

Valneva presents its FY 2019 financial results

Analyst Presentation
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Agenda



Introduction

Key R&D Updates

Financial Report FY 2019

Outlook

Q&A



2019 Highlights - Major Pipeline Progress, Record Product Sales and Strengthened Capital Position

Pipeline Progress

Valneva regained **full control of R&D assets** through termination of GSK SAA

Lyme disease vaccine candidate VLA15: Phase 2 patient recruitment completed

Chikungunya vaccine candidate VLA1553: Phase 1 completed, preparing for Phase 3

- \$23.4 million awarded by CEPI to support vaccine development for LMIC countries
- 2020: EoP2 meeting with FDA in Q1 aiming to move into Phase 3 asap

Strong financial results¹

- **Product sales of €129.5m** (+25% AER / +22% CER²) – at the top end of the guidance of €125m - €130m
- **>€64m cash** at the end of 2019
- 2020: **signed a new debt financing arrangement** to support late stage development of Lyme and chikungunya

¹ unaudited ² CER at constant exchange rates as 12M average Act 2019

Agenda



Introduction

Key R&D Updates

Financial Report FY 2019

Outlook

Q&A



Lyme Disease is a Massively Important Health Issue – Media Attention Spiked Again in January 2020

No approved options that can protect humans against Lyme disease

Analysis suggests a Lyme vaccine in the US and EU could have peak revenue potential of more than ~\$1b¹

Lyme disease cases may rise 92 per cent in US due to climate change (New Scientist)²




¹ Lyme Disease. L.E.K. interviews, research and analysis, ² <https://www.newscientist.com/article/2232705-lyme-disease-cases-may-rise-92-per-cent-in-us-due-to-climate-change/>



VLA15 – Key Value Driver in 2020 and Beyond

The only Lyme disease vaccine candidate in clinical development today



- 1 Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe**
- 2 Phase 2 interim data (primary endpoint) expected mid-2020**
- 3 FDA Fast Track Designation granted**
- 4 Established and proven Mode of Action for a Lyme disease vaccine**
- 5 Favorable safety profile and no associated safety concerns in Phase 1 studies¹
Phase 2 run-in (higher dosages than Phase 1) confirmed favorable safety profile of VLA15**

¹ Valneva PR: [Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate](#)



VLA15 Phase 2 Progressing Extremely Well

– Clinical development overview

Patient recruitment for both Phase 2 studies completed September 2019

Phase 2 first data due mid-2020

+ Initial data: Day 85 after base immunization schedule expected mid-2020

Phase 3 initiation planned in 2021/2022

+ Two placebo-controlled Phase 3 efficacy studies

› 8,000 subjects in each of US and Europe

› Based on current estimates of Lyme disease incidence rates in order to demonstrate efficacy of the vaccine in Lyme endemic regions in the U.S. and Europe

+ Detailed plans for Phase 3 entry to be discussed with FDA based on Phase 2 data

+ Timing depends on schedule, tick season(s), Phase 2 data and other factors

*Subject to development progress, regulatory approvals and company funding

Chikungunya is a Growing and Enduring Problem



Currently there is no vaccine or any **treatment options** for chikungunya

Global market including endemic regions (see below)
Traveller vaccine market at up to €250m¹

2019 - 2020: outbreaks² in Africa (Ethiopia, Kenya, Djibouti, Sudan), **Asia** (Thailand, Philippines); and **South America** (Brazil, Colombia)



¹ Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market., ² *Ethiopia, Kenya, Djibouti, Sudan; Thailand, Philippines; Brazil, Colombia*



VLA1553 – Key Growth Driver for Future Valneva Sales

The only single-shot vaccine candidate against chikungunya today



- 1** VLA1553 is a monovalent live attenuated¹ prophylactic vaccine targeting chikungunya virus neutralization
- 2** Currently no preventive vaccines or effective antiviral treatments exist for chikungunya
- 3** FDA Fast Track Designation granted. Priority Review Voucher eligible
- 4** Phase 1 complete. Aiming for accelerated approval pathway with potential Phase 3 start in Q2 2020; FDA EoP2 meeting February 2020
- 5** Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset
- 6** Up to \$23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI

¹ CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; Photo credit: James Gathany ([source](#)))



VLA1553 – Excellent Data and Progressing Rapidly

Status and clinical development overview

End of Phase 2 FDA meeting (EoP2) held

- Detailed Phase 3 design confirmation expected during Q1
- Confirmation for the Accelerated Approval Pathway already received
- Excellent Phase 1 previously reported

Additional non-clinical studies requested by FDA fully completed

- Mosquito transmission studies
- NHP study addressing biodistribution
- Passive transfer study in NHPs to develop surrogate of protection using human sera from VLA1553-101

Awaiting confirmation from FDA to initiate Phase 3* mid 2020

*Subject to FDA approval

Agenda



Introduction

Key R&D Updates

Financial Report FY 2019

Outlook

Q&A

2019 Product Sales Revenues up 25% AER (CER 22 %)

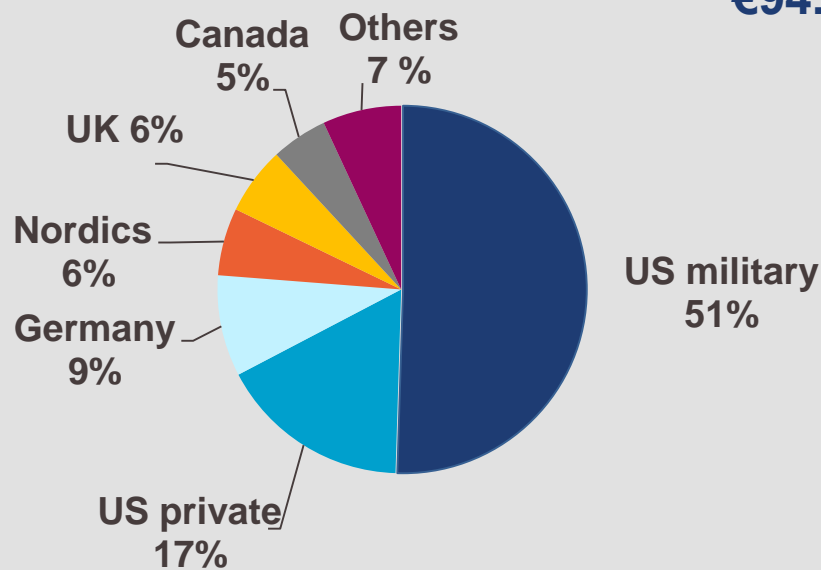


US drove top line growth, supported by other markets

IXIARO®/JESPECT®: North America driving growth

FY '19 product sales analysis

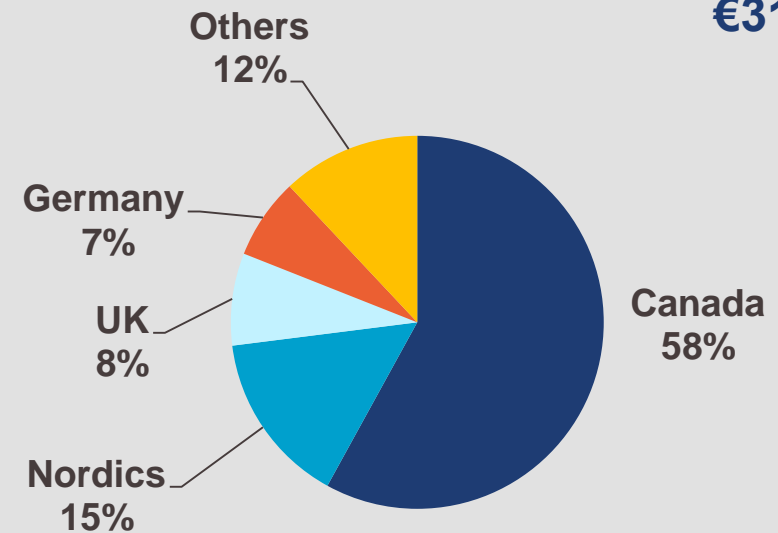
€94.1m



DUKORAL®: Canada remains our key market

FY '19 product sales analysis

€31.5m



All 2019 results are unaudited, excludes 3PP



IXIARO[®] Generated > 70% of 2019 Product Sales

– IXIARO[®] for traveler markets continuing to drive growth, USM sales peaked in 2019

€m (CER ¹)	FY 2019 (unaudited) Actual	FY 2018 CER	CER %	FY 2018 Actual
IXIARO [®] /JESPECT [®]	94.1	71.7	31%	69.6
DUKORAL [®]	31.5	30.7	3%	30.4
Third party products	3.9	3.6	9%	3.5
Total	129.5	105.9	22%	103.5

All 2019 results are unaudited, 1 CER at constant exchange rates as 12M average Act 2019

GSK SAA Termination Impacted 2019 Total Revenues by €10.7m



Net revenue effect according to IFRS

€m	
Total revenues (excl. effect of GSK SAA termination)	136.9
Settlement Fee (One time, fixed)	(9.0)
Settlement Fee (Milestone related, conditional; discounted) ¹	(6.0)
Release of SAA related contract liability	4.3
Net effect of GSK SAA termination	(10.7)
Total revenues (incl. effect of GSK SAA termination)	126.2

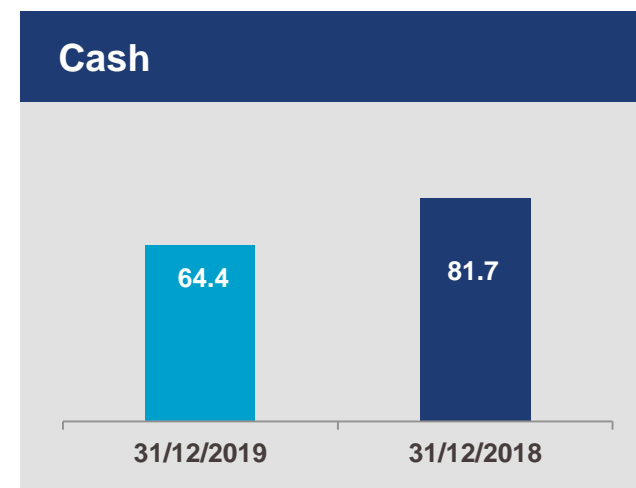
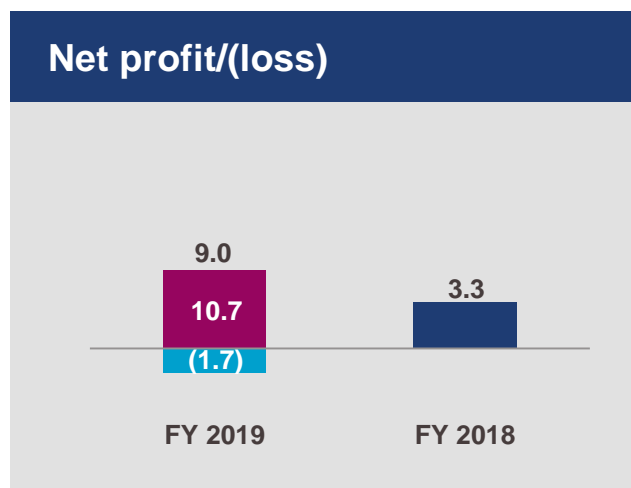
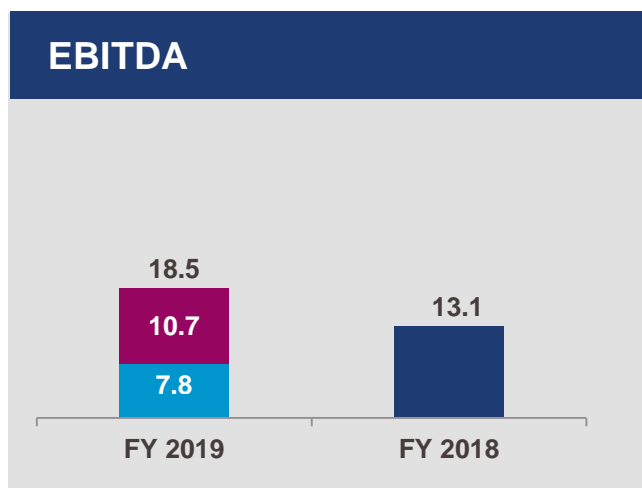
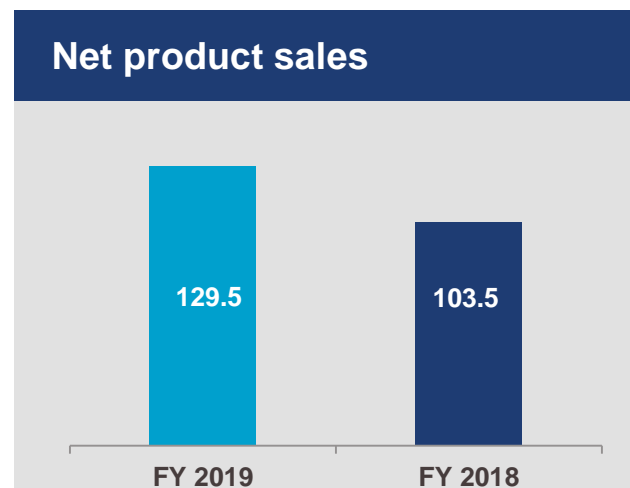
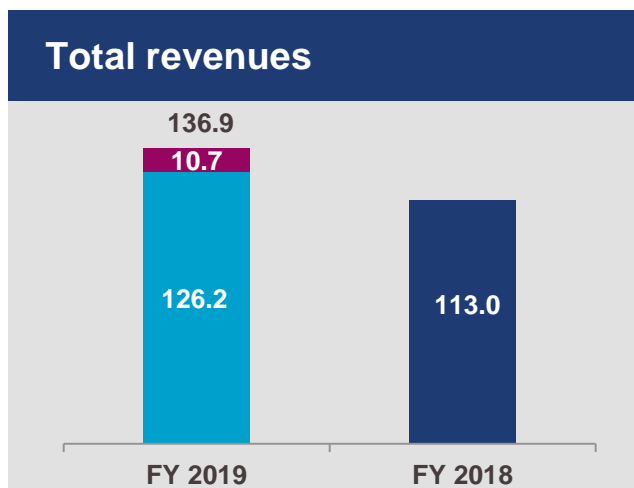
¹ €7m Milestone payment valued at fair value applying a 2.98% p.a. incremental borrowing rate

Strong Financials in 2019 (unaudited)



Financial results highlights (IFRS, € million) incl. GSK SAA termination effects

GSK SAA
termination
effects





Excellent Performance Management Across The Business

2019 P&L Report incl. GSK SAA termination effects (at AER)

* excluding SAA termination accounting / revenue recognition effect

€m	FY 2019 unaudited	FY 2019 excl. SAA effect unaudited	FY 2018
Product sales	129.5		103.5
Revenues from collaboration, licensing and services	(3.3)	7.4	9.6
Revenues	126.2	136.9	113.0
Cost of goods and services	(50.0)		(44.4)
Research and development expenses	(37.9)		(25.3)
Marketing and distribution expenses	(24.1)		(20.9)
General and administrative expenses	(18.4)		(16.9)
Other income / (expense), net	6.3		4.0
Amortization and impairment	(3.0)		(3.2)
Operating profit/loss	(0.8)	9.9	6.3
Finance, investment in associates & income taxes	(0.9)		(3.0)
Profit/loss for the period	(1.7)	9.0	3.3
EBITDA¹	7.8	18.5	13.1

¹ FY 2019 EBITDA was calculated by excluding €8.6m of depreciation and amortization from the €0.8m operating loss as recorded in the condensed consolidated income statement under IFRS; FY 2018 EBITDA was calculated by excluding €6.8m of depreciation and amortization from the €6.3m operating profit.



Gross Margin and Net Operating Margin Both Improved

Gross margin on product sales revenues FY (at AER)

Gross Margin	FY 2019 unaudited	FY 2018
Total product sales revenues (€m)	129.5	103.5
Total Product Sales Gross Margin (IXIARO [®] , DUKORAL [®] and Third Party Products)	65.3%	61.7%

Net Operating Margin	FY 2019 unaudited	FY 2018
Total product sales revenues	129.5	103.5
Cost of goods and services	(45.0)	(39.7)
Commercial costs ¹	(40.2)	(38.9)
Net operating margin	44.3	25.0
as % Revenues	34.2%	24.2%

¹ S&M, G&A, R&D, Other income/costs and amortization of intangibles

Agenda



Introduction

Key R&D Updates

Financial Report FY 2019

Outlook

Q&A

Financial Outlook 2020 – Investing in our Valuable R&D Assets



Traveler market sales growth, USM one time decline in 2020 after peak in 2019

	2019 unaudited	2020 Outlook
Product sales revenues <i>US military</i>	€48.0m	~€40m
Product sales revenues <i>Private market</i>	€81.5m	€85m - €95m
Total revenues	€126.2m	€135m - €145m
R&D investments	€37.9m	Up to €85m
Gross margin	65.3%	~65%
Net operating margin	34.2% ¹	30% - 35%
EBITDA	€7.8m	Up to (€35m)

¹ Net operating margin is based on the P&L for the Commercial Products segment including an allocation (56%) of G&A costs from Corporate Overheads and Amortisation of Intangibles related to IXIARO®



Lyme disease vaccine candidate VLA15

- **First Phase 2 data expected mid-2020**

Chikungunya vaccine candidate VLA1553 (Analyst Call will be held)

- **Final Phase 3 plans following EoP2 meeting with FDA expected during Q1**
- **Phase 3 initiation (Detailed design/timing, pending confirmation from FDA)**

New IXIARO[®] contract with the U.S. Department of Defense expected H1 2020

US IPO update during H2 2020

Agenda



Introduction

Key R&D Updates

Financial Report FY 2019

Outlook

Q&A

Thank you
Merci
Danke
Tack

