

Valneva business update and unaudited FY 2020 financial results

Analyst Presentation
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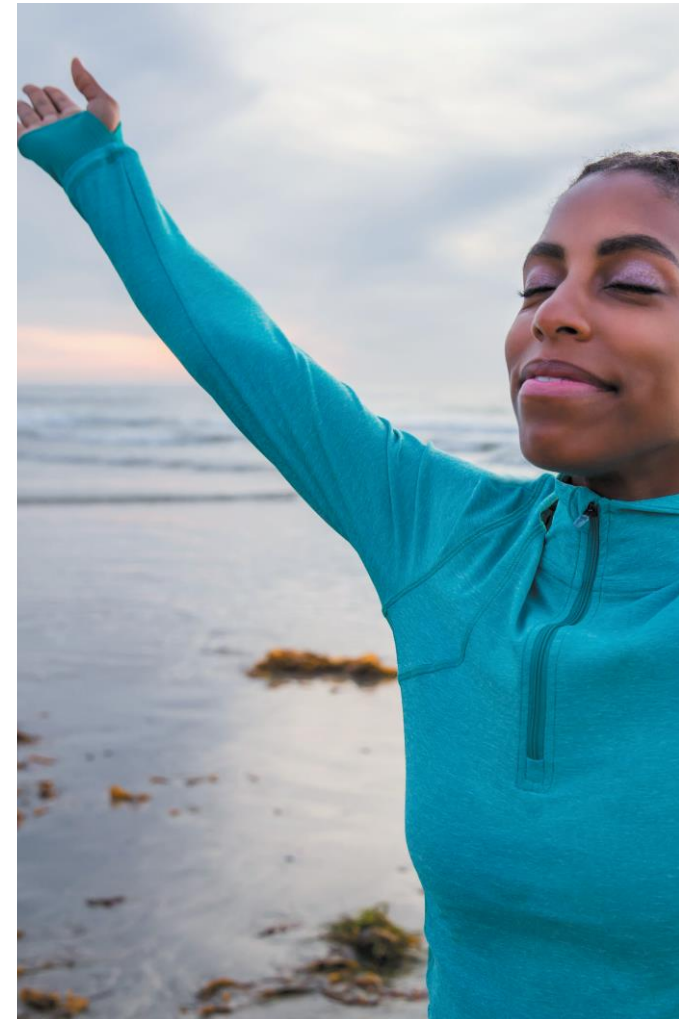
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Valneva Reports FY 2020 Results and Major Corporate Achievements

- **Excellent progress on clinical programs**
 - Lyme partnered with Pfizer
 - Chikungunya in Phase 3
- **COVID – strong response to contribute to global situation**
 - Whole-virus inactivated product in clinical development in Europe
 - UK partnership, leveraging manufacturing plants
- **FY 2020 cash and cash equivalents of €204.4 million underlining strong balance sheet**
 - Despite lower product sales due to pandemic
- **EGM passes resolutions to allow preparation for possible Nasdaq listing and US IPO**



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VLA15: The Only Lyme Disease Vaccine in Clinical Development Today



- 1 Exclusive, worldwide partnering deal with Pfizer**
- 2 FDA Fast Track Designation granted**
- 3 Positive initial results reported from Phase 2 studies^{1,2}
Initiation of accelerated pediatric study (VLA15-221) planned for Q1 2021³**
- 4 Multivalent vaccine (six serotypes) to protect against Lyme disease in North America and Europe**
- 5 Follows proven Mechanism of Action for a Lyme disease vaccine**

¹ [Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate](#); ² [Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15](#); ³ [Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate](#)

VLA15: Exclusive, Worldwide Partnering Deal with Pfizer



Collaboration with Pfizer for late stage development and future commercialization¹

- Pfizer funding 70% of development costs through program completion
- Valneva eligible to receive a total of \$308 million upfront and milestone payments (\$130 million received in June 2020²)
- Valneva to receive tiered royalties starting at 19%



Positive initial Phase 2 results reported^{3,4}

- Positive seroconversion data, dose and schedule agreed

Initiation of pediatric study VLA15-221 (aged 5-17 years), planned for March 2021⁵

¹ Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15; ² Valneva Reports H1 Results Marked by Major Corporate Achievements and Strong Cash Position; ³ Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate; ⁴ Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15; ⁵ Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

VLA15: Development Outlook



Phase 2 study (VLA15-221) in adults and pediatric subjects to start enrollment in March 2021 (adults first)¹

- Study will include participants from 5-65 years of age and a reduced immunization schedule (Month 0-6 compared to Month 0-2-6)
- The study will trigger a milestone payment of \$10 million, upon dosing of the first subject, from Pfizer to Valneva
- Initial pediatric population data expected in Q2 2022¹
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the 6 Month dose¹

Phase 3 pivotal efficacy trial planned to commence pending positive readout from VLA15-221 in 2022¹

- Clinical readout, based on one tick season, projected end 2023

Subject to regulatory approval first licensure anticipated H1 2025

¹ [Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate](#)



VLA1553: Most Advanced Chikungunya Vaccine Candidate in the World



1

Phase 3 initiated in September 2020¹, now over 80% enrolled; Positive EoP2 meeting with the FDA; Accelerated Approval Pathway confirmed²

2

Potentially eligible for Priority Review Voucher³; FDA Fast Track⁴ and EMA PRIME⁵ designation granted

3

Up to \$23.4 million awarded to Valneva for R&D by CEPI, Partnership with Instituto Butantan for LMICs⁶

4

Compatible with existing commercial and manufacturing capabilities

5

Single shot, monovalent live attenuated⁷ prophylactic vaccine targeting chikungunya virus neutralization

¹ Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553; ² Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study; ³ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>; ⁴ Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate; ⁵ Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation; ⁶ Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; ⁷ CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); **Photo credit:** [James Gathany](#)



VLA1553: Development Outlook

Pivotal Phase 3 study initiated in September 2020

Phase 3 Clinical Development Program underway

- Pivotal Phase 3 safety and immunogenicity trial in ~4,000 healthy volunteers ongoing
 - Initial data mid-2021
 - Primary read-out on Day 29 (based on surrogate of protection¹) mid-2021
- Lot-to-Lot consistency trial initiated in ~400 subjects²
- Adolescents clinical trial in 750 volunteers in Brazil planned to commence in 2021³

Accelerated approval pathway agreed in principle with FDA in EoP2 meeting

VLA1553 may be eligible for Priority Review Voucher⁴

¹ proposed seroprotection threshold under FDA review, ² Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate ³ in collaboration with development partner Instituto Butantan, under CEPI funding, ⁴ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>

VLA2001: First Inactivated COVID-19 Vaccine in European Clinical Trials



- 1 UK government deal worth up to €1.4 billion¹ with development and manufacturing funding; advanced discussions with European Commission announced²; ongoing dialogue with other potential customers**
- 2 Facilitated program acceleration through use of Valneva's FDA-registered facility; commercial manufacturing commenced January 2021³**
- 3 Combines Valneva's proven track record with inactivated vaccines and Dynavax's advanced CpG 1018 adjuvant⁴**
- 4 Phase 1/2 clinical trial initiated in December 2020⁵, recruitment complete³**
- 5 Subject to regulatory approval, deliveries planned to commence H2 2021**

¹ [Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government](#); ² [Valneva in Advanced Discussions with European Commission to Supply up to 60 Million Doses of Inactivated, Adjuvanted COVID-19 Vaccine Candidate](#); ³ [Valneva Commences Manufacturing of its Inactivated, Adjuvanted COVID-19 Vaccine, Completes Phase 1/2 Study Recruitment](#); ⁴ [Valneva and Dynavax Announce Commercial Supply Agreement for Inactivated, Adjuvanted COVID-19 Vaccine](#); ⁵ [Valneva Initiates Phase 1/2 Clinical Study of Inactivated, Adjuvanted COVID-19 Vaccine Candidate](#); **Photo credit:** [CDC/Alissa Eckert, MSMI](#); [Dan Higgins, MAMS](#)



VLA2001 – Overview

Only inactivated COVID-19 vaccine candidate developed in Europe and adjuvanted with Alum+CpG 1018

- 1 **Well-known inactivated approach:** proven technology with few safety restrictions
- 2 Might be used **in all population groups** including most vulnerable populations
- 3 SARS-CoV2 inactivated vaccines (adjuvanted with Alum only) have already reported **safety and efficacy**¹
- 4 The addition of **CpG 1018** (approved as part of **HEPLISAV-B**[®]) in our candidate has shown to induce consistently **higher antibody levels** in mice than Alum only vaccine formulations
- 5 **Standard cold chain storage** requirements (2° to 8°)
- 6 **Manufactured in Europe**, by an experienced vaccine producer, leveraging its own FDA/EMA/MHRA facilities and a process that has already been fully industrialized

¹ Sinopharm: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30831-8/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30831-8/fulltext), Sinovac: [https://www.thelancet.com/article/S1473-3099\(20\)30843-4/fulltext](https://www.thelancet.com/article/S1473-3099(20)30843-4/fulltext), [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30987-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30987-7/fulltext)



VLA2001: Collaboration to Provide up to 190 Million Doses of Inactivated, Adjuvanted Vaccine to the UK



UK Government Agreement Worth up to €1.4 Billion

- Valneva to supply up to 190 million doses in a deal worth up to €1.4 billion¹
- Including 60 million doses for 2021
 - › Option to order 40 million doses for supply in 2022 exercised in Jan. 2021²
 - › UK Government retains options over a further 90 million doses for supply between 2023 and 2025²

Agreement includes funding support for expansion of Valneva's manufacturing facilities³ and clinical development in the UK

In advanced discussions with European Commission to supply up to 60 million doses⁴

¹ Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government ; ² Valneva Announces UK Government Exercise of Option for 40 Million Doses of its Inactivated, Adjuvanted COVID-19 Vaccine ; ³ Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program; ⁴ Valneva in Advanced Discussions with European Commission to Supply up to 60 Million Doses of Inactivated, Adjuvanted COVID-19 Vaccine Candidate

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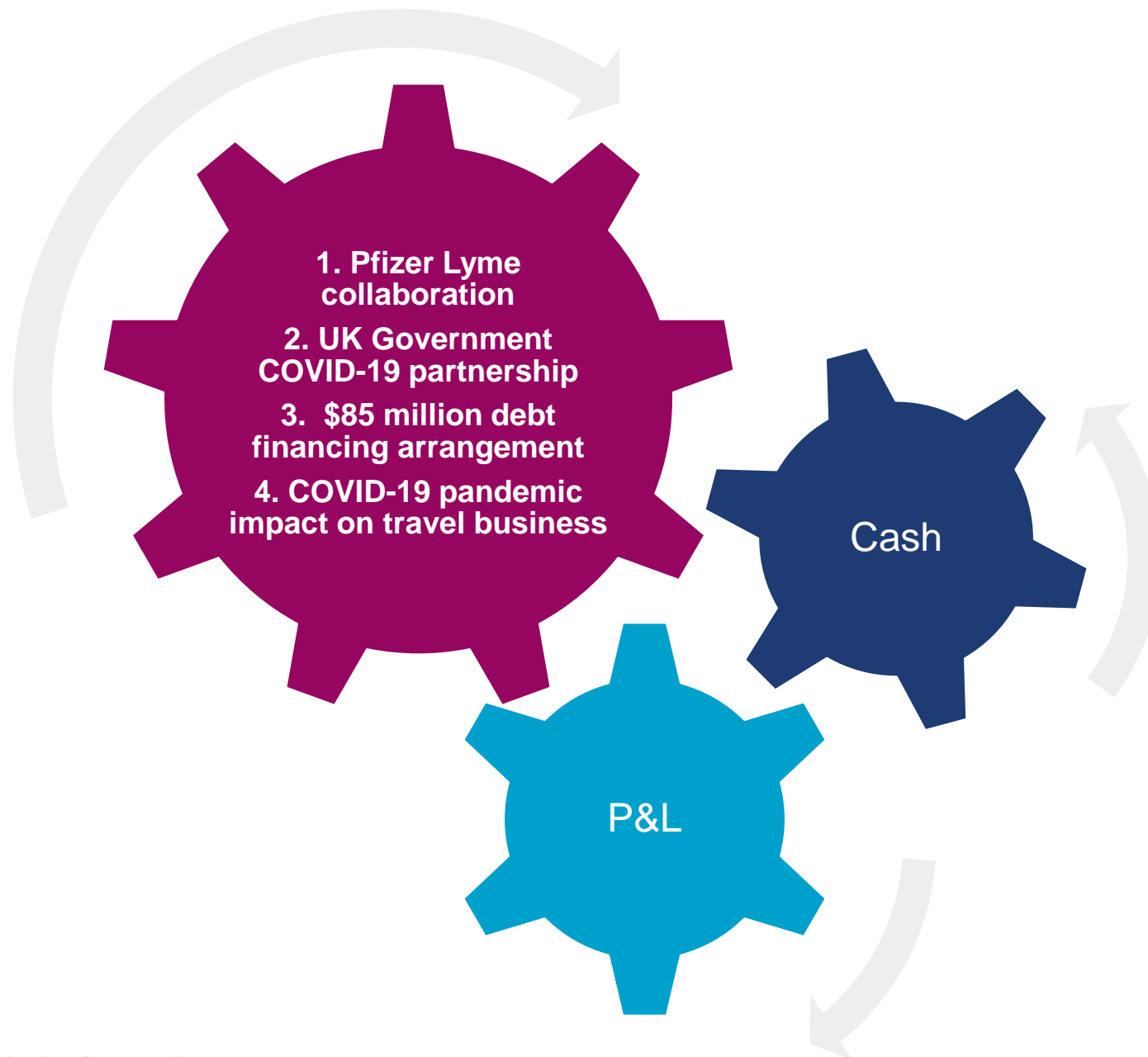
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Several Key 2020 Events Affect Cash and Financial Results



Strong Cash Position of €204.4 million at End of December

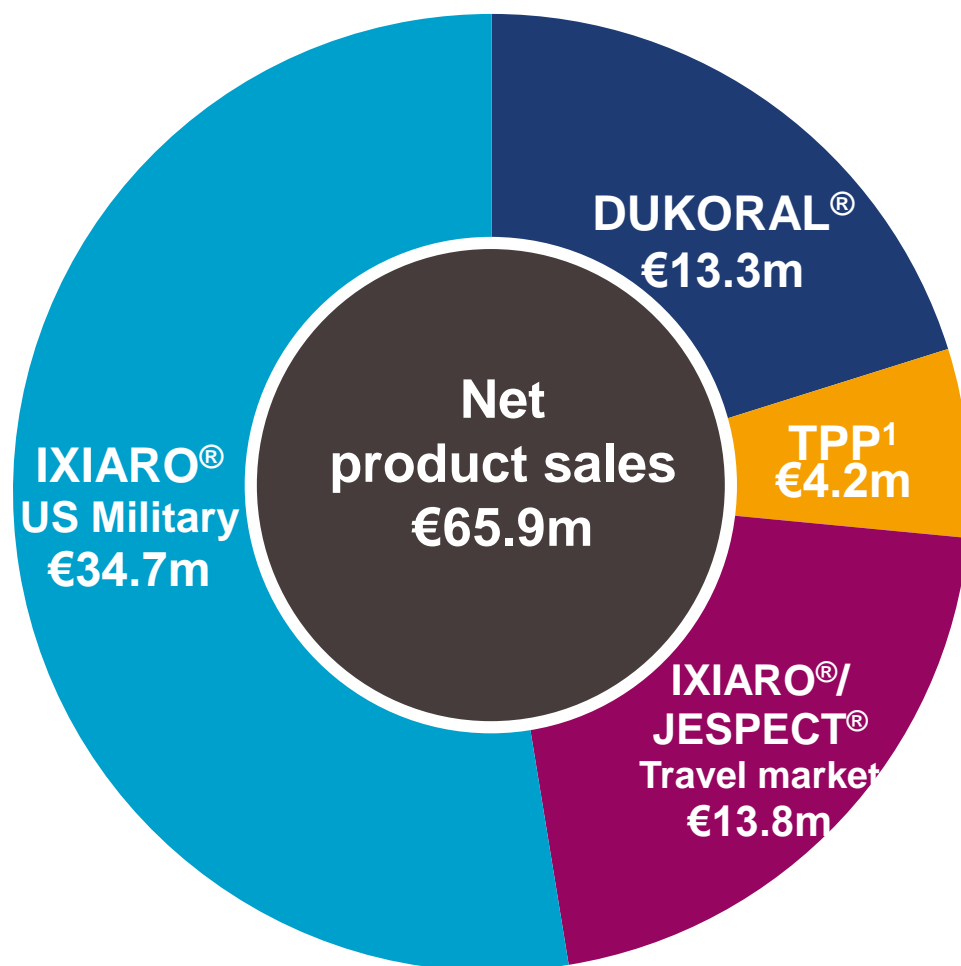


FY 2020 cash and cash equivalents of €204.4 million, exceeding guidance

- FY 2020 cash and cash equivalents include
 - \$130 million (€116.9 million) from the Lyme disease collaboration with Pfizer
 - €96.7 million from the UK COVID-19 vaccine partnership
- \$60 million (€53.8 million) drawn down from the \$85 million debt financing arrangement with Deerfield Management Company and OrbiMed
- Further COVID-19 payments from UK Government in Q1 2021 based on 60m dose payment instalment plan and exercise of 40m dose option



FY 2020 Product Sales (AER, unaudited)



Product sales²
-49% AER / -48% CER

Direct sales
82%

Gross margin³
36.6%

¹ Third party products sold by Valneva, ² YoY comparison for same period, AER: Actual exchange rates, CER: Constant exchange rates ³ Gross margin on product sales



FY 2020 Product Sales Analysis

Pandemic impact on travel industry adversely impacted product sales

| €m | FY 2020 (unaudited) (AER) | FY 2019 (AER) | FY 2019 (CER) | CER ¹ % |
|---|---------------------------------|------------------|------------------|-----------------------|
| IXIARO [®] /JESPECT [®] | 48.5 | 94.1 | 91.9 | -47.2% |
| DUKORAL [®] | 13.3 | 31.5 | 31.6 | -57.9% |
| Third party products | 4.2 | 3.9 | 3.8 | +8.5% |
| Total | 65.9 | 129.5 | 127.3 | -48.2% |

¹ CER at constant exchange rates as Full Year average Act 2020

EBITDA Loss Also Reflects Increase in R&D Investments



| €m (2020 unaudited) | FY 2020 | FY 2019 |
|---|---------------|--------------|
| Product sales | 65.9 | 129.5 |
| Revenues from collaboration, licensing and services | 44.4 | (3.3) |
| Revenues | 110.3 | 126.2 |
| Cost of goods and services | (54.3) | (52.8) |
| Research and development expenses | (84.5) | (38.0) |
| Marketing and distribution expenses | (18.3) | (24.1) |
| General and administrative expenses | (27.5) | (18.4) |
| Other income / (expense), net | 19.1 | 6.3 |
| Operating loss | (55.1) | (0.8) |
| Finance, investment in associates & income taxes | (9.3) | (0.9) |
| Profit/loss for the period | (64.4) | (1.7) |
| EBITDA¹ | (45.2) | 7.8 |

¹ FY EBITDA was calculated by excluding €9.9 million (2019: €8.6 million) of depreciation and amortization from the €55.1 million (2019: €0.8 million) operating loss as recorded in the consolidated income statement under IFRS.



Effect of COVID-19 Program on Group P&L – FY2020

COVID to be reported as separate segment as of 2021

| €m (2020 unaudited) | FY 2020 | FY2020 | FY 2020 |
|---|---------------|---------------|---------------|
| | Group | COVID only | excl. COVID |
| Product sales | 65.9 | | 65.9 |
| Revenues from collaboration, licensing and services | 44.4 | | 44.4 |
| Revenues | 110.3 | | 110.3 |
| Cost of goods and services | (54.3) | | (54.3) |
| Research and development expenses | (84.5) | (19.0) | (65.5) |
| Marketing and distribution expenses | (18.3) | | (18.3) |
| General and administrative expenses | (27.5) | (0.8) | (26.8) |
| Other income / (expense), net | 19.1 | 2.4 | 16.7 |
| Operating loss | (55.1) | (17.3) | (37.8) |
| Finance, investment in associates & income taxes | (9.3) | | (9.3) |
| Profit/loss for the period | (64.4) | (17.3) | (47.0) |
| EBITDA¹ | (45.2) | (17.3) | (27.8) |

¹ FY EBITDA was calculated by excluding €9.9 million (2019: €8.6 million) of depreciation and amortization from the €55.1 million (2019: €0.8 million) operating loss as recorded in the consolidated income statement under IFRS.

FY 2020 Margins Adversely Affected by the COVID-19 Pandemic



Gross and Net Operating Margin (on Product Sales) at AER (unaudited)

| Gross Margin | FY 2020 | FY 2019 |
|---|-----------------------------|-----------------------------|
| Total product sales revenues (€m) | 65.9 | 129.5 |
| Total Product Sales Gross Margin (IXIARO®, DUKORAL® and Third Party Products) | 36.6% 40.8% ¹ | 63.1% 65.2% ¹ |
| Net Operating Margin on Product Sales (€m) | FY 2020 | FY 2019 |
| Total product sales revenues | 65.9 | 129.5 |
| Cost of goods and services | (41.8) | (47.8) |
| Commercial costs ² | (35.2) | (37.5) |
| Net operating margin on product sales | (11.1) | 44.2 |
| as % Revenues | (16.9%) | 34.1% |

¹ Gross Margin before re-classification of Depreciation & Amortization of Intangibles

² S&M, G&A, R&D and Other income/costs

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Guidance related to VLA2001 revenues

The Company is not providing guidance related to its VLA2001 revenues and program at this time. This guidance will be material to the Company, therefore needs to be based on robust information.

Non-VLA2001 related business

Total revenues of €100 million – €115 million

R&D investments of €65 million – €75 million

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Lyme disease vaccine candidate VLA15

- Initiation of Phase 2 study VLA15-221, including pediatric development, planned for Q1 2021; further Phase 2 milestones and read-outs expected during 2021

Chikungunya vaccine candidate VLA1553

- Initial Phase 3 data expected mid-2021

COVID-19 vaccine candidate VLA2001

- Phase 1/2 Initial data expected in April
- Phase 3 initiation/further development subject to Phase 1/2 data and regulatory discussions

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Thank you
Merci
Danke
Tack

