Valneva Reports H1 2021 Financial Results and Provides Business Update

Analyst Presentation
August 10, 2021

valneva

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Non-IFRS Financial Measures
Management uses and presents IFRS results as well as the non-IFRS measure of EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful as an aid to further understand Valneva's current performance, performance trends, and financial condition.
EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.
A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth in this presentation.

Agenda

- **Introduction**
- **Business Update**
- **Financial Report H1 2021**
- **Newsflow**
- **Q&A**

Valneva Reports H1 2021 Financial Results and Provides Business Update

Major R&D objectives achieved

- Positive topline Phase 3 results for chikungunya vaccine candidate VLA1553
  - › World's first ever Phase 3 trial results for a chikungunya vaccine
- Excellent progress on unique clinical assets
  - › Lyme – recruitment completed for Phase 2 trial VLA15-221 including pediatric age group
  - › COVID-19 – recruitment completed for pivotal Phase 3 trial VLA2001-301

Strong financial position and platform

- $107.6 million raised in US IPO
- Cash and cash equivalents of €329.8m at June 30, 2021

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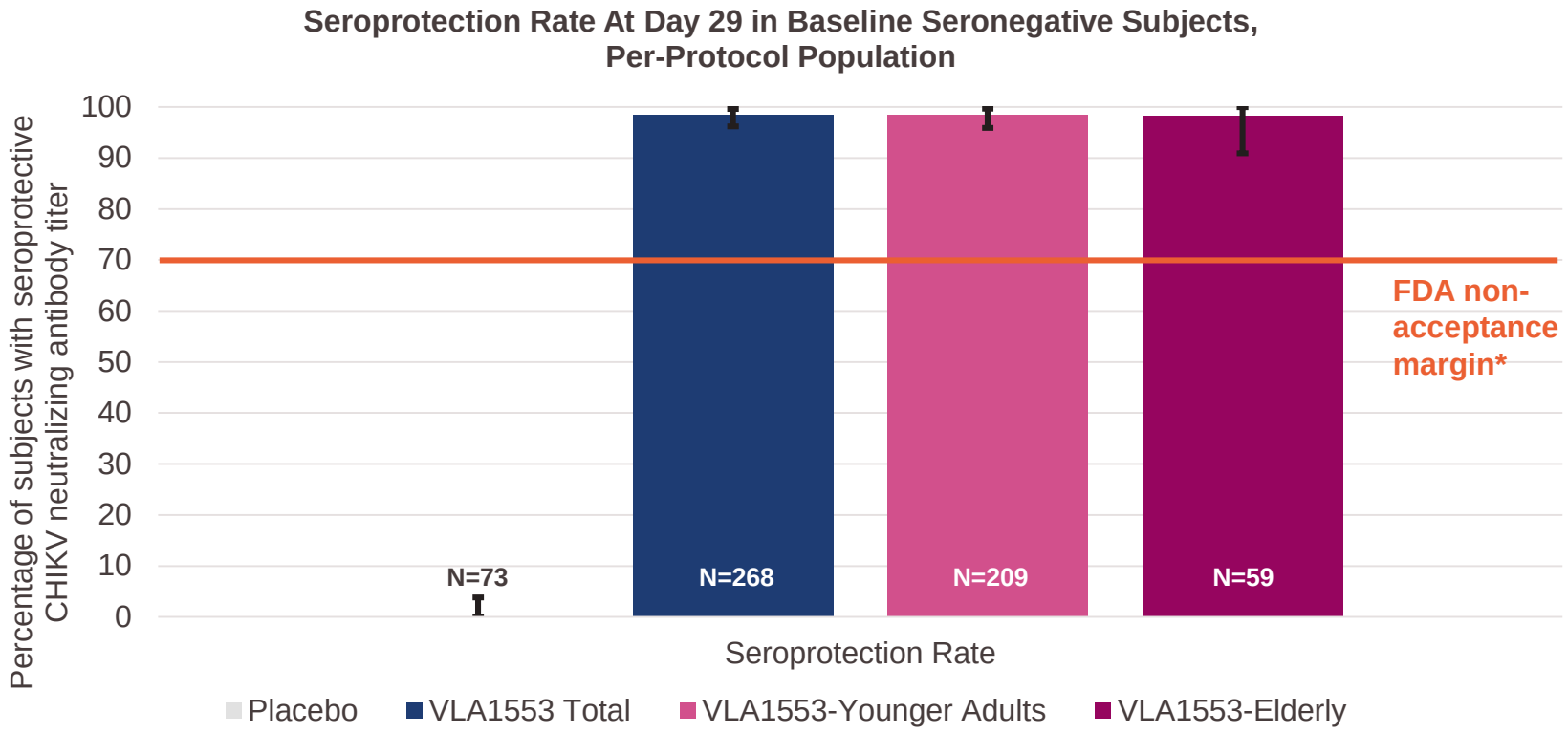
VLA1553-301: Primary Endpoint Met

Protective CHIKV Neutralizing Antibody Titers Reported in 98.5% of Subjects After a Single Shot

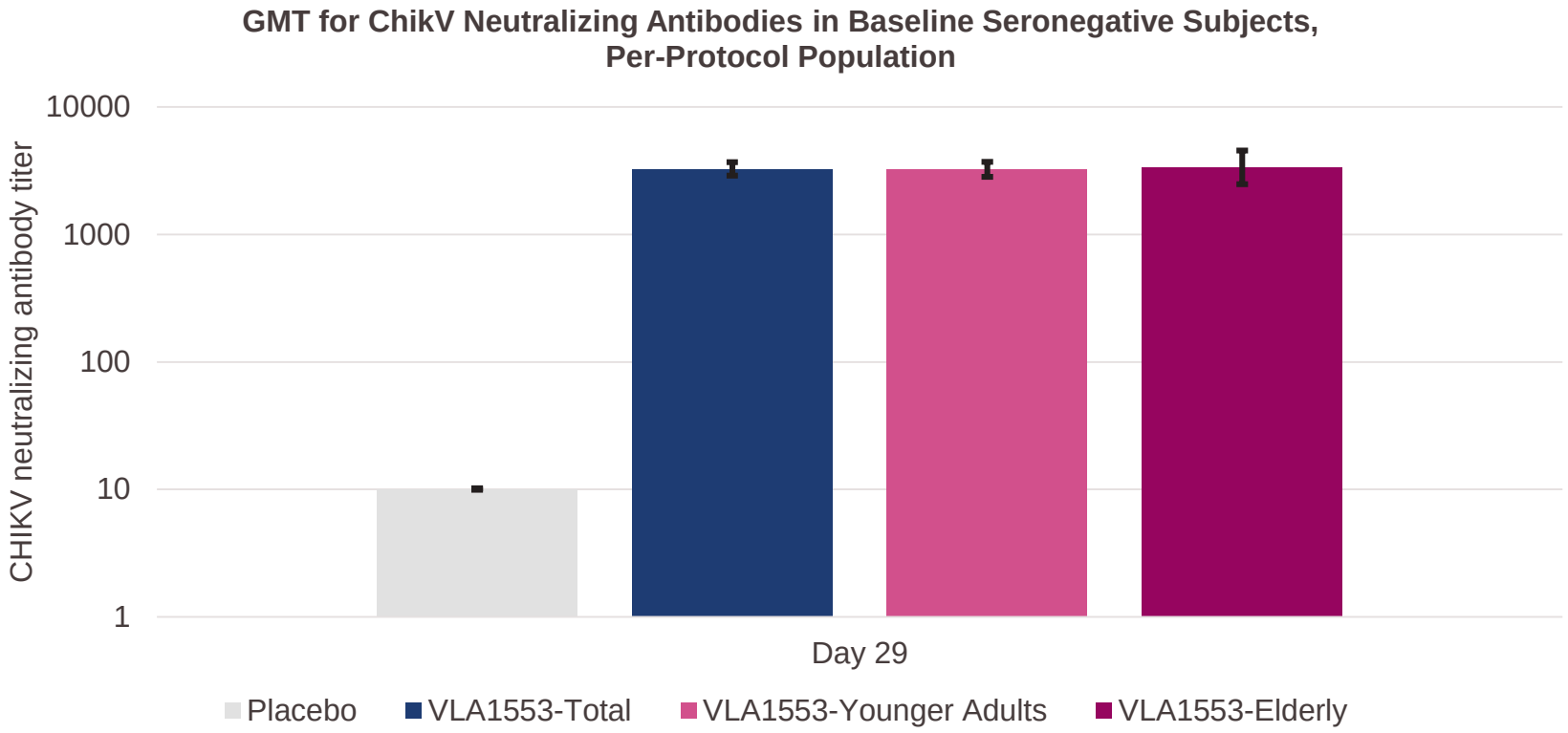


* The lower bound of the 95% Confidence Interval for the Seroprotection Rate needed to exceed 70%
Neutralizing antibody titers determined using a µPRNT$_{50}$ assay

Error Bars represent 95%CI

VLA1553-301: High Neutralizing Antibodies

Highly Immunogenic Across All Age Groups Including Elderly



Chikungunya virus neutralizing antibody titers were determined using a µPRNT$_{50}$ assay. Values below the quantification limit are set to 10.

Error Bars represent 95%CI

VLA1553 - Well Tolerated Across All Age Groups

Safety was evaluated in 3,082 participants who received VLA1553

- Independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns
- Safety profile consistent with Phase 1:
  - › Majority of solicited adverse events were mild or moderate and resolved within 3 days.
    - 1.6% reported severe solicited adverse events, most commonly fever
  - › Approximately 50% of study participants experienced solicited systemic adverse events, most commonly[1] headache, fatigue and myalgia
  - › Approximately 15% of participants experienced solicited local adverse events
- Equally good safety profile in elderly
- Final safety analysis expected within the next six months

1 Seen in more than 20% of subjects

VLA1553: Development Outlook

Pivotal Phase 3 Trial – Final Data Expected Within the Next 6 Months

Most advanced clinical development program in the world

- Pivotal Phase 3 safety and immunogenicity trial progressing towards final analysis, expected within the next six months[1]
- Lot-to-Lot consistency trial fully recruited (VLA1553-302), data expected late 2021[2]
- Antibody persistence follow-up trial (VLA1553-303) ongoing – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization[1]

Valneva is discussing with the FDA to bring VLA1553 to a potential licensure as soon as possible

1 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **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** Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates **5** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.

VLA15 – Multivalent Lyme Disease Vaccine Candidate

Only Lyme Disease Program in Advanced Clinical Development Today

1. **FDA Fast Track Designation granted**
2. **Initial results reported from Phase 2 trials [1, 2], Recruitment completed for Phase 2 trial VLA15-221 incl. pediatric participants[3]**
3. **Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe**
4. **Follows proven Mechanism of Action for a Lyme disease vaccine**
5. **Exclusive, worldwide partnership with Pfizer**

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 Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate

VLA15: Development Progress

Phase 2 trial[1] in Adults and Pediatric Subjects Ongoing

VLA15-221 recruitment completed with a total of 625 participants, 5 to 65 years of age, randomized[2]

- The trial triggered a milestone payment of $10 million, upon dosing of the first subject, from Pfizer to Valneva
- Topline results for VLA15-221 are expected in the first half of 2022.
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the 6 Month dose[1]

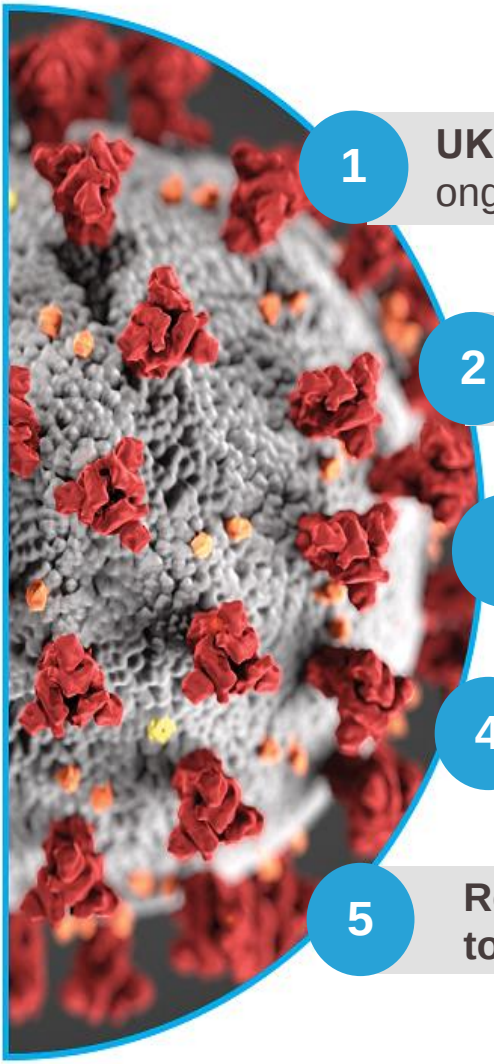
Phase 3 pivotal efficacy trial planned to commence pending positive readout from VA15-221 in 2022[1]

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

Initial submission for regulatory approval anticipated in H2 2024, assuming positive data

1Valneva 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

VLA2001 – The Only Inactivated Vaccine in Clinical Development in Europe



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding; ongoing dialogue with the European Commission
2. **Program acceleration enabled through use of Valneva's FDA-registered facility in UK; commercial manufacturing commenced January 2021**[2]
3. **Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant**[3]
4. **Phase 1/2 clinical trial results reported**[4]**, Phase 3 trial "Cov-Compare" fully recruited**
5. **Regulatory submission to MHRA planned in autumn 2021, deliveries thereafter, subject to approval**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva announces major COVID-19 vaccine partnership with U.K. Government.**2** Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. **3** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **4** Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

VLA2001: Development Outlook

Pivotal Phase 3 trial “Cov-Compare” Recruitment Completed[1]

“Cov-Compare” (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in over 4,000 adults

- Immunological comparison against a licensed vaccine to reasonably predict efficacy (superiority of VLA2001 in a two-dose immunization schedule four weeks apart - GMTs of neutralising antibodies, at two weeks after the second vaccination)
- Study conducted in UK supported by DHSC/NIHR, including funding
- Protocol agreed with MHRA; discussion with other regulatory bodies ongoing
- Cov-Compare Phase 3 topline data expected early in the fourth quarter. Valneva expects to commence rolling submission with MHRA in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

Valneva participating in the world’s first COVID-19 vaccine booster trial in the UK[2]

Additional studies planned (including reduced booster dose)

Valneva studying other variants, to be in a position to manufacture variant-based vaccines

1 Valneva Completes Phase 3 Trial Recruitment for its Inactivated COVID-19 Vaccine Candidate, 2 Valneva to Participate in the World’s First COVID-19 Vaccine Booster Trial in the UK

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Results Dynamics and Outlook

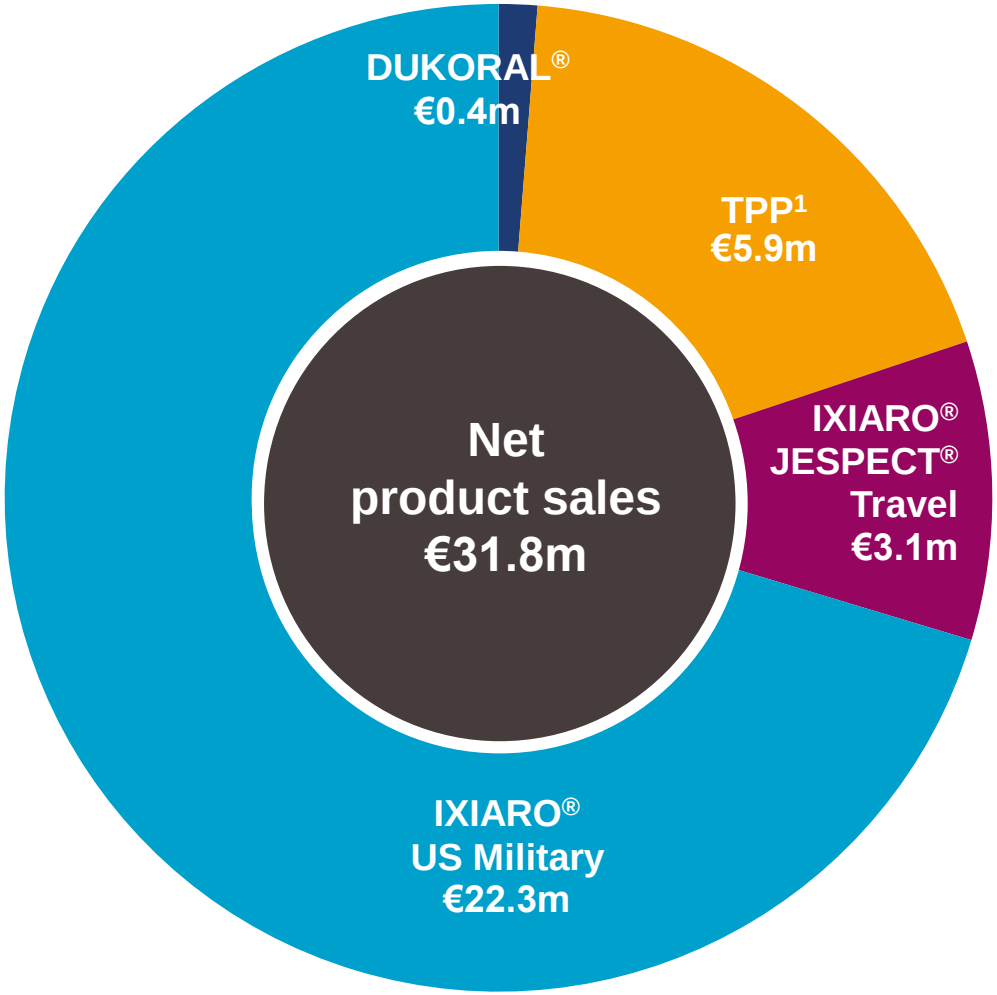
Updated guidance including COVID-19 expected

- Ongoing Phase 3 trials and regulatory discussions
- Role of VLA2001 as a booster
- Studying variants in order to be in a position to produce variant-based vaccines
- Ongoing discussions with EC

Valneva reconfirms its 2021 financial guidance (excluding COVID-19)

- Total revenues, excluding VLA2001, of €80 million to €105 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million

H1 2021 Sales Adversely Affected by the COVID-19 Pandemic



Product sales (Unaudited)[2]
-22% AER / -19% CER

Direct sales
98%

Gross margin[3]
39.2%

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

EBITDA Loss Reflecting Increasing R&D Expenses

H1 2021 Profit & Loss Report (unaudited)

€m	H1 2021	H1 2020
Product sales	31.8	40.9
Revenues from collaboration, licensing and services	15.7	7.0
Revenues	**47.5**	**47.9**
Cost of goods	(23.5)	(18.1)
Cost of services	(11.3)	(4.4)
Research and development expenses	(78.7)	(33.1)
Marketing and distribution expenses	(9.6)	(10.0)
General and administrative expenses	(20.9)	(10.6)
Other income / (expense), net	10.4	6.5
Operating profit / (loss)	**(86.2)**	**(21.9)**
Finance, investment in associates & income taxes	(0.2)	(3.7)
Loss for the period	**(86.4)**	**(25.6)**
EBITDA[1]	**(80.1)**	**(17.2)**

1 EBITDA is a non-IFRS financial measure. A reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS, is included herein. H1 2021 EBITDA was calculated by excluding €6.1 million (H1 2020: €4.7 million) of depreciation and amortization from the €86.2 million operating loss (H1 2020: €21.9 million) as recorded in the consolidated income statement under IFRS.

Effect of COVID-19 Program on Group P&L

COVID-19 Program Reported as Separate Segment as of 2021

€m	H1 2021 *Group*	H1 2021 *COVID only*	H1 2021 *excl. COVID*
Product sales	31.8		31.8
Revenues from collaboration, licensing and services	15.7		15.7
Revenues	**47.5**		**47.5**
Cost of goods	(23.5)	(4.2)	(19.3)
Cost of services	(11.3)		(11.3)
Research and development expenses	(78.7)	(46.1)	(32.6)
Marketing and distribution expenses	(9.6)	(0.4)	(9.2)
General and administrative expenses	(20.9)	(9.4)	(11.5)
Other income / (expense), net	10.4	4.7	5.7
Operating profit / (loss)	**(86.2)**	**(55.5)**	**(30.7)**
Finance, investment in associates & income taxes	(0.2)		(0.2)
Loss for the period	**(86.4)**	**(55.5)**	**(30.9)**
EBITDA[1]	**(80.1)**	**(52.8)**	**(27.3)**

Strong Cash Position of €329.8 million at End of June

Balance Sheet as of June 30, 2021

ASSETS	Jun 30, 2021	Dec 31, 2020
NON-CURRENT ASSETS	183,145	140,737
+ Intangible Assets	34,424	35,409
+ Right Of Use Assets	48,239	43,374
+ Property, plant & equipment	74,789	34,779
+ Other non-current assets	25,693	27,176
CURRENT ASSETS	561,277	308,427
+ Inventories	125,664	26,933
+ Trade receivables	18,007	19,232
+ Other current assets	87,841	57,828
+ Cash & current financial assets	329,766	204,435
TOTAL ASSETS	**744,422**	**449,164**

EQUITY & LIABILITIES	Jun 30, 2021	Dec 31, 2020
EQUITY	76,385	77,422
NON-CURRENT LIABILITIES	211,119	195,872
+ Borrowings, long term	47,402	46,375
+ Refund Liabilities	104,493	97,205
+ Other long term liabilities, including Lease Liabilities	59,224	52,292
CURRENT LIABILITIES	456,917	175,870
+ Trade payables and accruals	71,502	36,212
+ Borrowings, short term	7,079	6,988
+ Contract Liabilities	338,474	89,578
+ Refund Liabilities	6,875	14,222
+ Other current liabilities, including Lease Liabilities	32,987	28,871
TOTAL EQUITY AND LIABILITIES	**744,422**	**449,164**

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Key Upcoming Catalysts and Potential Inflection Points

Chikungunya vaccine candidate VLA1553

- Final Phase 3 trial results
- Topline data of clinical lot-to-lot consistency Phase 3 trial

Lyme disease vaccine candidate VLA15

- Further Phase 2 milestones and read-outs

COVID-19 vaccine candidate VLA2001

- Clinical results including Cov-Compare and COV-Boost
- Marketing authorization submission, subject to data
- Further clinical development plans to complement UK trials

Supplemental Disclosures Regarding Non-IFRS Financial Measures

EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth below:

€ in million	6 months ending June 30	
	2021	2020
Operating (loss)/Profit	(86.2)	(21.9)
Add:		
Amortization	3.1	3.0
Depreciation	3.0	1.7
EBITDA	**(80.1)**	**(17.2)**

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Thank you
Merci
Danke
Tack

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