya and Zika |
| ✓ **Significant business milestones** | + New IXIARO® supply contract with US Government worth up to $70m<br>+ Accelerated IXIARO® vaccination schedule approved by FDA and Health Canada |
| ✓ **Focusing on best capital markets** | + €50m raised in oversubscribed placement led by blue-chip U.S. healthcare investors<br>+ Delisting from the VSE announced. Company to focus on best capital markets for life science companies |

CER: at constant exchange rates; all 2018 results are unaudited

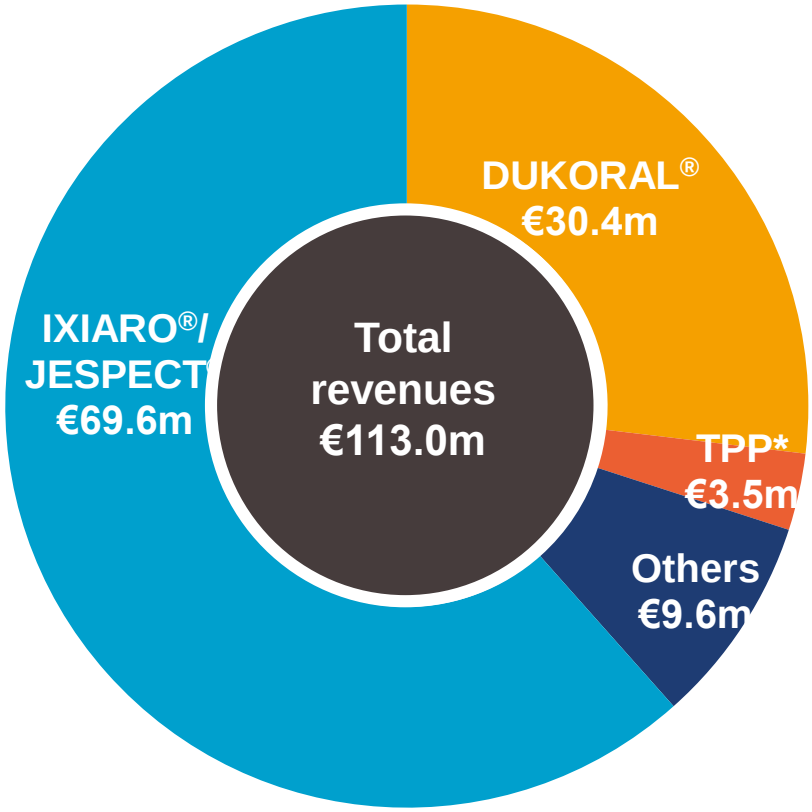
# Agenda

- Introduction
- **Financial Report FY 2018**
- R&D Portfolio Update
- Outlook
- Q&A

# Valneva's profitable commercial business funding key R&D programs

**Repeated double digit product sales growth**
**16% CER in 2018 vs. 2017**

***2018 Full-year results***




Product sales
€103.5m

Direct sales
81.2%

Gross
margin
60.7%

Cash
generated
€16.3m

**Innovative R&D pipeline in areas of high unmet medical need**



CER: at constant exchange rates; all 2018 results are unaudited
*Third party products sold by Valneva's commercial organization

# Revenue analysis

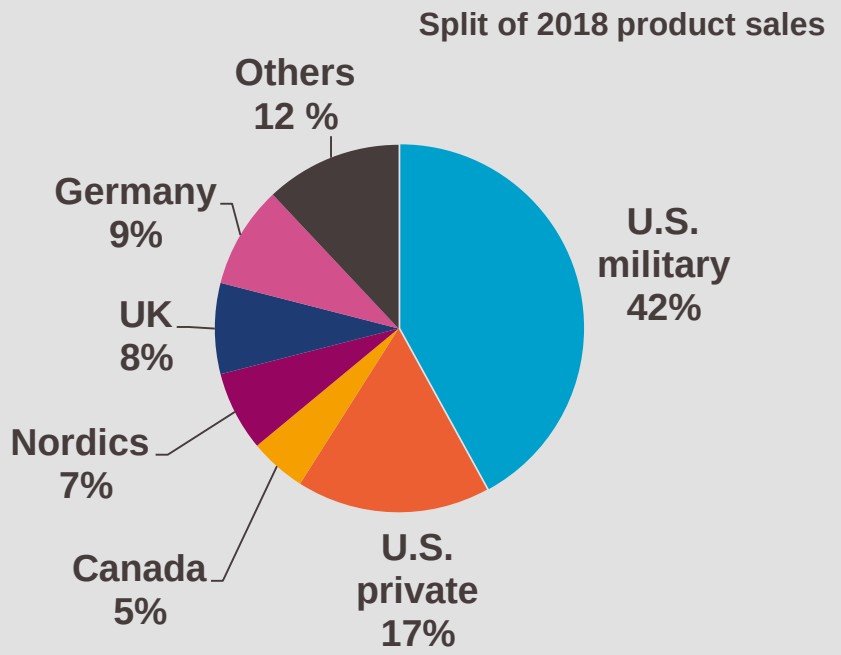
| €m (CER[1]) | FY 2017 | | FY 2018 (unaudited) | | 2019 Guidance |
|---|---|---|---|---|---|
| | Actual | CER | Actual | CER growth | |
| *Product sales revenues* | | | | | |
| IXIARO®/JESPECT® | 60.0 | 58.3 | 69.6 | 19% | |
| DUKORAL® | 28.5 | 27.1 | 30.4 | 12% | |
| Third party products | 3.9 | 3.9 | 3.5 | | |
| **Product revenues** | **92.6** | **89.3** | **103.5** | **16%** | **115 - 125** |
| | | | | | |
| Other revenues | 12.7 | 12.4 | 9.6 | | |
| **Total revenues** | **105.3** | **101.7** | **113.0** | | **125 - 135** |
| | | | | | |
| Grants / R&D tax credits | 4.5 | 4.5 | 4.3 | | |
| **Total revenues & grants[2]** | **109.8** | **106.2** | **117.3** | | |

**1** CER at constant exchange rates as FY avg. Act 2018 ***2*** "Grant income" was reclassified from the position "Revenue and Grants" and included in "Other income/expense" for periods starting Jan 1, 2018. The comparable period was adjusted accordingly to maintain comparability.

# Product sales growth expected to continue in 2019

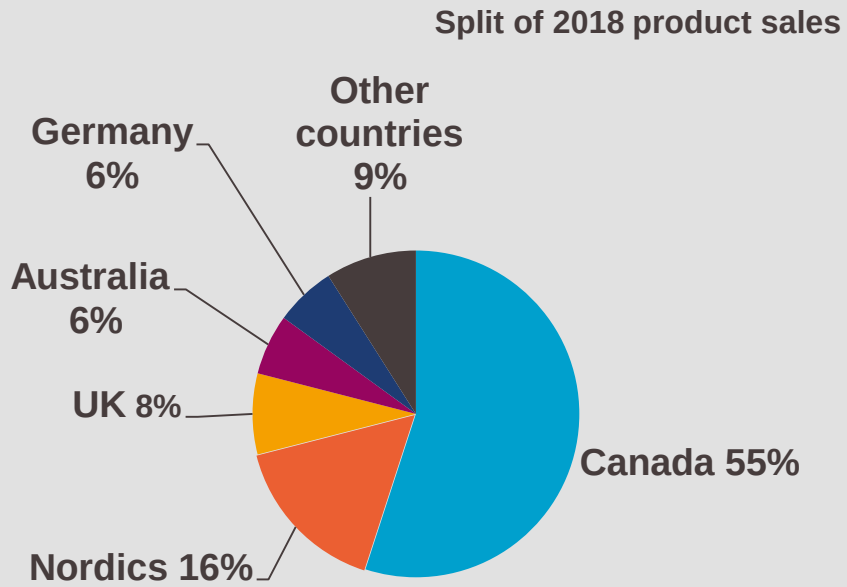
## US and Canada driving top line growth, supported by other markets

### IXIARO®/JESPECT®: North America is the biggest contributor




**Growth expected to be 15% CER or more in 2019**

### DUKORAL®: Canada is the biggest contributor




**Revenues to grow by up to 5% CER in 2019**

CER: at constant exchange rates; all 2018 results are unaudited

# FY 2018 Profit & Loss Report (all figures at AER)

## Strong financial performance

| €m | 12 months ended December | |
|---|---|---|
| | 2018 (unaudited) | 2017 |
| Product Sales | 103.5 | 92.6 |
| Revenues from collaboration, licensing and services | 9.6 | 12.7 |
| **Revenues**[1] | **113.0** | **105.3** |
| Cost of goods and services | (44.4) | (46.0) |
| Research and development expenses | (25.3) | (23.4) |
| Marketing and distribution expenses | (20.9) | (17.9) |
| General and administrative expenses | (16.9) | (15.5) |
| Other income[1] / (expense), net | 4.0 | 4.2[1] |
| Amortization and impairment | (3.2) | (10.7) |
| **OPERATING PROFIT/LOSS** | **6.3** | **(4.0)** |
| Finance, investment and income taxes | (3.0) | (7.5) |
| **PROFIT/LOSS FOR THE PERIOD** | **3.3** | **(11.5)** |
| **EBITDA**[2] | **13.1** | **10.8** |

AER: at actual exchange rates **1** "Grant income" was reclassified from the position "Revenue and Grants" and included in "Other income/expense" starting Jan 1, 2018. The comparator period was adjusted accordingly to maintain comparability. **2** Full Year 2018 EBITDA was calculated by excluding €6.8 million of depreciation and amortization from the €6.3 million operating profit as recorded in the condensed consolidated income statement under IFRS.

# Cash and debt position

| €m | December 2018 (unaudited) | December 2017 |
|---|---|---|
| **CASH & CASH EQUIVALENTS** [1] | **81.7** | **38.1** |
| | | |
| Finance Lease Liabilities | (25.8) | (26.7) |
| -/- Cash Deposit (Finance Lease related) [2] | 11.3 | 11.3 |
| Non current borrowings | (14.3) | (27.4) |
| **TOTAL NON-CURRENT LIABILITIES** (>1 year) | **(28.8)** | **(42.8)** |
| | | |
| Finance Lease Liabilities | (0.9) | (0.9) |
| Current borrowings | (16.7) | (16.5) |
| **TOTAL CURRENT LIABILITIES** (<1 year) | **(17.5)** | **(17.4)** |
| | | |
| **TOTAL BORROWINGS** | **(46.3)** | **(60.2)** |
| **NET CASH/ DEBT** [3] | **35.4** | **(22.1)** |

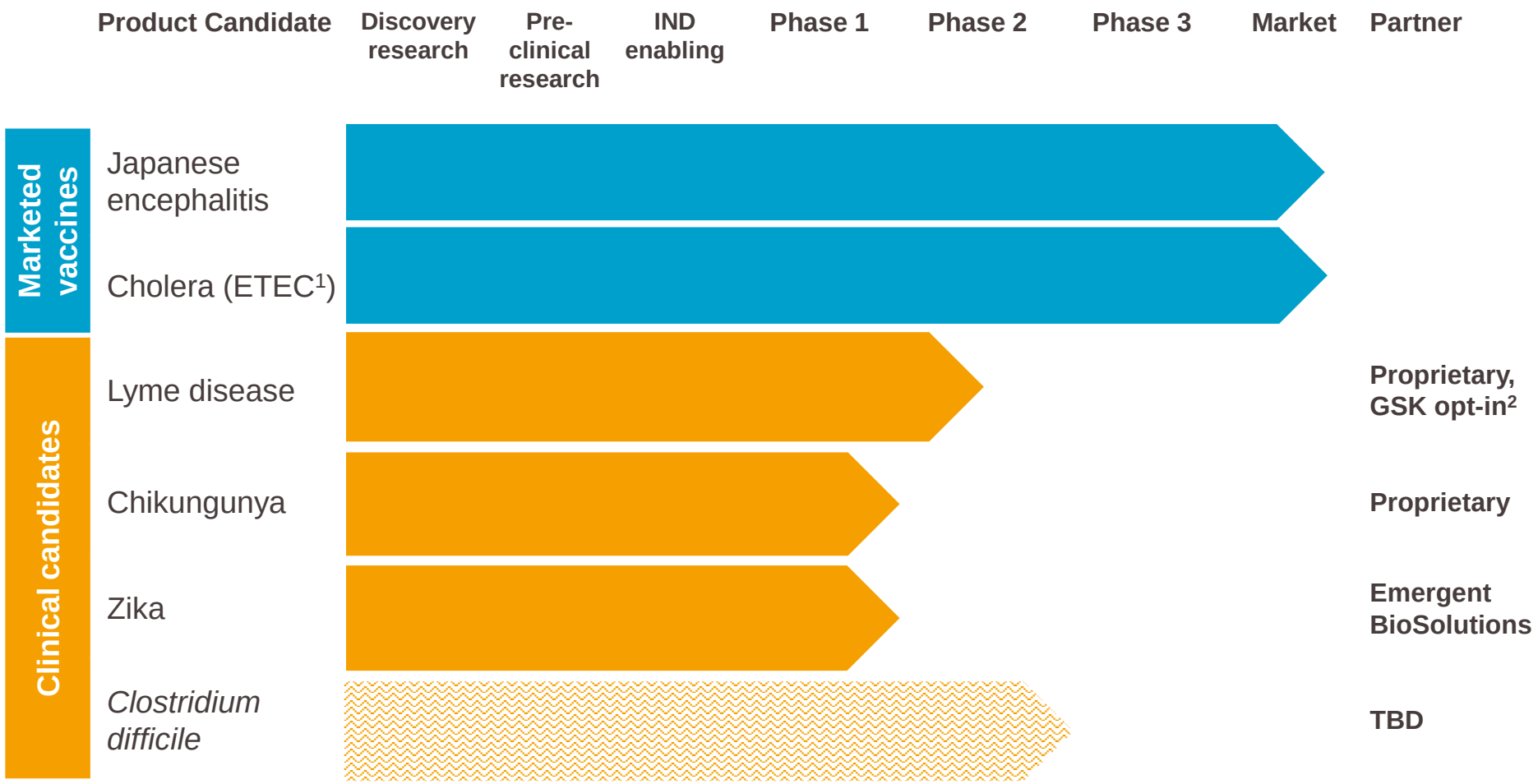
**1** Net proceeds from €50m capital increase included; **2** included in Other non-current assets on the condensed consolidated interim balance sheet; **3** Net Debt calculated by deducting current and non-current liabilities from Cash & Cash Equivalents.

# Agenda

- Introduction
- Financial Report FY 2018
- R&D Portfolio Update
- Outlook
- Q&A

# Valneva's R&D pipeline

## Focusing on innovative vaccine candidates with high unmet medical need




**1** Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = *Enterotoxigenic Escherichia coli* (E. Coli) bacterium; **2** Based on a strategic partnership agreement signed in 2007, GSK has an opt-in after Phase 2 on products developed by Valneva Gmbh

# Key R&D progress reported in 2018 and early 2019

**January 2019**

+ Positive initial booster data & final Phase 1 data for Lyme disease vaccine candidate (VLA15)
+ Positive Phase 1 interim results for Chikungunya vaccine candidate (VLA1553)

**December**

+ Initiation of Phase 2 for Lyme disease vaccine candidate (VLA15)
+ FDA Fast Track Designation for chikungunya vaccine candidate (VLA1553)

**November**

+ Positive Phase 1 results for Zika vaccine candidate (VLA1601)

**October**

+ Positive feedback from EMA on further development for Lyme disease vaccine (VLA15)
+ Initiation of 2nd stage of Phase 1 study for chikungunya vaccine candidate (VLA1553)

**July**

+ Successful conclusion of end of Phase 1 process for Lyme disease vaccine candidate with FDA and Phase 2 strategy alignment (VLA15)

**March**

+ Positive Phase 1 interim results for Lyme disease vaccine candidate (VLA15)
+ Initiation of Phase 1 study to evaluate vaccine candidate against chikungunya (VLA1553)

**February**

+ Initiation of Phase 1 study to evaluate Zika vaccine candidate (VLA1601)

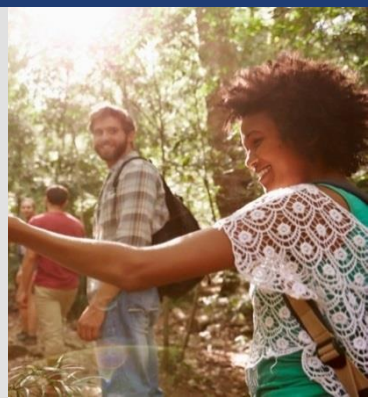
# VLA15: the only Lyme disease vaccine in clinical development

## Lyme disease

- **Transmitted by *Ixodes scapularis* ticks (Northeastern & Midwestern US) and *Ixodes ricinus* ticks (Europe)[1]**
- **Most common vector borne illness in the Northern Hemisphere (over 300,000 cases per year in US[2] and at least 200,000 cases per year in Europe[3])**
- **Delayed or inadequate treatment can lead to disabling sequelae**

## Valneva's vaccine candidate

- **Only active clinical program, no vaccine on the market**
- **Multivalent, protein subunit-based vaccine**
- **Targets the outer surface protein A (OspA) of *Borrelia* (proven mode of action)**
- **FDA Fast Track Designation**



## Positive initial booster data and final Phase 1 data

- **Final Phase 1 results confirmed favorable safety profile and encouraging immunogenicity[4]**
- **Positive initial booster data: single re-vaccinations resulted in a significant immune-response[4]**
- Preclinical data showed that the vaccine has the potential to provide protection against the majority of *Borrelia* species pathogenic for humans[5]

## Phase 2 ongoing

- **Phase 2 investigating higher doses and vaccination schedules**
- **Phase 2 initial data expected mid-2020**
- **Medical need for Lyme vaccine steadily increasing as the disease footprint widens[6]**

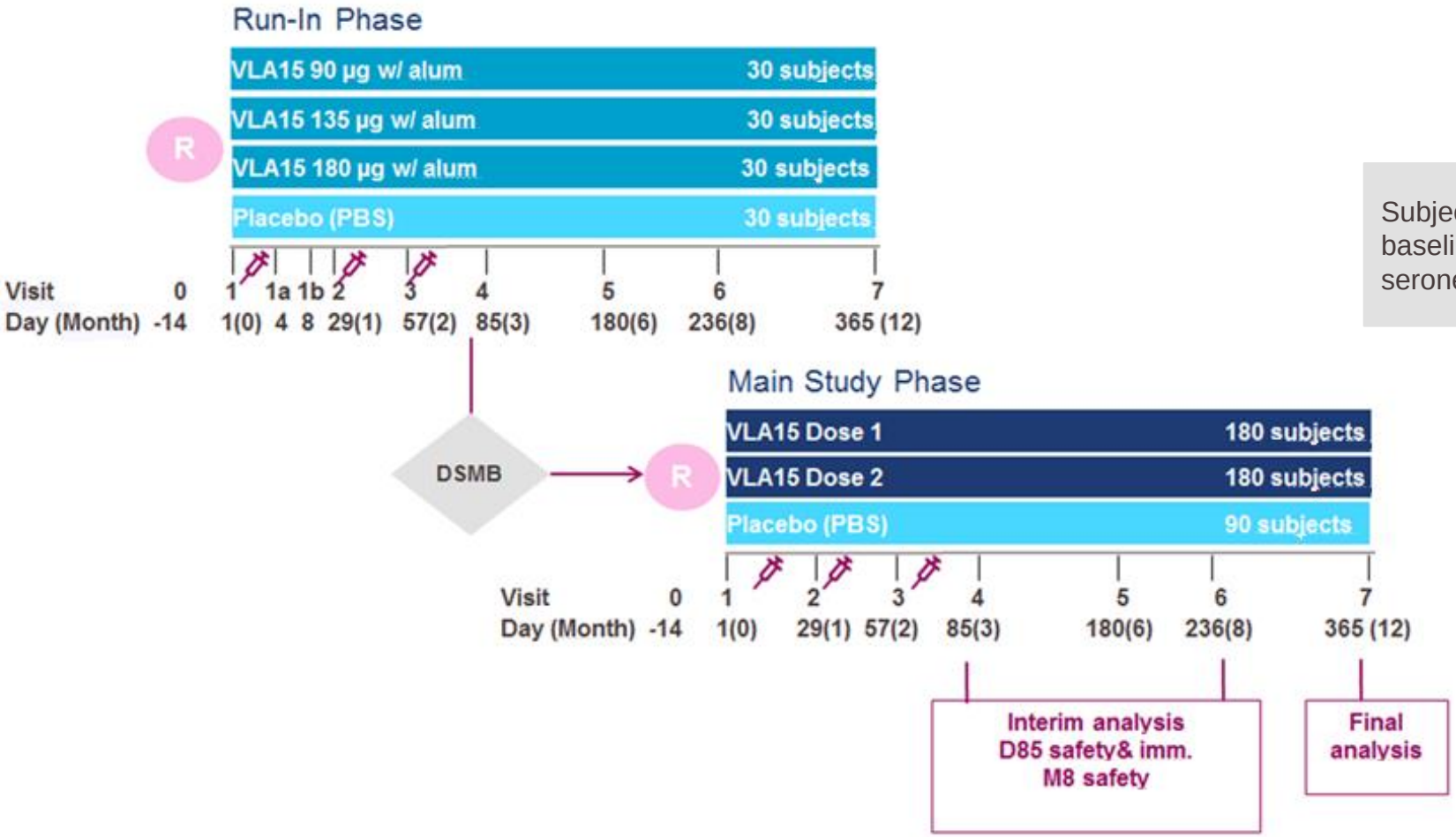
**1** Stanek et al. 2012, The Lancet 379:461–473; **2** As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article; **3** Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report; **4** Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate, **5** Plos One; Design and Development of a Novel Vaccine for Protection against Lyme Borreliosis; **6** New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017.

# VLA15 (Lyme): Phase 2 study (VLA15-201)

## Observer-blind, randomized, placebo-controlled, multicenter study

**Phase 2 study conducted in US and EU**

- Main Study Phase: 3 groups (2 adjuvanted dose levels and placebo)
- Run-in Phase: 120 healthy volunteers (18 to 40 years)
  Main Study Phase: 470 healthy volunteers (18 to 65 years)
- Primary objective: Immunogenicity data at Month 3
- Secondary objectives: Immunogenicity and safety data until M12




Subjects
baseline seropositive or seronegative

# Lyme (VLA15) – Development
## Key milestones

| Current Development Assumptions | | |
|---|---|---|
| Phase 2 initiation (VLA15-201) | end 2018 | ✓ |
| Phase 1 final data (D365) and initial Booster data | Q1 / 2019 | ✓ |
| Run-in Phase (Phase 2) completed | mid 2019 | |
| Second Phase 2 initiation (VLA15-202) | mid 2019 | |
| Phase 2 data (primary) | mid 2020 | |
| Phase 3 initiation | Q4 / 2021 | |
| Phase 3 data* | Q4 / 2022 | |
| 1st possible BLA submission* | Q4 / 2023 | |
| 1st possible licensure* | Q3 / 2024 | |

*If pivotal field efficacy trial sufficient over one tick season – otherwise +1 year / rolling submission under Fast Track

# VLA15: Outlook

## Striving towards first BLA submission in 2023[1]

**Phase 3 – Current Hypothesis[2]**

**Pivotal, double-blind, placebo controlled field efficacy study in endemic countries**

**Key objective:**

- Efficacy against Lyme disease (all serotypes) with vaccine at final dose and schedule
- Adults (18-70 yrs)

  Possible inclusion of younger age group (12-17)

**Likely ~ 16,000 subjects**

- US and Europe, possibly also Canada
- Study sites in high-risk, endemic areas
- Two tick seasons with interim results submitted after the first tick season
  - Subject to data, possible BLA submission based on one season

**Pediatric studies (Ph2/Ph3) largely in parallel**

**1** Assumes licensure with data from one tick season; **2** Based on company assumptions and estimates. No detailed discussions with regulatory authorities have yet taken place.

# VLA1553: A differentiated Chikungunya vaccine candidate

## Potential single-shot vaccine against a severe, growing threat

### Chikungunya

- Mosquito-borne viral disease caused by the Chikungunya virus (CHIKV), a Togaviridae virus
- Transmitted by *Aedes* mosquitoes
- Causes clinical cases in 72-92% of infected humans who can develop serious, long-term health impairments[1]
- Outbreaks in Asia, Africa, Europe & the Americas (as of Feb. 2017, > 1 million reported cases in the Americas)[2]
- No preventive vaccines or effective treatments exist

### Valneva's vaccine candidate

- Monovalent, single dose, live attenuated prophylactic vaccine[3]
- Aims for long-lasting protection of individuals > 1 year of age
- Protective against various CHIKV outbreak phylogroups & strains[4]
- FDA Fast Track Designation

### Positive Phase 1 interim data

- **Positive Phase 1 interim results showed excellent immunogenicity with acceptable safety profile[5]**
- **Long term protection shown in preclinical testing**
  Data from non-human primates (NHP) show vaccine's good safety profile and its potential to provide long-term protection after a single immunization[6]

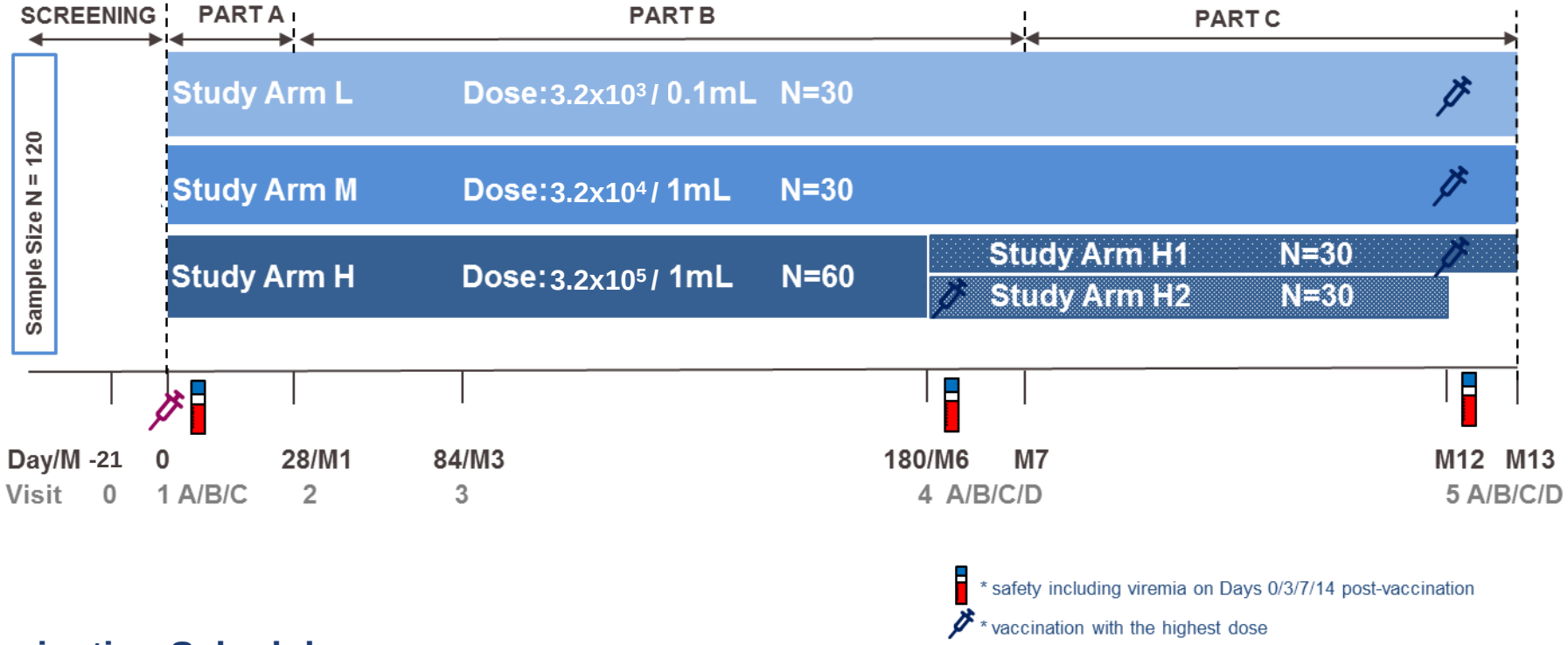
### Phase 1 progression on track to conclude early 2020

- **Group of study participants being re-vaccinated** with highest vaccine dose to provide early intrinsic human challenge
- **Chikungunya now eligible for FDA Priority Review Voucher (PRV)[7]**
- **Target populations include travelers, military personnel and individuals at risk living in endemic regions**

**1** PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016) https://www.paho.org/hq/dmdocuments/2016/2016-aug-19-cha-chikv-cases-ew-33.pdf ; **2** PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 5 (February 3, 2017) https://www.paho.org/hq/dmdocuments/2017/2017-feb-3-phe-CHIKV-cases-ew-5.pdf ; **3** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **4** Hallengärd et al. 2013. J Virology 88:2858–2866; **5** Pooled analysis of all study groups since study continues with additional vaccination to potentially obtain a first indication for efficacy **6** Roques et al. 2017JCI Insight 2 (6): e83527; **7** As of August 23, 2018 https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm618097.htm

# VLA1553: Chikungunya vaccine candidate, Phase 1 study design

## Blinded, randomized, dose-escalation study




### Vaccination Schedule

+ Single-dose vaccination (Day 0)
+ Re-vaccination with highest dose (Month 6 and 12)
  - (1) to show that single-shot is sufficient to induce high titer neutralizing antibodies;
  - (2) to serve as indirect human viral challenge demonstrating that subjects are protected from viremia and thereby indicating early VE

# Chikungunya Phase 1 study (VLA1553-101) Interim Results

## Excellent immunogenicity with acceptable safety profile[1]

### Immunogenicity

- 100% Seroconversion Rate (SCR)[2] at day 28 after single dose[1]
- 96.5% of subjects achieving ≥ 16 fold rise in antibody titres[2]
- High Geometric Mean Titre (GMT) in pooled analysis

**Excellent immunogenicity profile after single vaccination**

### Safety

- No Serious Adverse Events (SAEs) up to day 28[1]
- No Adverse Events of Special Interest (AESIs) up to day 28[1]
- Local tolerability excellent
- Systemic adverse events included short-term fever, headache and fatigue
- Transient cases of reduced levels of neutrophils, lymphocytes or leucocytes w/o clinical symptoms[3]

**Safety profile acceptable and supporting further development**

**1** Pooled analysis across all study groups since study continues with additional vaccination to potentially obtain a first indication for efficacy; **2** SCR defined as proportion of subjects achieving a CHIKV specific neutralizing antibody titre as NT50 ≥ 20; **3** As for other live-attenuated vaccines

# Agenda

- Introduction
- Financial Report FY 2018
- R&D Portfolio Update
- Outlook
- Q&A

# Financial Outlook

## Continued double-digit sales growth and positive EBITDA, higher R&D investment driven by clinical development progression

| | 2018 (unaudited) | 2019 |
|---|---|---|
| Product sales revenues | €103.5m | €115m - €125m |
| Total revenues | €113.0m | €125m - €135m |
| R&D investments | €25.3m | €35m - €40m |
| Gross margin | 60.7% | > 60% |
| Net operating margin[1] | 27.9% | 25% - 35% |
| EBITDA | €13.1m | €5m - €10m |

CER: at constant exchange rates, **1** Net operating margin prior to R&D investment is calculated by excluding R&D expenses from the operating profit as recorded in the consolidated income statement under IFRS divided by total revenues

# An exciting year ahead – Further double-digit product sales growth and significant R&D progress expected in 2019

**15-20% CER product sales growth expected in 2019**

**Major confirmatory and supportive data points for the Lyme vaccine candidate (VLA15)**

**Development acceleration of chikungunya vaccine candidate (VLA1553)**

**Potential partnering and business development opportunities**

# Agenda

- Introduction
- Financial Report FY 2018
- R&D Portfolio Update
- Outlook
- Q&A

Thank you
Merci
Danke
Tack

valneva