Valneva presents its H1 2018 financial results

Analyst Presentation
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valneva

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Agenda

- Introduction
- Financial Report H1 2018
- Lyme Update
- Outlook
- Q&A

Valneva consistently delivering positive newsflow in 2018

July
Valneva announced positive outcome of FDA End of Ph1 process

June
Renewal of the term of office of its Management Board Members

May
Valneva reports strong Q1 results and continues to advance key R&D programs

April
Valneva presents on Lyme disease and Zika at the 18th World Vaccine Congress

March
Valneva delivers strong 2017 financial results and advances key R&D programs

Chikungunya: Valneva initiates Phase 1 clinical study

Lyme disease: Valneva reports positive Phase 1 interim results for its Lyme vaccine candidate

February
Zika: Emergent BioSolutions and Valneva initiate Phase 1 clinical study

Valneva H1 2018 performance at a glance

On track to meet 2018 targets and guidance

✓ **Delivered on financial targets**	+ Product Sales +11.4% AER* (19% CER**) vs. H1 2017, in line with FY double-digit growth guidance + EBITDA of €5.8m in line with FY €5m - €10m guidance
✓ **Executed well on key growth drivers**	+ Good penetration of US private market led to over 19% AER* (27% CER**) IXIARO® sales growth vs H1 2017 + IXIARO® patent extended until 2032 in US
✓ **Advanced R&D pipeline**	+ Positive Ph1 interim results and EOP1 meeting with FDA for Lyme vaccine candidate. Ph2 initiation at end of 2018 + Zika and Chikungunya Ph1 initiated + recruitment completed

*AER: Actual Exchange Rate; **CER: Constant Exchange Rate

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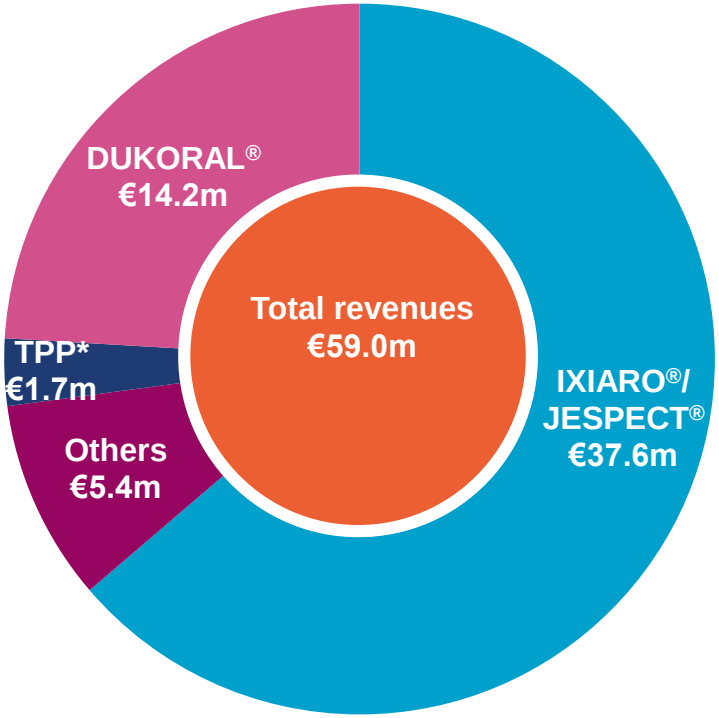
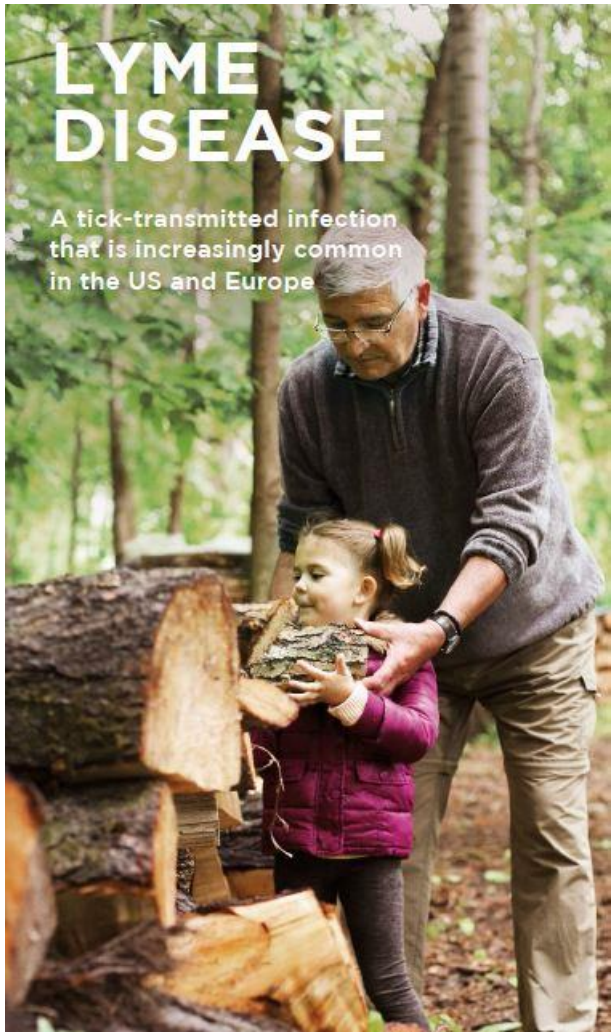
Valneva‘s Main Value Drivers Both Delivering

Ongoing Double Digit Product Sales Growth and R&D Progress



- Product sales €53.5m (11% AER, 19% CER)
- Direct sales now make up 81.9%
- Gross Margin 59.3%
- Cash generated from operating activities €13.7m



* Third Party Products

H1 2018 Profit & Loss Report

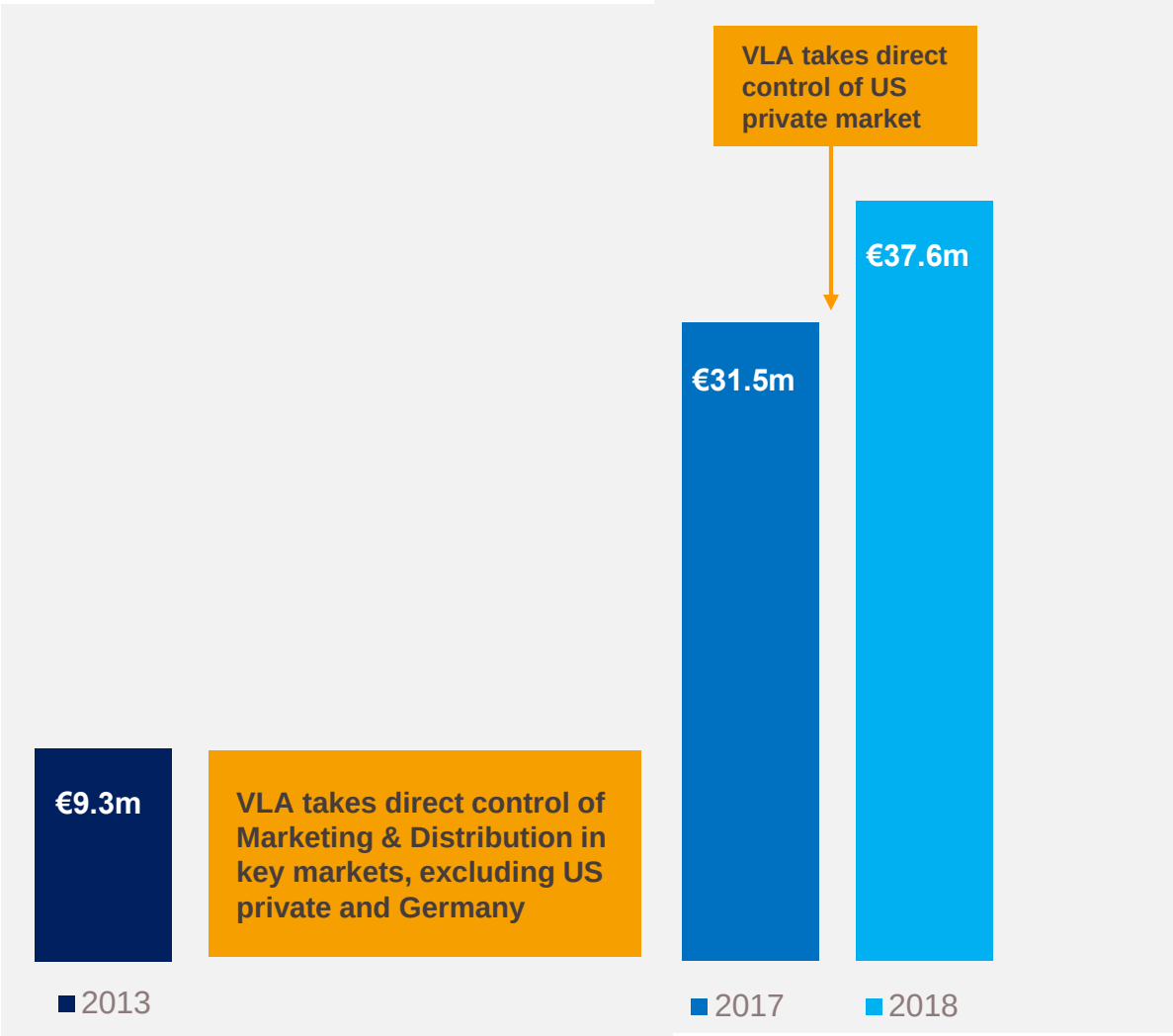
Strong revenue performance driven by IXIARO® sales

€m	6 months ended June 30	
	2018	2017
Product Sales	53.5	48.1
Revenues from collaboration, licensing and services	5.4	5.8
Revenues	**59.0**	**53.9**
Cost of goods and services	(24.0)	(24.4)
Research and development expenses	(12.9)	(9.7)
Marketing and distribution expenses	(10.9)	(8.2)
General and administrative expenses	(8.8)	(7.4)
Other income[1] / (expense), net	1.6	1.3[1]
Amortization and impairment	(1.6)	(3.6)
OPERATING PROFIT	**2.3**	**1.8**
Finance results and tax	(2.5)	(6.2)
LOSS FOR THE PERIOD	**(0.2)**	**(4.4)**
EBITDA[2]	**5.8**	**7.6**

1 "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. **2** First half 2018 EBITDA was calculated by excluding €3.5 million of depreciation and amortization from the €2.3 million operating profit as recorded in the condensed consolidated income statement under IFRS

IXIARO®: Transformational Sales Growth

H1 IXIARO® product sales revenues 2013 - 2018

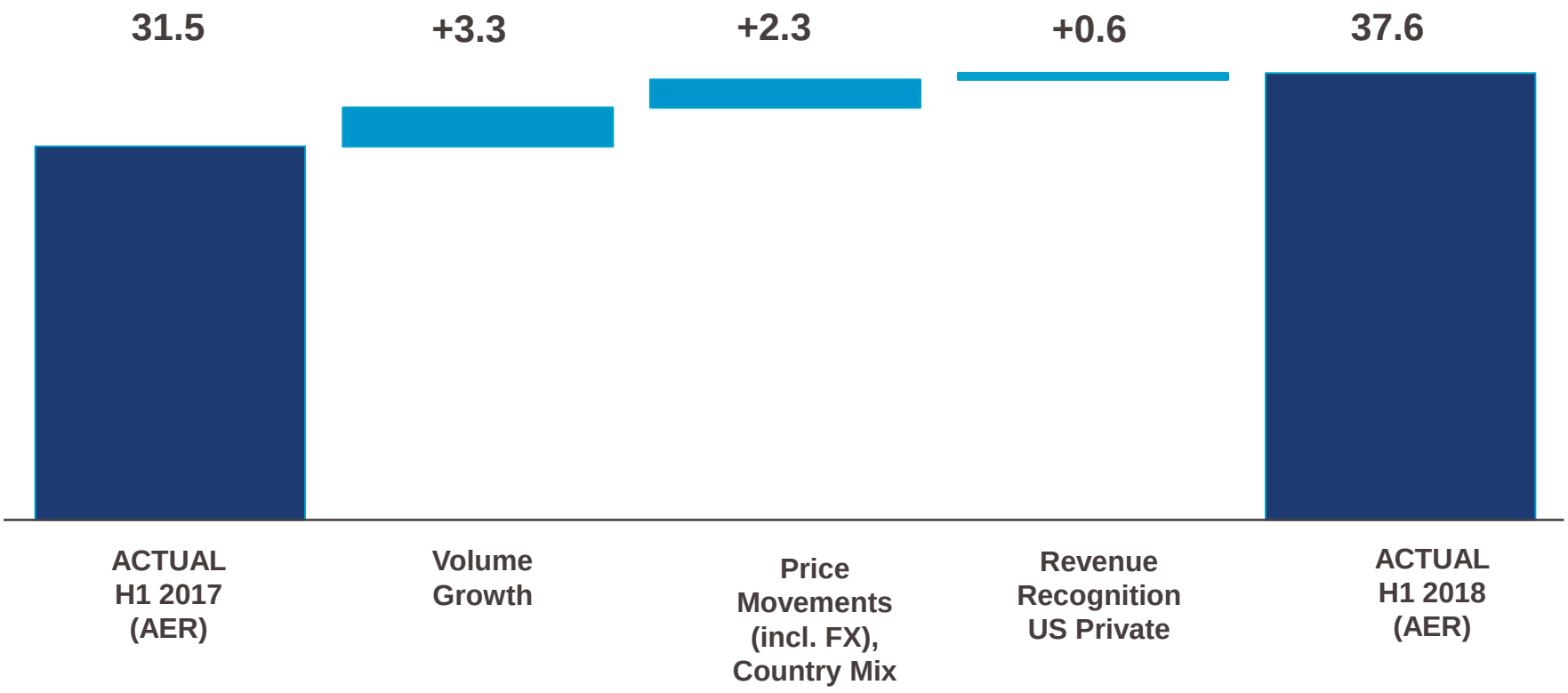


Highlights

- **Over 300% growth in IXIARO® sales revenues since 2013**
- **US biggest contributor to topline (60% in H1 2018)**
- **Double digit growth to continue 2018 through:**
  - › Increased penetration in key markets
  - › Rapid schedule adoption (eg. Canada)
  - › Development of commercial network, including US private market
- **Further margin improvement expected**
  - › Largely fixed manufacturing cost structure to translate into margin growth

IXIARO Sales Analysis

Breakdown of year-on-year sales growth (€m AER)



Revenue analysis

Actual (AER) and Constant (CER) Exchange Rates

€m (CER as H1 avg. Act 2018)	H1 2017		H1 2018		2018 Guidance
	Actual	CER	Actual	CER	
Product sales revenues					
IXIARO®/JESPECT®	31.5	29.5	37.6	37.6	
DUKORAL®	15.4	14.4	14.2	14.2	
Third party products	1.2	1.1	1.7	1.7	
Total product sales	**48.1**	**45.1**	**53.5**	**53.5**	**>100**
Other revenues	5.8	5.6	5.4	5.4	
Total revenues	**53.9**	**50.7**	**59.0**	**59.0**	
Grants / R&D Tax credits	1.5	1.5	1.9	1.9	
Total revenues & grants[1]	**55.4**	**52.2**	**60.9**	**60.9**	**110 - 120**

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VLA15: the only Lyme disease vaccine in clinical development

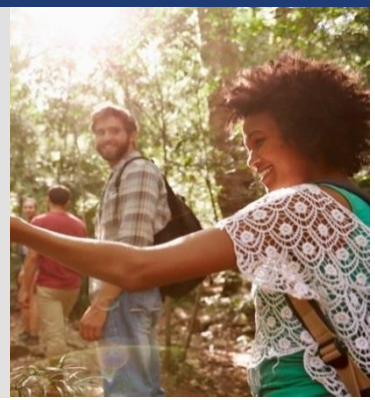
Market potential of approximately €700m - €800m[1]

Lyme disease

+ **Transmitted by *Ixodes scapularis* ticks (Northeastern & Midwestern US) and *Ixodes ricinus* ticks (Europe)[2]**
+ **Most common vector borne illness in the Northern Hemisphere (over 300,000 cases per year in US[3] and at least 200,000 cases per year in Europe[4])**
+ **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)**



Positive Phase 1 initial data

+ **Positive Phase 1 initial results showed favorable safety profile and encouraging immunogenicity for VLA15**
+ **FDA Fast Track Designation received mid 2017**
+ Preclinical data showed that the vaccine has the potential to provide protection against the majority of *Borrelia* species pathogenic for humans[5]

Acceleration towards Phase 2

+ **Valneva concluded the EoP1 process with FDA and reached alignment on Phase 2 strategy**
+ **Phase 2 initiation expected at end of 2018, subject to regulatory clearances**
+ **Medical need for Lyme vaccine steadily increasing as the disease footprint widens[6]**

1 Company estimate supported by independent market studies; **2** Stanek et al. 2012, The Lancet 379:461–473; **3** As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article; **4** 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; **5** http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294; **6** New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/

VLA15: Status Update

Progression into Phase 2 at end 2018 on track

Recent progress

- **Phase 1 (initiated early 2017)**
  - › Interim data (March 2018):
    - Study primary endpoint met (safety)
    - Encouraging immunogenicity data
  - › Study extension for Booster (Month 13)
    - ~ 60 subjects (EU only), fully recruited
    - Safety & Immunogenicity read-out (Month 19)
    - Data expected H1/2019
  - › End of Phase 1 (EOP1) process with FDA successfully concluded (July 2018)
    - Alignment on Phase 2 strategy
- **Continuous CMC[2] development for further industrialization**
- **Increasing investments in in-house capabilities and capacity to support ongoing progress**

Phase 2 – Current assumptions[1]

- **Key objectives**
  - › Dose optimization / final dosage[3]
    - Further doses will be included
  - › Confirmation of final schedule
    - Alternative schedule will be tested
- **Primary endpoint: Immunogenicity**
  - › GMTs (Geometric Mean Titers) for IgG against OspA ST1-ST6 (1 month after primary immunization)
- **~ 800 subjects**
  - › Conducted in US and EU (split tbc)
  - › >10 study sites
  - › In endemic areas
    - Including seropositive subjects
  - › Extended age range (18-70 yrs)

1 Study protocol(s) subject to regulatory approval(s); **2** Chemistry Manufacturing & Control; **3** Only adjuvanted formulations in Phase II

VLA15 outlook

Striving towards filing for licensure 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 incidence-driven interim analysis results submitted for after the first tick season
- **Pediatric studies (Ph 2/Ph3) largely in parallel**

Key upcoming milestones

- **Phase 2 initiation - End 2018**
- **Phase 2 data - H2 2020**
- **First filing for licensure – H2 2023**

1 Assumes licensure with data from one tick season; **2** Company assumptions. No detailed discussions with regulatory authorities have yet taken place

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2018 Financial Outlook

Ongoing double-digit sales growth, positive EBITDA with higher R&D investment driven by clinical development progression

	2017 Actual	2018 Outlook	Growth
Product sales	€92.6m	> €100m	> 10%
R&D investment	€23.4m	€30 – 35m	N/A
EBITDA	€10.8m	€5 – 10m	N/A

Total revenues and grants were €109.8m in 2017. Other revenues, (including service revenue and royalties) which tend to fluctuate from year to year, are expected to bring the company's overall revenue to between €110m and €120m for the year 2018.

Valneva 2018 – Exciting upcoming newsflow

+ Further product sales growth during the year

+ New IXIARO® supply contract with US DoD expected in Q4

+ Lyme Phase 2 initiation expected at end of year

+ Chikungunya Phase 1 execution with first data early 2019

+ Zika Phase 1 execution with first data end 2018 or early 2019

Thank you
Merci
Danke
Tack

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