Valneva Reports Full Year 2021 Results and Provides Corporate Updates

Analyst Presentation
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valneva

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Agenda

- **Introduction**
- **Business Update**
- **Financial Report FY 2021**
- **Financial Outlook**
- **Newsflow**
- **Q&A**

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Excellent progress in all clinical programs

- **Lyme disease**: Further positive Phase 2 results reported, including booster response; Phase 3 dose and schedule selected
- **COVID-19:** Positive Phase 3 results reported; EUA granted in Bahrain; reviews ongoing with EMA and MHRA
- **Chikungunya**: Final positive Phase 3 results and topline lot-to-lot data reported; Adolescent Phase 3 trial initiated

Strong full-year 2021 revenues and cash position

- Total revenues of €348.1m in 2021 compared to €110.3m in 2020 – an increase of 216%
- Cash position of €346.7m (December 31, 2021)

Successful Nasdaq Initial Public Offering (IPO), European placement and follow-on offering

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VLA15: Multivalent Lyme Disease Vaccine Candidate

Only Lyme Disease Program in Advanced Clinical Development Today

1. **FDA Fast Track Designation granted**
2. **Exclusive, worldwide partnership with Pfizer**
3. **Topline results reported from Phase 2 trials[1,2,3], incl. booster response[4]; Phase 3 schedule selected; Topline pediatric data expected in Q2 2022**
4. **Multivalent vaccine candidate (six serotypes) to help protect against Lyme disease in the United States and Europe**
5. **Follows validated 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 and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate **; 4** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

VLA15: Development Progress and Outlook

Positive Topline Phase 2 Results[1] in Adults Reported; Topline Pediatric Data Expected in Q2

VLA15-221 recruited 625 randomized participants, 5 to 65 years of age[2]

- Three-dose primary series vaccination schedule selected for use in adults for Phase 3, based on stronger immune response vs. two-dose schedule; sub-analysis reported February 2022[3]
- Topline pediatric data are expected in the second quarter of 2022
- As with VLA15-202, VLA15-221 will also investigate a booster dose of VLA15, administered one year following the six-month dose[1]

VLA15-202 results and topline booster data announced in Sep. 2021[4]

- VLA15 immunogenic across all dose groups; elicited high antibody responses across all serotypes one month after primary vaccination series (primary endpoint)
- Booster dose one year following the six-month dose elicited strong anamnestic response

Phase 3 pivotal efficacy trial planned to commence in Q3 2022[1]

- Clinical readout, based on one tick season, projected early 2024
- $25m milestone payment due to Valneva upon trial initiation

1 Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate., **2** Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate; **3** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; **4** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

VLA1553: Single Shot Chikungunya Vaccine Candidate

Most Advanced Chikungunya Vaccine Program worldwide

1. **Final positive pivotal Phase 3 results[1] and topline lot-to-lot data[2] reported; Adolescent Phase 3 trial initiated in January 2022[3]**
2. **FDA Breakthrough Therapy[5], Fast Track[6] and EMA PRIME[7] designations granted; Potentially eligible for Priority Review Voucher[4]; FDA Pre-submission process expected in Q2 2022**
3. **Single shot, live attenuated[8] prophylactic vaccine targeting chikungunya virus neutralization**
4. **Up to $23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs[9]**
5. **Excellent fit with existing commercial and manufacturing capabilities**
6. **Global market, including endemic regions, estimated to exceed $500 million annually by 2032[10]**

Note: Photo credit: James Gathany. **1** Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; **3** Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate **;** **4** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program; **5** Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate ; **6** Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate; **7** Valneva's Chikungunya vaccine candidate awarded EMA prime designation; **8** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); **9** Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-Income countries ; **10** VacZineAnalytics Chikungunya virus vaccines Global demand analysis. February 2020.

VLA1553: Development Outlook

FDA Pre-submission Process Expected to Commence in Q2 2022

First and only program to have reported positive Phase 3 results worldwide

- Six-month follow-up completed - all Phase 3 immunogenicity and safety endpoints met - seroprotection in 98.9% of participants after one month and 96.3% after six months - good safety and tolerability profile confirmed
- Positive topline lot-to-lot consistency trial results reported (VLA1553-302)[2], final data expected in Q2 2022
- Antibody persistence follow-up trial (VLA1553-303) ongoing: up to 375 volunteers from the VLA1553-301 trial will be followed annually for five years
- Adolescent Phase 3 trial initiated in January 2022 to support potential label expansion, funded by the Coalition for Epidemic Preparedness Innovations (CEPI)[3]

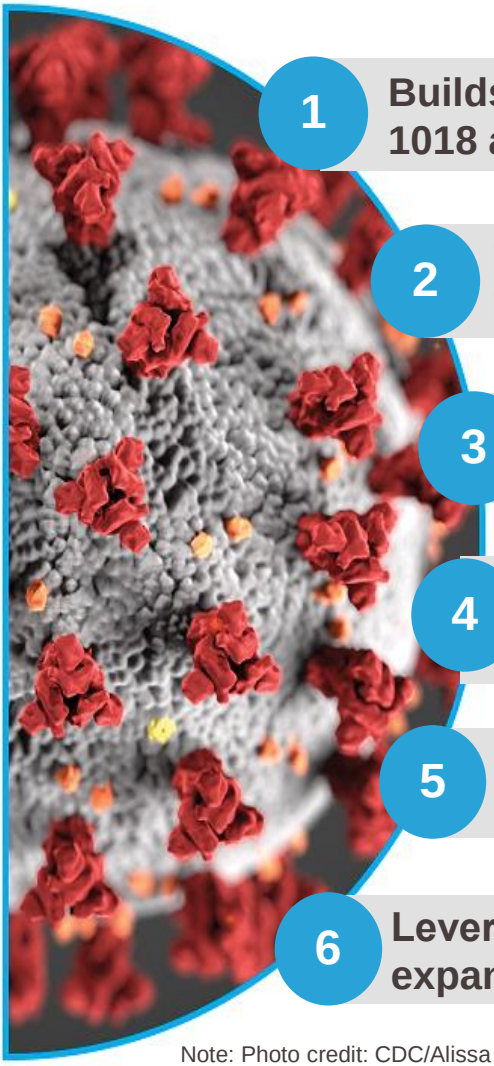
Pre-submission process with FDA expected to commence in Q2 2022

The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher[4]

1 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; **3** Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate; **4** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program;

VLA2001: Inactivated whole virus COVID-19 Vaccine Candidate

Only Inactivated COVID-19 Vaccine Program in the Clinics in Europe



1. **Builds on Valneva's IXIARO® manufacturing technology combined with Dynavax's CpG 1018 adjuvant[1]**
2. **Bahraini NHRA Emergency Use Authorization received March 2022[2]; EMA and UK MHRA rolling reviews ongoing**
3. **Advance purchase agreements for up to 60 million doses with European Commission[3] and for one million doses with Bahrain[4];**
4. **Pivotal Phase 3 showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability[5]; Positive topline homologous booster data reported[6]; Shown to neutralize Omicron and Delta variants in laboratory studies[7]**
5. **Ongoing clinical trials aiming to gradually extend target product profile (label) and geographical reach**
6. **Leveraging Valneva's manufacturing sites in Scotland and Sweden; capacity being expanded, including CMO[8] – targeting >100m doses per annum[9]**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **2** Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; **3** Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001; **4** Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; **5** Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001; **6** Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva; **7** Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant; **8** Valneva and IDT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001; **9** Based on a combination of in-house capacity and external/contracted manufacturing.

VLA2001: Pivotal Phase 3 "Cov-Compare Study" Results

EMA and UK MHRA Rolling Reviews Ongoing

Immunogenicity

- **VLA2001 met its co-primary endpoints** vs AZD1222, demonstrating:
  - **Superiority** in terms of **geometric mean titer** for neutralization antibodies (GMT ratio = 1.39, p<0.0001), as well as
  - **Non-inferiority** in terms of **seroconversion rate**
- **VLA2001 induced broad** antigen-specific IFN-gamma producing **T-cells reactive against the S (74.3%), N (45.9%) and M (20.3%) proteins**

Safety and Tolerability

- **VLA2001 was generally well tolerated:**
  - **Significantly more favorable profile** compared to AZD1222
  - Participants 30 years and above reported **significantly fewer solicited adverse events,** including **injection site reactions**, and **systemic reactions**
- Participants **18-29 years** old showed an **overall safety profile comparable to the older age group**

COVID-19 Cases

- The **occurrence of COVID-19** cases (exploratory endpoint) was **similar between treatment groups** (age 30+)
- The **complete absence** of **any severe COVID-19 cases** could suggest that **both vaccines** used in the study **prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta)**

VLA2001: Current Purchase Agreements and Grants

First EU Deliveries expected in Q2 2022, subject to EMA approval

European Commission: Up to 60 million doses of VLA2001 to be supplied in 2022-23[1]

- 24.3 million doses to be supplied in the second and third quarters of 2022; EC has the option to increase its initial purchase, the remainder of which would be delivered in 2023

Bahrain: One million doses of VLA2001 to be supplied in 2022-23[2]

- NHRA Emergency Use Authorization received; first deliveries expected at the end of March 2022[3]

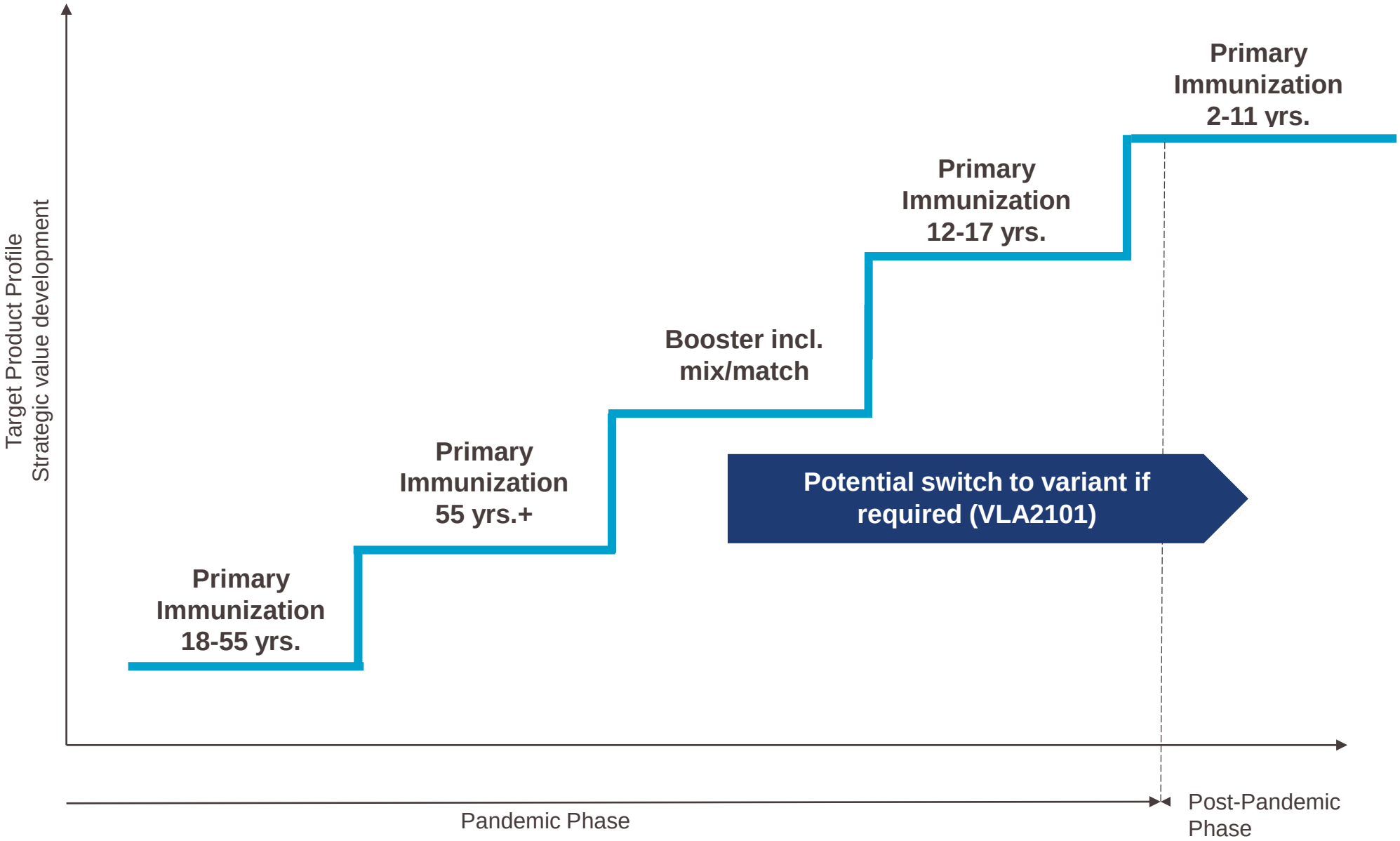
Up to £20 Million awarded by Scottish Enterprise to advance vaccine development[4]

- Grants totaling up to £20 million expected to be received over the next three years, commencing March 2022
- The first grant of up to £12,500,000 will support R&D related to VLA2001 manufacturing; the second grant of up to £7,500,000 will support R&D connected to manufacturing of Valneva's other vaccine candidates

1 Valneva Announces European Commission Approval of Advance Purchase Agreement for up to 60 Million Doses of Inactivated COVID-19 Vaccine VLA2001; **2** Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; **3** Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; **4** Valneva Awarded Up to £20 Million by Scottish Enterprise to Advance Vaccine Development

VLA2001: Planned Label Extensions

Ongoing and Future Clinical Studies Expected To Strengthen Product Profile



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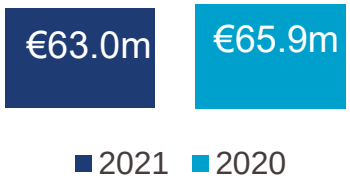
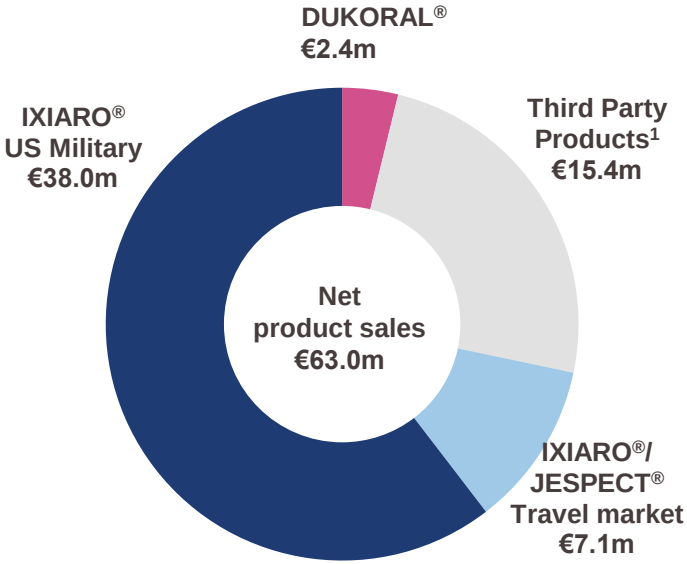
Full Year 2021 Financials: Total Revenues of €348m

Growth attributed to recognized revenues from terminated UK agreement

Total Revenues²
+215.5%



Product sales²
-4.5%



Direct sales
98%

1 Third party products sold by Valneva, **2** YoY comparison for same period

Full Year 2021 Financials: Product Sales of €63m

Continued pandemic impact on travel industry, strong increase in third party product sales

€m	FY 2021 (audited)	FY 2020 (audited)	%
IXIARO®/JESPECT®	45.1	48.5	**-6.9%**
DUKORAL®	2.4	13.3	**-81.7%**
Third party products	15.4	4.2	**+271.0%**
Total	**63.0**	**65.9**	**-4.5%**

Full year 2021 Financials: EBITDA of - €47.1m

Reflects Pandemic Impact on Sales and Significant R&D Investments

€m (2020 unaudited)	FY 2021	FY 2020
Product sales	63.0	65.9
Other Revenues	285.1	44.4
Revenues	**348.1**	**110.3**
Cost of goods and services	(187.9)	(54.3)
Research and development expenses	(173.3)	(84.5)
Marketing and distribution expenses	(23.6)	(18.3)
General and administrative expenses	(47.6)	(27.5)
Other income / (expense), net	23.0	19.1
Operating loss	**(61.4)**	**(55.1)**
Finance, investment in associates & income taxes	(12.0)	(9.3)
Profit/loss for the period	**(73.4)**	**(64.4)**
EBITDA[1]	**(47.1)**	**(45.2)**

1 FY EBITDA was calculated by excluding €14.3 million (2020: €9.9 million) of depreciation and amortization from the €61.4 million (2020: €55.1 million) operating loss as recorded in the consolidated income statement under IFRS.

Full Year 2021 Financials: Impact of COVID-19 Program on P&L

COVID-19 reported as separate segment as of 2021

€m (2021 audited)	FY 2021 Group	FY2021 COVID only	FY 2021 excl. COVID
Product sales	63.0		63.0
Other Revenues	285.1	253.3	31.8
Revenues	**348.1**	**253.3**	**94.8**
Cost of goods and services	(187.9)	(122.8)	(65.1)
Research and development expenses	(173.3)	(113.9)	(59.4)
Marketing and distribution expenses	(23.6)	(1.2)	(22.5)
General and administrative expenses	(47.6)	(23.0)	(24.6)
Other income / (expense), net	23.0	11.5	11.4
Operating loss	**(61.4)**	**3.9**	**(65.3)**
Finance, investment in associates & income taxes	(12.0)		(12.0)
Profit/loss for the period	**(73.4)**	**3.9**	**(77.4)**
EBITDA[1]	**(47.1)**	**11.6**	**(58.7)**

1 FY EBITDA was calculated by excluding €14.3 million (2020: €9.9 million) of depreciation and amortization from the €61.4 million (2020: €55.1 million) operating loss as recorded in the consolidated income statement under IFRS.

Full Year 2021 Financials: Balance Sheet 2020/2021

Net Assets impacted by COVID as well as cash proceeds from public offerings

€m (2021 audited)	December 31st, 2021	December 31st, 2020
NON-CURRENT ASSETS	***231.5***	***140.7***
- Property, Plant & Equipment	125.5	34.8
- Other Non-current Assets	106.0	106.0
CURRENT ASSETS	***585.8***	***308.4***
- Inventory	124.1	26.9
- Trade Receivables & Other current assets	115.0	77.1
- Cash & Cash Equivalents	346.7	204.4
TOTAL ASSETS	***817.4***	***449.2***

Full Year 2021 Financials: Balance Sheet 2020/2021 (cont.)

Liabilities & Equity increased due to COVID contracts and public offerings

€m (2021 audited)	December 31st, 2021	December 31st, 2020
EQUITY	***170.6***	***77.4***
NON-CURRENT LIABILITIES	***277.8***	***195.9***
- Refund Liabilities	159.0	97.2
- Other Non-Current Liabilities	*118.7*	*98.7*
CURRENT LIABILITIES	***369.0***	***175.9***
- Trade Payables & Accruals	68.1	36.2
- Contract Liabilities	124.0	89.6
- Refund Liabilities	95.6	14.2
- Provisions	48.7	10.2
- Other Current Liabilities	32.5	25.7
TOTAL EQUITY AND LIABILITIES	***817.4***	***449.2***

Full year 2021 Financials: Impact of Terminated UK Agreement

Terminated Supply Agreement Impacted Revenue Recognition and Balance Sheet

Total cash considerations received *	**€ 420m**
Reported as Other Revenue in 2021	**€ 253m**
Remaining on December 2021 Balance Sheet as Refund Liability	**€ 167m**
- Refund Liability on Royalty Payments	€ 87m
- Refund Liability on CAPEX advances	€ 80m

*) Cash receipts originating from a) terminated UK COVID-19 vaccine supply agreement for non-refundable payments received during the duration of the contract, b) Clinical Trial Agreement payments; includes €7.8m of outstanding payments; includes EUR / GBP FX effects on funds received

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Valneva 2022 Financial Guidance

Substantial growth expected from anticipated COVID business

Total revenues expected between €430 to €590 million, including:

- €350 to €500 million of COVID-19 vaccine sales subject to regulatory approvals and deliveries of VLA2001[1]
- €60 to €70 million of other vaccine sales
- Approximately €20 million of Other Revenues (revenues from collaborations, licensing and services)

R&D investments expected between €160 million and €200 million

- R&D investments reflecting pipeline progression

1 *Valneva Confirms Clinical Trial and Regulatory Submission Timelines for its Inactivated COVID-19 Vaccine Candidate VLA2001*

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Key Upcoming Catalysts and Newsflow in 2022

Lyme disease vaccine candidate VLA15

- First pediatric data expected in Q2 2022
- Phase 3 trial initiation expected in Q3 2022

Chikungunya vaccine candidate VLA1553

- Pre-submission process expected to commence in Q2 2022
- Final lot-to-lot Phase 3 data expected in Q2 2022

COVID-19 vaccine candidate VLA2001

- Possible regulatory approvals
- Supplies and further purchase agreements
- Further clinical trials and data expected

Thank you
Merci
Danke
Tack

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