

# Valneva presents its Q1 2020 financial results

Analyst Presentation  
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# Q1 2020 Highlights: Lyme Collaboration with Pfizer, Solid Financial Results, Further R&D Milestones

## Solid Q1 2020 results, limited COVID-19 impact

- Product sales revenue of €32.7 million
- EBITDA of €2.4 million
- Strong cash position of €80.8 million at the end of March 2020

## Significant R&D milestones

- Unprecedented partnering deal with Pfizer signed for Phase 2 Lyme vaccine candidate VLA15
- Positive End of Phase 2 meeting granted by the FDA for chikungunya vaccine candidate VLA1553
- SARS-CoV 2 vaccine development initiated

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## **Valneva and Pfizer Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15**

**This partnership provides the opportunity for the rapid development and launch of a vaccine that has the potential to address a major unmet medical need.**

**The collaboration with Pfizer validates Valneva's strong vaccine R&D capabilities.**

**As an established global leader in the pharmaceutical industry with a strong commitment to vaccines and infectious diseases, Pfizer is the best partner for VLA15.**

# Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15



**Valneva and Pfizer will work closely together throughout the development of VLA15.**

## valneva

- Valneva is eligible to receive a total of \$308 million cash payments consisting of a \$130 million upfront payment, \$35 million in development milestones and \$143 million in early commercialization milestones.
- Valneva will fund 30% of all development costs through completion of the development program.
- Pfizer will pay Valneva tiered royalties starting at 19%.



- Pfizer will fund 70% of all development costs through completion of the development program.
- Pfizer will lead late-stage development and have sole control over commercialization.

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# Lyme Disease is a Massively Important Health Issue

Media attention spiked again in January 2020

**No available treatment to protect against Lyme disease**

**Major unmet medical need in North America and Europe**

**Lyme disease cases may rise 92 per cent in US due to climate change (New Scientist)<sup>2</sup>**




<sup>1</sup> Lyme Disease. L.E.K. interviews, research and analysis, <sup>2</sup> <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 studies<sup>1</sup>  
Phase 2 run-in (higher dosages than Phase 1) confirmed favorable safety profile of VLA15

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



# Chikungunya is a Growing and Enduring Problem

Representing a major public health threat

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

Global market including endemic regions (see below)  
**Traveler vaccine market at up to €250m<sup>1</sup>**

**2019 - 2020: outbreaks<sup>2</sup> in Africa** (Ethiopia, Kenya, Djibouti, Sudan), **Asia** (Thailand, Philippines); **and South America** (Brazil, Colombia)




<sup>1</sup> Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market., <sup>2</sup> *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 attenuated<sup>1</sup> 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. Potential Phase 3 start as soon as the COVID-19 situation permits (currently planned for Q4 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

<sup>1</sup> 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 delayed due to COVID-19 situation
- Accelerated Approval Pathway already confirmed
- 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

**Phase 3 initiation preparation proceeding**

\*Subject to FDA approval

# VLA2001 – SARS-CoV-2 Vaccine Development Program for COVID-19

## Collaboration with Dynavax

### Leveraging Valneva's technical and platform capabilities to develop an inactivated, adjuvanted whole virus vaccine candidate.

- Existing BSL3 labs recommissioned to undertake pre-clinical activities
- Resources from other early stage programs reallocated to support the project; grant funding also sought for clinical development and manufacturing
- Valneva and Dynavax to align with regulatory authorities on the optimal strategy for an expedited clinical development program
- Goal to initiate clinical trials before the end of 2020 (subject to successful preclinical work and receipt of appropriate funding)
- Production of clinical trial material expected in Valneva's FDA approved plant in Livingston, Scotland



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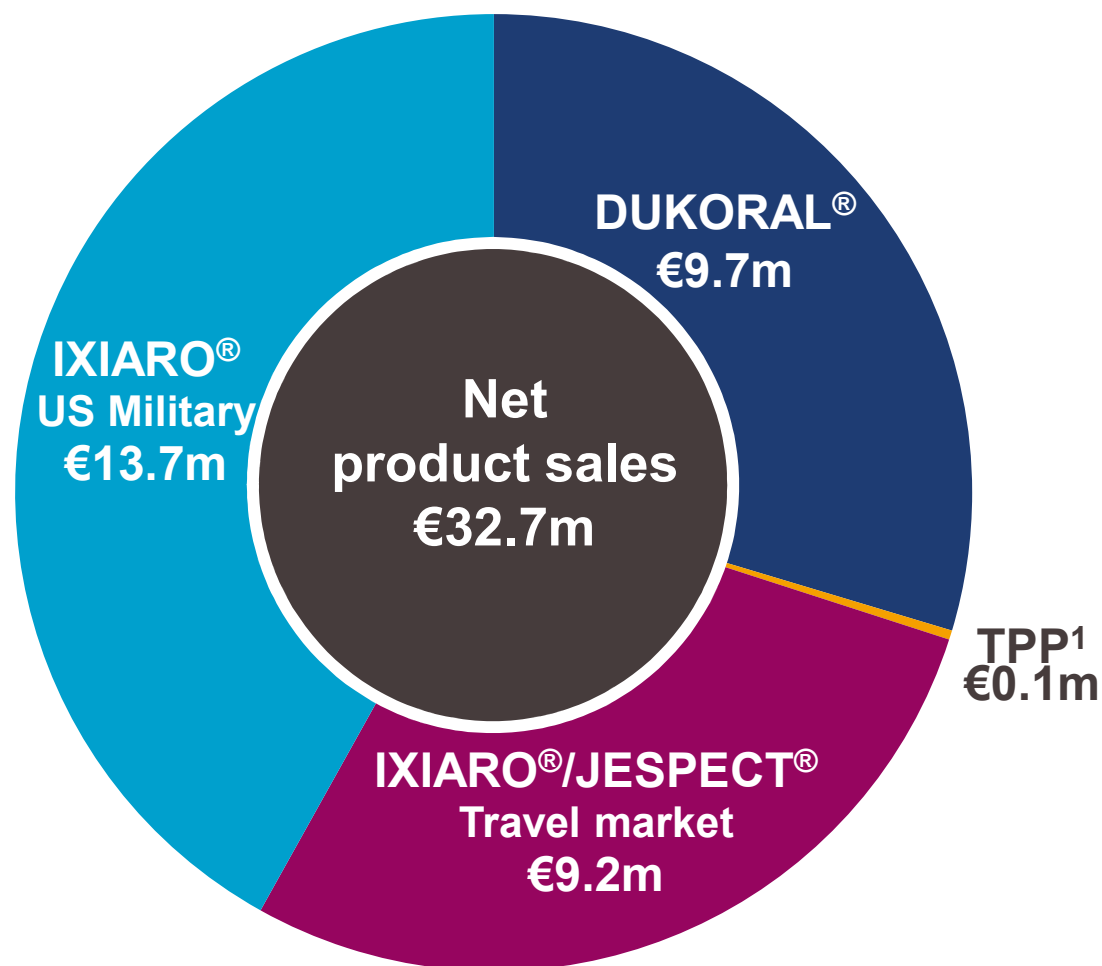
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# Top Line Performance Consistent With Q1 2019

## Q1 2020 Product sales, Unaudited (at AER)



**Product sales growth<sup>2</sup>**  
0% AER / -2% CER

**Direct sales**  
87%

**Gross margin<sup>3</sup>**  
69.4%

CER: at constant exchange rates; <sup>1</sup> Third party products sold by Valneva's commercial organization, <sup>2</sup> YoY comparison for same period <sup>3</sup> Gross margin on product sales



# Limited COVID-19 Impact on Q1 Product Sales



€m	Q1 2020 (unaudited) Actual (AER)	Q1 2019 (AER)	Q1 2019 (CER)	CER %
IXIARO®/JESPECT®	22.9	22.4	22.8	0%
DUKORAL®	9.7	9.6	9.7	0%
Third party products	0.1	0.8	0.8	-89%
<b>Total</b>	<b>32.7</b>	<b>32.8</b>	<b>33.3</b>	<b>-2%</b>

<sup>1</sup> CER at constant exchange rates as 3M average Act 2020



# Positive EBITDA Including Increase in R&D Investments

## Q1 2020 Profit & Loss Report (at AER)

€m	Q1 2020 unaudited	Q1 2019
Product sales	32.7	32.8
Revenues from collaboration, licensing and services	2.5	2.1
<b>Revenues</b>	<b>35.2</b>	<b>34.9</b>
Cost of goods and services	(12.1)	(12.2)
Research and development expenses	(13.3)	(6.3)
Marketing and distribution expenses	(6.0)	(5.6)
General and administrative expenses	(5.2)	(4.5)
Other income / (expense), net	2.2	0.8
Amortization and impairment	(0.7)	(0.7)
<b>Operating profit</b>	<b>0.1</b>	<b>6.2</b>
Finance, investment in associates & income taxes	(1.3)	(1.4)
<b>Profit/loss for the period</b>	<b>(1.2)</b>	<b>4.9</b>
<b>EBITDA<sup>1</sup></b>	<b>2.4</b>	<b>8.2</b>

<sup>1</sup> Q1 2020 EBITDA was calculated by excluding €2.3 million of depreciation and amortization from the €0.1 million operating profit as recorded in the consolidated income statement under IFRS.



## Healthy Gross Margin and Net Operating Margin

Gross Margin Calculated on Product Sales Revenues (at AER)

<b>Gross Margin</b>	<b>Q1 2020 unaudited</b>	<b>Q1 2019 unaudited</b>
Total product sales revenues (€m)	32.7	32.8
Total Product Sales <b>Gross Margin</b> (IXIARO <sup>®</sup> , DUKORAL <sup>®</sup> and Third Party Products)	69.4%	66.2%

<b>Net Operating Margin</b>	<b>Q1 2020 unaudited</b>	<b>Q1 2019 unaudited</b>
Total product sales revenues	32.7	32.8
Cost of goods and services	(10.0)	(11.1)
Commercial costs <sup>1</sup>	(10.7)	(10.0)
<b>Net operating margin</b>	<b>12.0</b>	<b>11.7</b>
as % Revenues	36.7%	35.7%

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

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# Commercial Environment and Sales Outlook Evolving

## Key assumptions (company estimates)

### Macro-environment

- Easing of social-distancing measures starting in Q2 (country-by-country)
- Slow recovery of international air travel due to border closures and recession (Q4 -50% vs PY) – higher impact in Europe vs North America<sup>1</sup>
- Approximately 60% of travelers would be ready to fly - either domestic or international – within two months of the end of the COVID-19 pandemic<sup>2</sup>
- Economic recovery supported through Government stimulus packages

### Product Sales

#### Travel segment

- Significant reduction in Q2 travel vaccines demand linked to global shutdown
- Re-opening of travel clinics/ travel services in phase with re-established demand
- Phased restart of traveler segments assumed (e.g. business vs leisure)
- Increased awareness of Travel Health / likelihood to consult before traveling<sup>3</sup>

#### USM

- Deployment of USM troops and dependents may resume over summer<sup>4</sup>
- Awarding of JE supply contract expected in Q2/Q3<sup>5</sup>

<sup>1</sup> IATA COVID-19 Updated Impact Assessment (Apr 14, 2020) <sup>2</sup> IATA Economics' Chart of the Week – Passenger Confidence (April 24, 2020) <sup>3</sup> Valneva commissioned survey of Canadian consumers (March 2020) <sup>4</sup> <https://www.militarytimes.com/news/your-military/2020/04/18/dod-travel-ban-extended-to-june-30/> <sup>5</sup> VLA Management estimate

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# Updated Financial Outlook 2020

Including Pfizer collaboration impact<sup>3</sup>

	Pre- COVID-19	COVID-19 Guidance <sup>2</sup>	Pfizer Deal Impact <sup>3</sup>	Q1 Guidance Update
Product sales revenues	~€40m <i>US Military</i>	€85m - €115m		€75m - €95m
	€85m - €95m <i>Travel</i>			
Other revenues	€10m	€10m	+€10m - +€30m	€20m - €40m
Total revenues	€135m - €145m	€95m - €125m		€95 - €135m
R&D investments	Up to €85m	Up to €80m		Up to €80m
Gross margin (on product sales revenue)	~65%	~65%		60% - 65%
Net operating margin <sup>1</sup>	30% - 35%	30% - 35%		15% - 20%
EBITDA	Up to (€35m)	Up to (€50m)	+€10m - +€30m	(€10m) - (€30m)

<sup>1</sup> 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® <sup>2</sup> 2020 Guidance from Press Release: [Valneva Provides Business Update on COVID-19 Situation](#); <sup>3</sup> subject to agreement on revenue recognition

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# Key Upcoming Newsflow



## **Lyme disease vaccine candidate VLA15**

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

## **Chikungunya vaccine candidate VLA1553**

- **Phase 3 initiation (pending COVID-19 & FDA confirmation)**

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

**COVID-19 vaccine candidate expected to enter clinical trials before the end of 2020**

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Thank you  
Merci  
Danke  
Tack

