Valneva presents its 9M 2020 financial results

Analyst Presentation
November 3, 2020

valneva

Disclaimer

This presentation does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva SE shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful. The Valneva shares may not be offered or sold in the USA. The offer and sale of the Valneva shares has not been registered under the 1933 US Securities Act, as amended.

Valneva is a European company. Information distributed is subject to European disclosure requirements that are different from those of the United States. Financial statements and information may be prepared according to accounting standards which may not be comparable to those used generally by companies in the United States.

This presentation includes only summary information and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of their affiliates, directors, officers, advisors and employees shall bear any liability for any loss arising from any use of this presentation.

Certain information and statements included in this presentation are not historical facts but are forward-looking statements. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.

Agenda

- **Introduction**
- **R&D Update**
- **Financial Report 9M 2020**
- **Financial Outlook**
- **Newsflow**
- **Q&A**

9M 2020 Results Marked by Further Major Corporate Achievements and Strong Cash Position

Q3 milestones

- Major COVID-19 vaccine partnership with UK Government
  - › Pre-clinical and industrialization activities on track
- Positive top-line results for Lyme Phase 2 studies
- First company to initiate Phase 3 study for chikungunya vaccine; EMA PRIME designation granted
- New contract with the US military/ Department of Defense for IXIARO®

Operating financial results impacted by COVID-19 pandemic

- Limited product sales in Q3
- Gross margin impacted by inventory write-offs and manufacturing idle costs
- Phasing of US military orders and supply into Q4
- Cost savings in Sales & Marketing
- Manufacturing staff gradually transitioning to COVID-19 vaccine production
- Strategic decision to retain commercial infrastructure with objective to ensure break-even for commercial business until recovery

Agenda

- Introduction
- R&D Update
- Financial Report 9M 2020
- Financial Outlook
- Newsflow
- Q&A

VLA15: Lyme Disease Vaccine Candidate

Partnering Deal with Pfizer, Positive Phase 2 Results

Exclusive, worldwide partnering deal with Pfizer for late stage development and future commercialization[1].

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

Positive initial results for two Phase 2 studies (VLA15-201 and VLA-202) reported[2].

- VLA15-202 Day 208 safety and immunogenicity data support advancing the program with the Month 0-2-6 schedule.

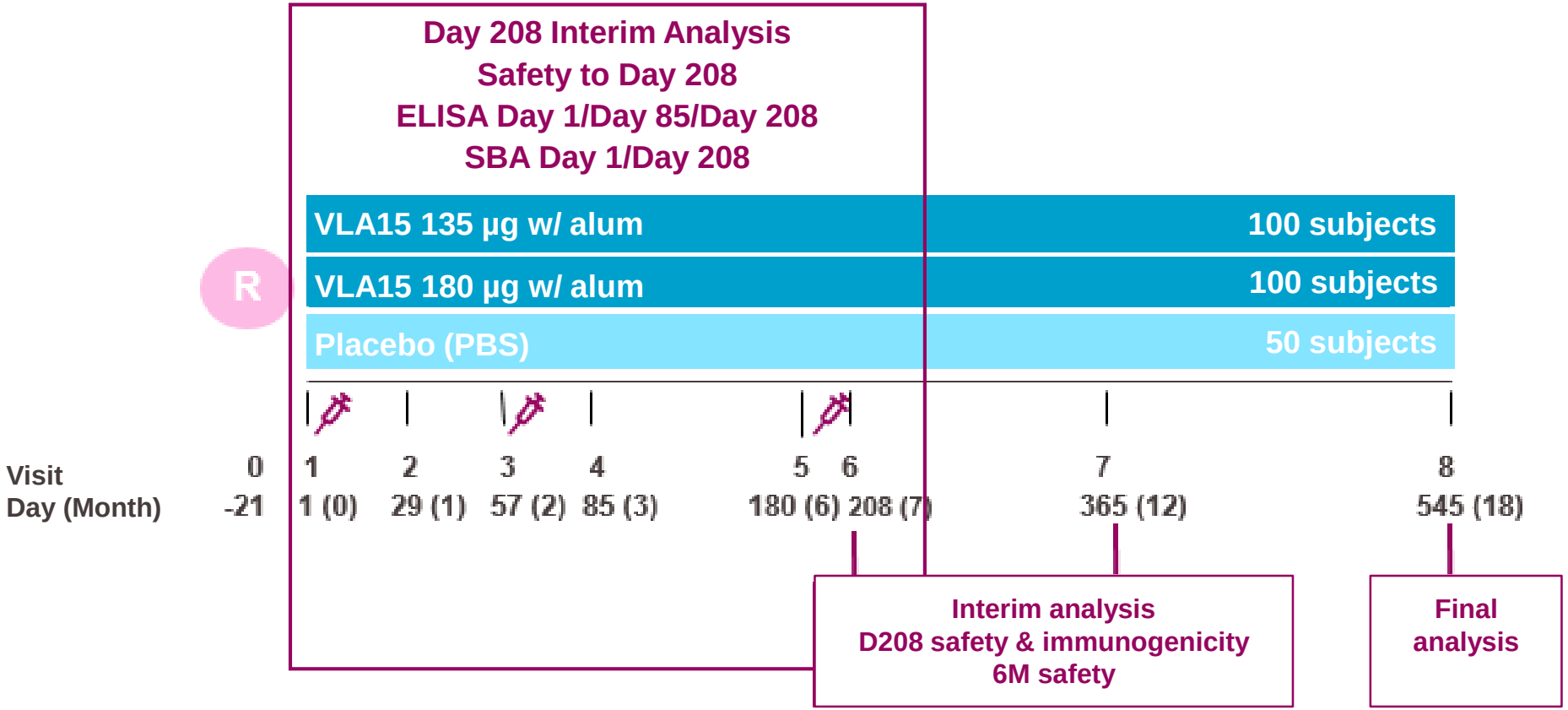
Valneva and Pfizer will prepare for the next development steps in the coming months.

1 Valneva PR Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15, **2** Valneva PR Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate; Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15

VLA15-202: Study Design

Observer-blind, Randomized, Multicenter, Phase 2 Study

- Study population: 246 subjects (Safety Population) 18-65 years were enrolled, 213 subject included in PP population



VLA15-202: Overall Study Conclusions

Phase 2 Study VLA15-202 Met its Endpoints

- VLA15 was generally safe across all doses and age groups tested. The tolerability profile including fever rates was comparable to other lipidated recombinant vaccines or lipid containing formulations.
- No related Serious Adverse Events (SAEs) were observed in any treatment group.
- Compared to study VLA15-201, immunogenicity was further enhanced using a Month 0-2-6 schedule. Seroconversion Rates ranged from 93.8% [ST1] to 98.8% [ST2, ST4].
- The immunological response in older adults, one of the main target groups for a Lyme vaccine, is particularly encouraging.
- A Serum Bactericidal Assay (SBA) was conducted for the first time and demonstrated functionality of antibodies against all OspA serotypes.
- Limited data from subjects with previous Borrelia infection are available but do not indicate an impact on safety or immunogenicity.

VLA15-202 Day 208 safety and immunogenicity support advancing the program with M0-2-6 schedule and 180 µg dose.

VLA1553: Chikungunya Vaccine Candidate
Phase 3 Initiated, PRIME Designation Granted

Valneva initiated a pivotal Phase 3 study in September 2020 and is currently the most advanced chikungunya vaccine program worldwide.

- The sponsor of the first chikungunya vaccine Biologics License Application (BLA) to be approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

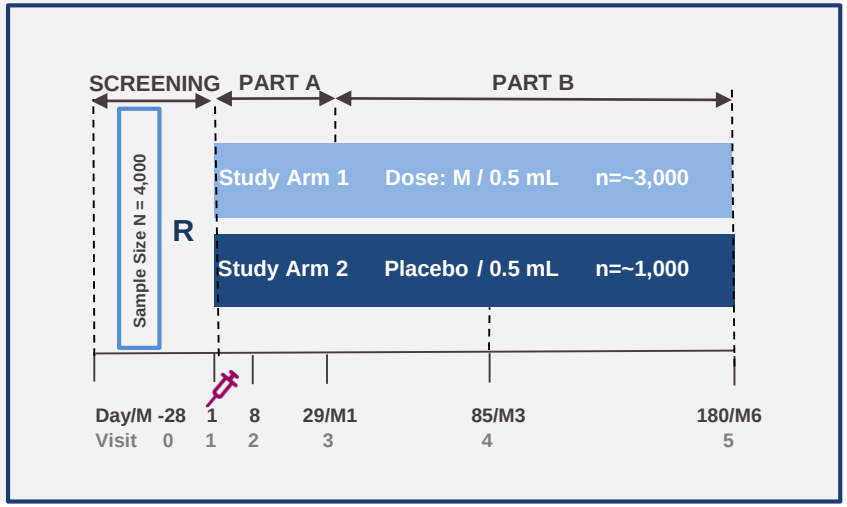
PRIME designation granted by the European Medicine Agency in October 2020

- Awarded by the EMA to promising medicines that demonstrate the potential to address substantial unmet medical need based on initial clinical data
- EMA considers PRIME designations a priority and provides medicine developers with special support, including enhanced interactions and dialogue, as well as a pathway for accelerated evaluation and review[1].

1 https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

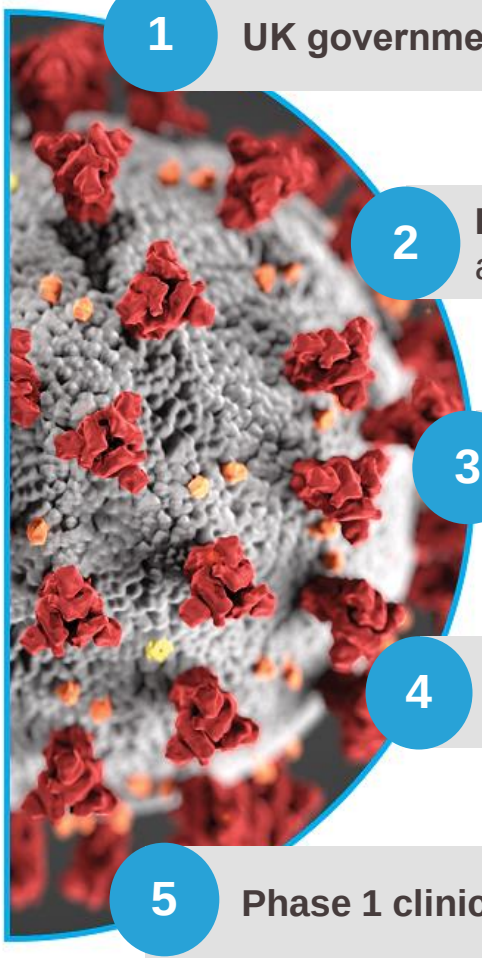
VLA1553-301: Pivotal Phase 3 Study
Double-Blinded, Controlled, Randomized Study

1. **Objectives:** pivotal safety and immunogenicity; Seroprotection rate at D29 based on an immunological surrogate (defined in NHPs for baseline negative subjects). [1]
2. **Population:** Healthy subjects aged 18 years and above, randomized 3:1 to VLA1553 or control
3. **Sample Size:** approx. N=4,060; Safety: VLA 1553 (n=3,000) vs. control (n=1,000); IMM subset (n=500)
4. **Trial Sites:** Multicenter study in non-endemic regions of the U.S.
5. **Prim. Endpoint:** Seroprotection rate at D29
6. **Schedule:** Single-shot i.m. immunization at Day 1
7. **Expected Duration:** 9 - 12 months**)



1 Seroprotection threshold subject to final approval by regulators
2 Duration may be impacted by different parameters, including adverse clinical operations implications due to ongoing pandemic

VLA2001: Only inactivated COVID-19 vaccine candidate in the US and the EU



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding
2. **Leveraging Valneva's existing capabilities:** BSL3 labs recommissioned for pre-clinical activities**;** Plug-and-play at Valneva's FDA-approved Livingston manufacturing facility
3. **Facilitated program acceleration through use of Valneva's FDA-approved platform**
4. **Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant**[2]
5. **Phase 1 clinical trials planned to commence by end of 2020**

1 Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government; **2** Valneva and Dynavax Announce Commercial Supply Agreement for Inactivated, Adjuvanted COVID-19 Vaccine; **Photo credit**: CDC/Alissa Eckert, MSMI; Dan Higgins, MAMS

VLA2001: Agreement to Provide 60-190 Million Doses of Inactivated 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 billion[1]
- UK government has purchased 60 million doses worth approximately €470 million for 2021
  - › Options to purchase up to 130 million doses worth up to €900 million between 2022 and 2025

Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Phase 1/2 clinical trials

- Vaccine to be manufactured at Valneva's facilities in Livingston, Scotland[2]
- Valneva plans further investments in both its Scottish and Swedish facilities

Pre-clinical and industrialization activities on track

1 Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government ; **2** Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program

VLA2001: Target Product Profile

(20102020)

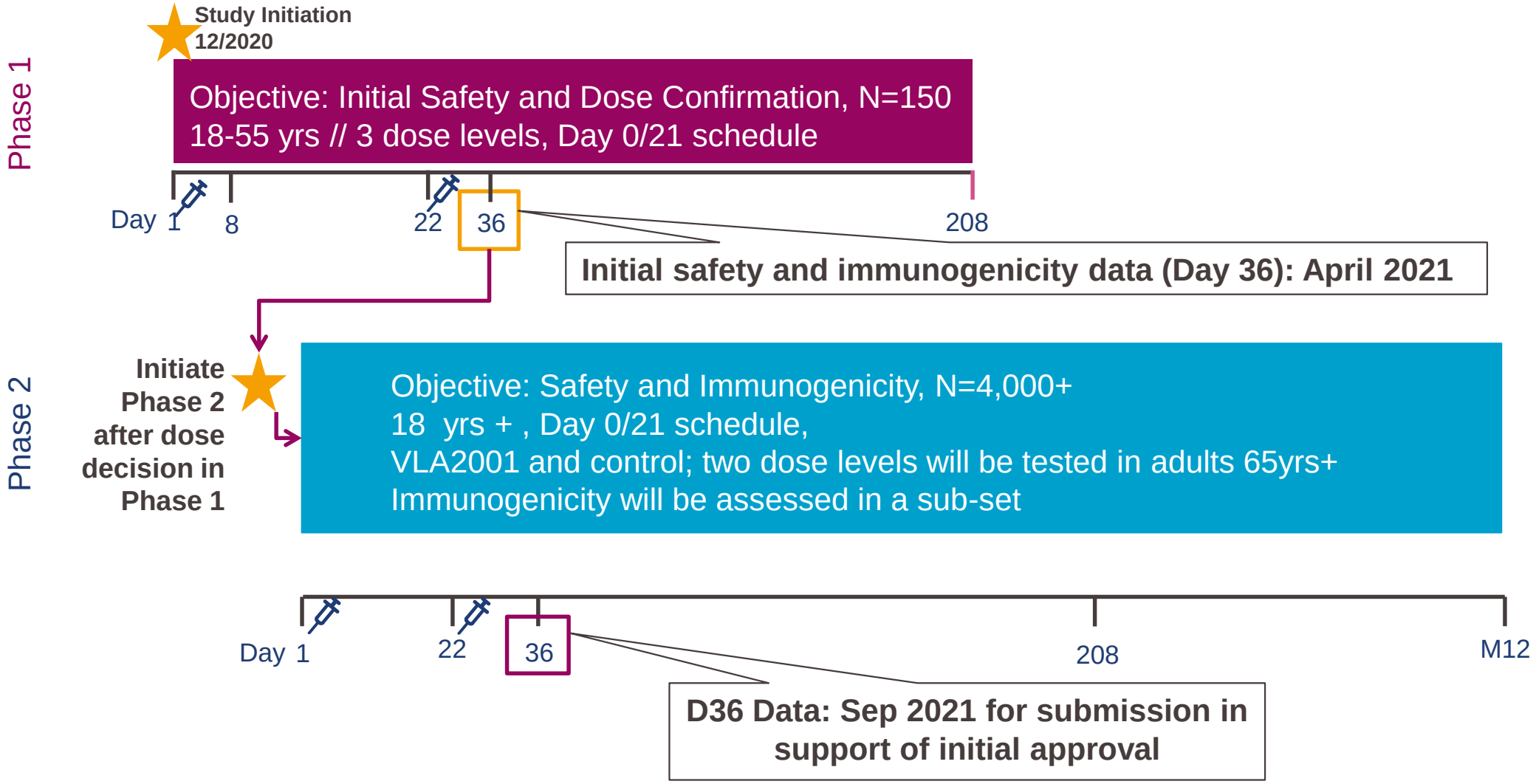
Based on platform experiences, expected to meet preferred/ critical criteria defined in WHO TPP*

	Vaccine Properties
Vaccine type	▪ Inactivated, adjuvanted (Alum, + „Th1“ adjuvant), whole virus, Vero cell substrate
Indication	▪ For active immunization of at-risk persons to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic; develop vaccine further for seasonal vaccination
Primary Target Population	▪ Persons at risk of COVID-19 aged 18 years and above, including high-risk populations (elderly and co-morbid i.e. immunocompromised, diabetics,) suitable for administration to pregnant and lactating women; step-wise broadening of age range (65-80 and 2-17 year of age)
Efficacy	▪ 70% (at least 50%)* efficacy regarding disease, severe disease, and/or shedding/transmission; protection lasts 12 months after priming *WHO position paper
Contraindications	▪ None expected, except severe allergic reaction after previous dose of vaccine or hypersensitivity to a component;
Co-vaccination	▪ Seasonal influenza, shingles and pneumococcal vaccines, pediatric vaccines
Initial Dosing, Administration	▪ Two doses administered i.m. 3 weeks apart
Booster	▪ Booster after ~ 12 months, 2nd booster after 10 years; pending further evolution of the pathogen, annual vaccination need to be confirmed and prepared for
Presentation	▪ 10-dose vial (pandemic); single dose vial (or syringe) TBD (seasonal)
Adverse Events	▪ Comparable to other inactivated vaccines

* https://www.who.int/blueprint/priority-diseases/key-action/WHO_Target_Product_Profiles_for_COVID-19_web.pdf?ua=1

VLA2001: SARS-CoV-2 inactivated vaccine

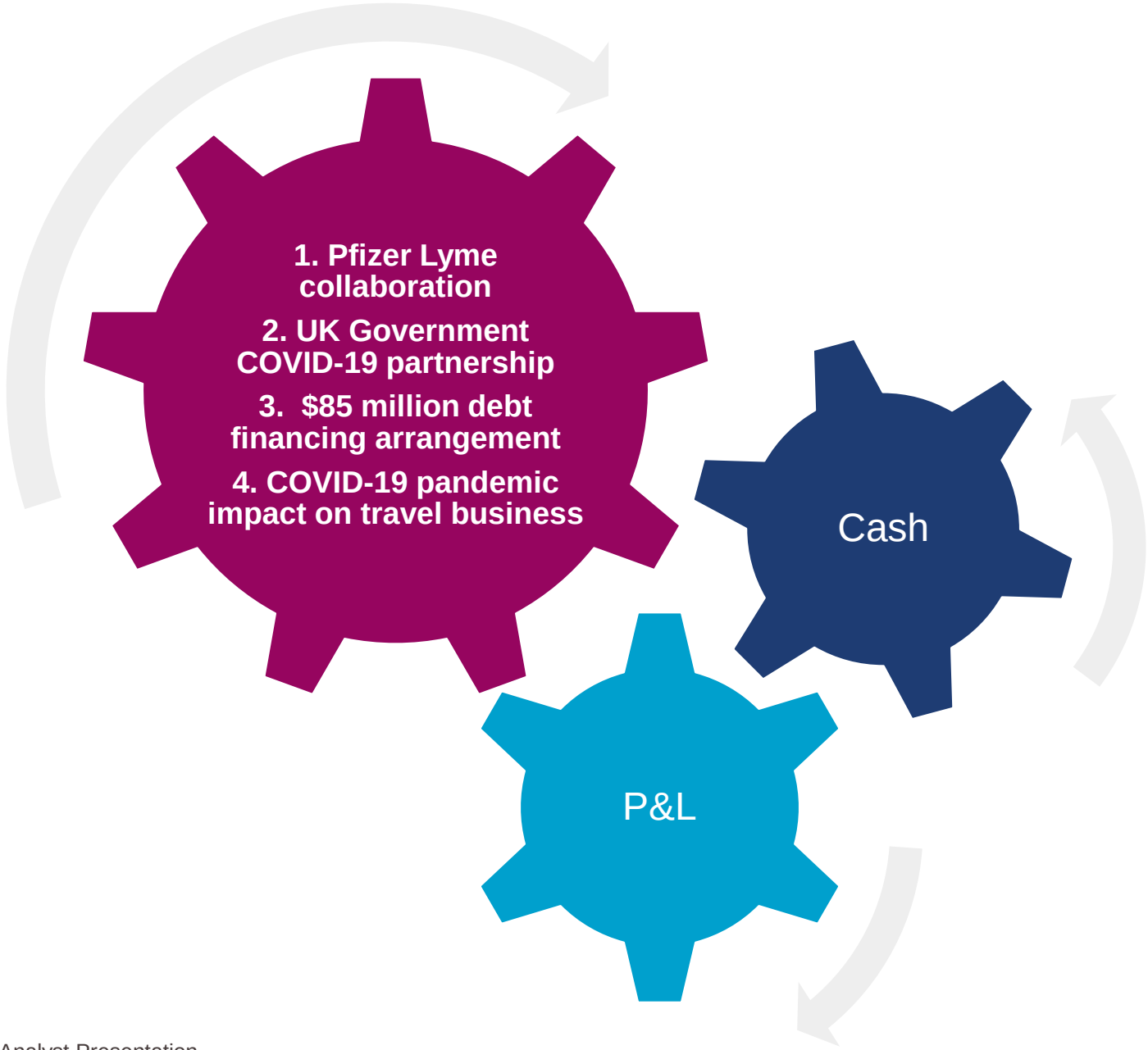
Clinical Entry December 2020, Initial Safety & Immunogenicity Data: April 2021



Agenda

- Introduction
- R&D Update
- **Financial Report 9M 2020**
- Financial Outlook
- Newsflow
- Q&A

Several Key 2020 Events Affect Cash and P&L



Cash position of €156 million at end of September

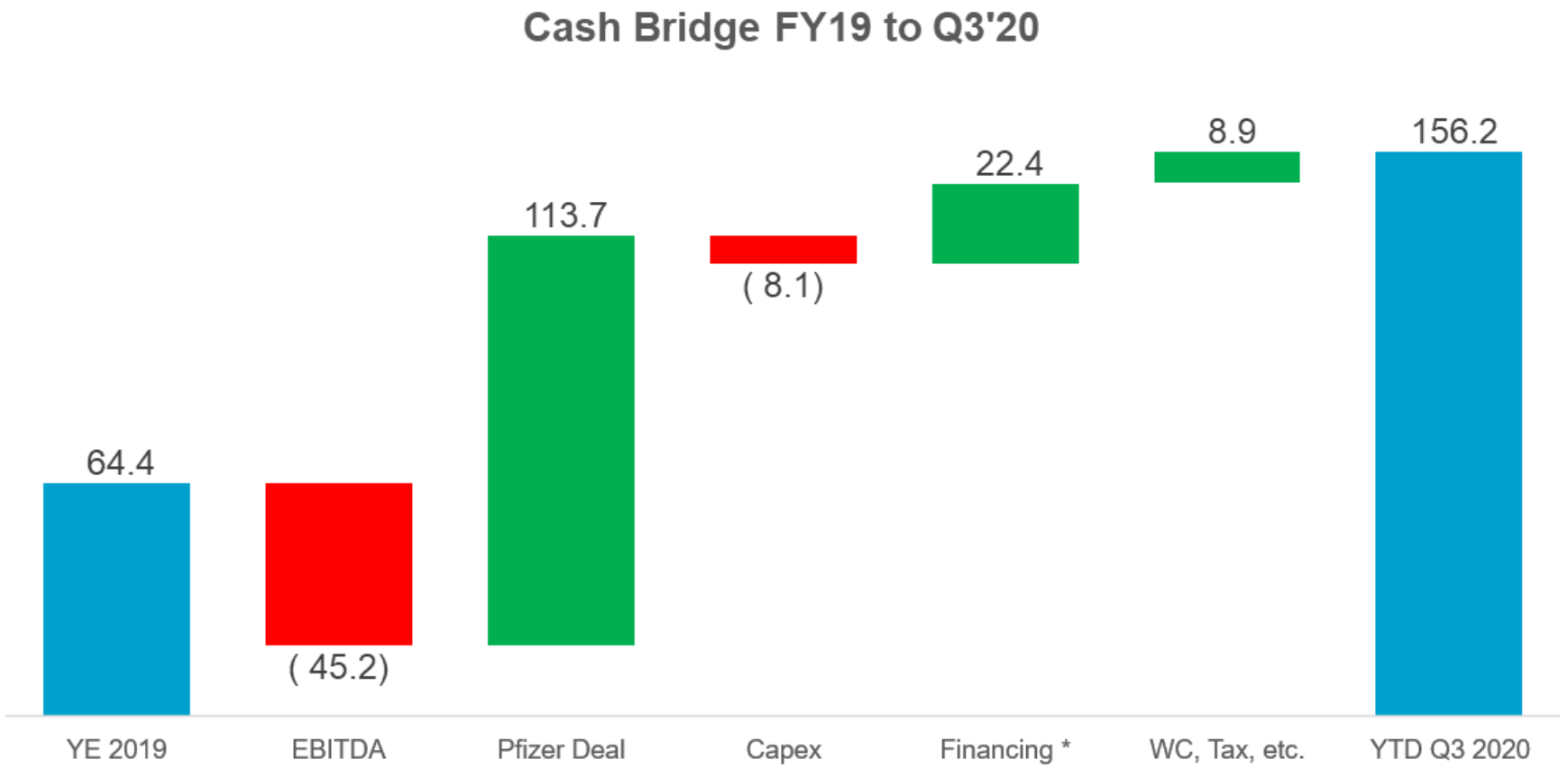
High September Receivables Turning Into Cash in Q4

FY 2020 cash outlook expected at between €180 million and €200 million

- UK government COVID-19 vaccine partnership deal executed in September, advance payments invoiced in September create high Q3 receivables position in excess of €100 million of receivables paid in October
- UK Government COVID-19 vaccine partnership will continue to provide funding for the Livingston site capacity expansion and UK VLA2001 clinical trials
- No further drawing from $85 million debt financing arrangement with leading U.S. funds expected for rest of 2020 ($60 million drawn in Q1 and Q2 2020)

Cash Bridge September 2020 to December 2019

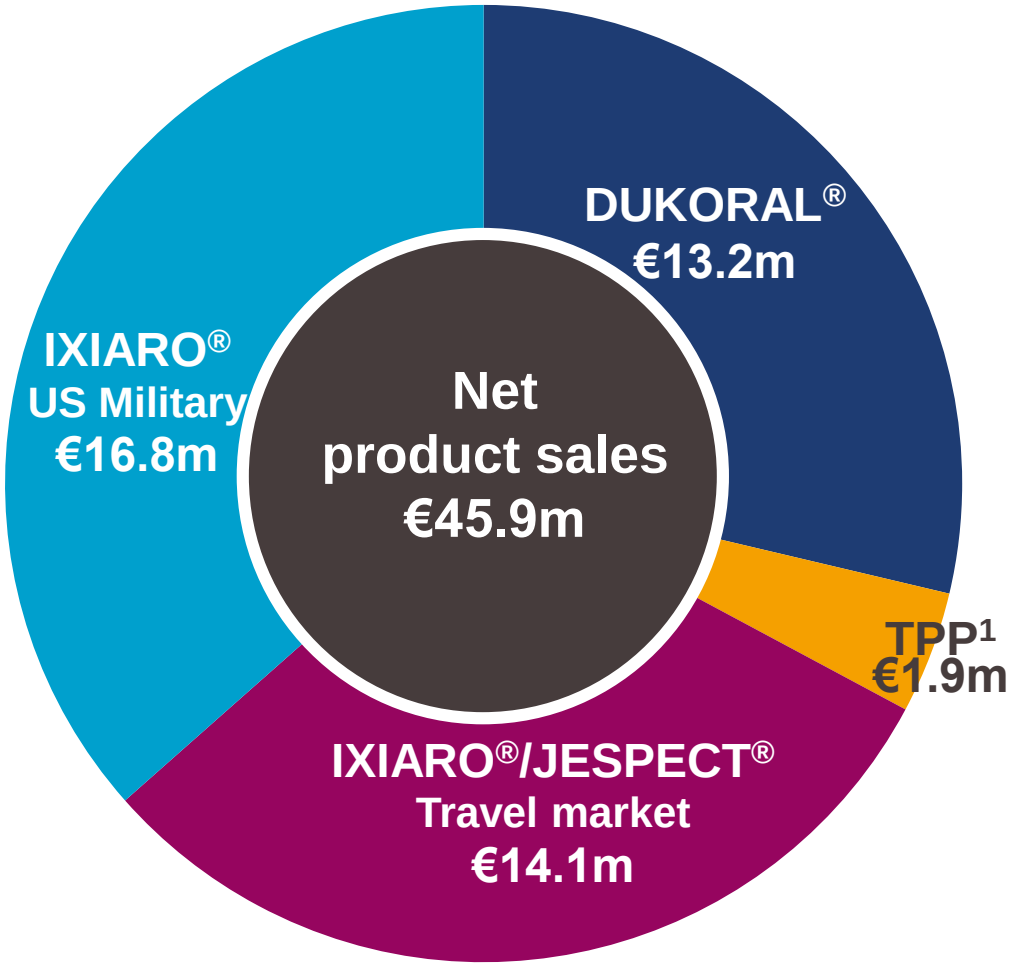
Cash Positively Impacted by Issuance of U.S. loan Facility & Pfizer Deal



***** Financing includes the issuance of a USD denominated loan facility ($60m drawn), the repayment of the EIB facility (€20m), and other costs related to financing activities

9M 2020 Product Sales Adversely Affected by the COVID-19 Pandemic

9M 2020 product sales at AER (unaudited)



Product sales[2]
-47% AER / -48% CER

Direct sales
74%

Gross margin[3]
37.4%

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

9M 2020 Product Sales Analysis

9M 2020 to 9M 2019 Comparison (unaudited)

€m	9M 2020 (unaudited) (AER)	9M 2019 (AER)	9M 2019 (CER)	CER[1] %
IXIARO®/JESPECT®	30.8	64.2	**65.3**	**-52.8%**
DUKORAL®	13.2	19.8	**20.0**	**-34.0%**
Third party products	1.9	2.4	**2.4**	**-21.3%**
Total	**45.9**	**86.4**	**87.6**	**-47.6%**

1 CER at constant exchange rates as 9M average Act 2020

Total Revenues of €58.8 Million in 9M 2020 (€81.4 Million in 9M 2019)

Overall FY 2020 revenue guidance now expected at around €120 million

- Product sales revenue of €45.9 million in 9M 2020 were adversely affected by COVID-19 pandemic (€86.4 million in 9M 2019) and the US military phasing in Q4
- FY 2020 Product sales revenue now expected at around €70 million
- FY 2020 total revenue to include €35 million to €40 million resulting from the Lyme vaccine partnership with Pfizer and approximately €10 million of Service and Technology revenues.
- No revenue associated with the UK COVID-19 partnership booked in Q3; IFRS accounting treatment being assessed during Q4

9M 2020 Gross Margin Analysis – Commercial Products

Lower Product Sales Having Knock-on Effects on Gross Margin

€m	9M 2020	9M 2019	Change vs. 9M 2019	Inventory write-offs	Idle Capacity	Other
IXIARO®/JESPECT®	47.5%	70.0%	**-22.5%**	-18.0%	-4.0%	-0.5%
DUKORAL®	15.4%	53.9%	**-38.5%**	-18.4%	-11.4%	-9.0%*
Third party products	26.4%	27.9%	**-1.4%**	-1.0%	-	-0.4%
Total	**37.4%**	**65.2%**	**-27.7%**	**-17.1%**	**-6.0%**	**-4.6%**

* mainly failed batches in Manufacturing

EBITDA Loss Reflecting Increasing R&D Expenses / Lower Sales

9M Profit & Loss Report at AER (unaudited)

€m	9M 2020	9M 2019
Product sales	45.9	86.4
Revenues from collaboration, licensing and services	13.0	(5.0)
Revenues	**58.8**	**81.4**
Cost of goods and services	(35.1)	(33.4)
Research and development expenses	(51.7)	(23.2)
Marketing and distribution expenses	(13.8)	(17.1)
General and administrative expenses	(19.3)	(13.0)
Other income / (expense), net	10.7	4.2
Amortization and impairment	(2.2)	(2.2)
Operating loss	**(52.5)**	**(3.2)**
Finance, investment in associates & income taxes	(9.8)	0.8
Profit/loss for the period	**(62.3)**	**(2.4)**
EBITDA[1]	**(45.2)**	**3.0**

1 9M EBITDA was calculated by excluding €7.3 million (2019: €6.2 million) of depreciation and amortization from the €52.5 million operating loss (€3.2m operating profit in 2019) as recorded in the consolidated income statement under IFRS.

9M 2020 Margins Adversely Affected by the COVID-19 Pandemic

Gross and Net Operating Margin at AER (unaudited)

Gross Margin	**9M 2020**	**9M 2019**
Total product sales revenues *(€m)*	45.9	86.4
Total Product Sales **Gross Margin** *(IXIARO®, DUKORAL® and Third Party Products)*	37.4%	65.2%

Net Operating Margin (€m)	**9M 2020**	**9M 2019**
Total product sales revenues	45.9	86.4
Cost of goods and services	(28.7)	(30.1)
Commercial costs[1]	(29.2)	(28.4)
Net operating margin	**(12.0)**	**27.9**
as % Revenues	(26.1%)	32.3%

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

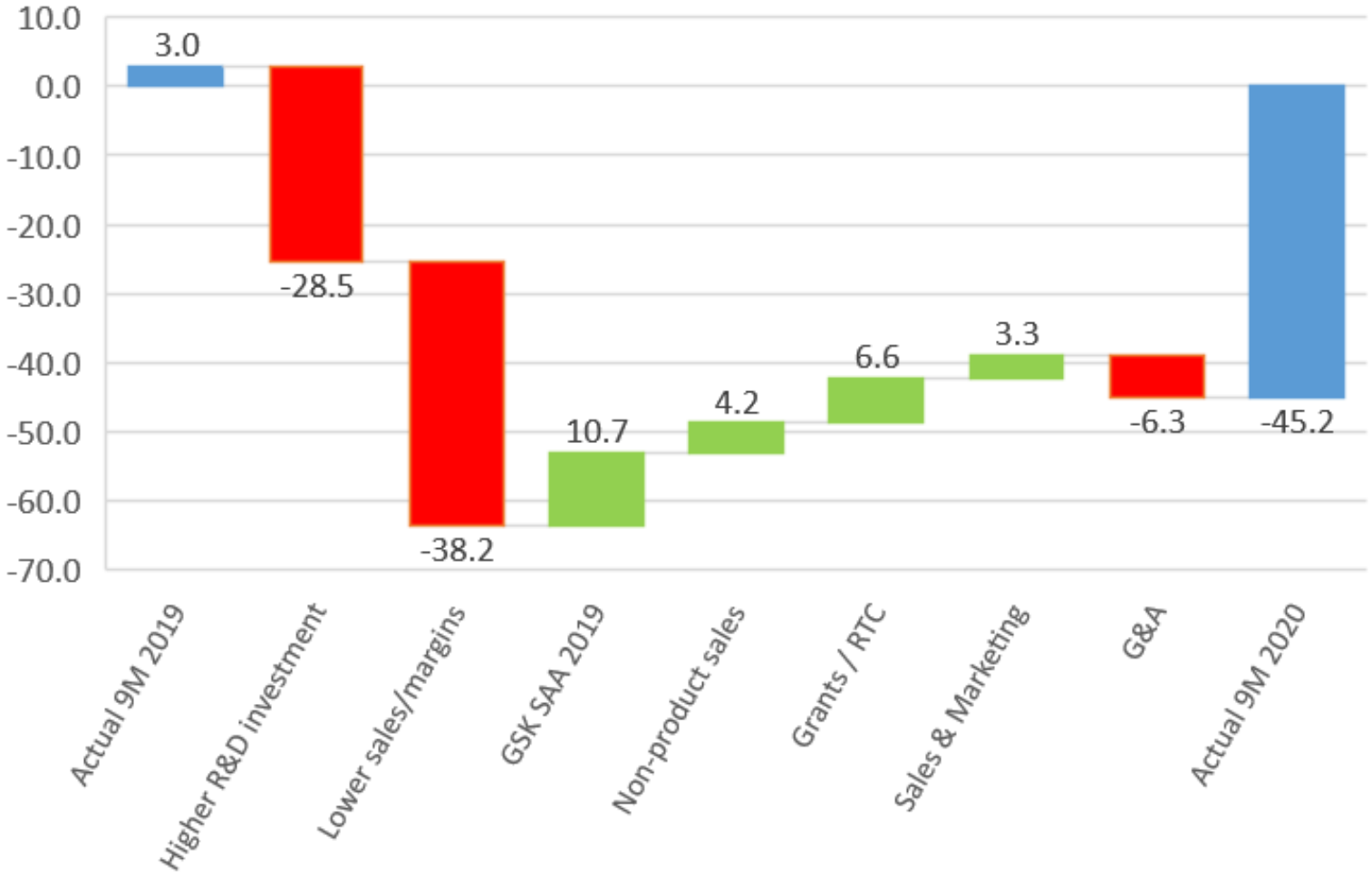
9M 2020 G&A Analysis

Increased Spend Driven by Non-operational Expenses

Total G&A spend increased in 9M 2020 to €19.3 million from €13.0 million in 9M 2019

- Employee Stock Option / Long-term-incentive programs including employer contribution costs: €3.5 million (non-cash)
- Higher costs related to Corporate Projects / Deals: €1.5 million
- Retirement costs for MB members: €1.3 million

EBITDA loss[1] of €45.2 million in 9M 2020 (EBITDA profit of €3.0 million in 9M 2019)



1 Nine-month 2020 EBITDA was calculated by excluding €7.3m of depreciation and amortization (€6.2m in the first nine months of 2019) from the €52.5m operating loss (€3.2m in the fist nine months of 2019) as recorded in the consolidated income statement under IFRS

Agenda

- Introduction
- R&D Update
- Financial Report 9M 2020
- **Financial Outlook**
- Newsflow
- Q&A

Valneva Guidance Update 9M2020

FY 2020 Cash Outlook Expected at Between €180m and €200m

Including Pfizer collaboration impact

	Initial Guidance (Pre-COVID-19)	9M Guidance Update
Product sales revenues	€125m – €135m	~€70m
Other revenues	€10m	~€50m
Total revenues	€135m – €145m	~€120m
R&D investments	Up to €85m	Up to €90m
Gross margin (on product sales revenue)	~65%	40% – 45%
Net operating margin[1]	30% – 35%	(10%) – (15%)
EBITDA	Up to (€35m)	(€40m) – (€50m)

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

Agenda

- Introduction
- R&D Update
- Financial Report 9M 2020
- Financial Outlook
- **Newsflow**
- Q&A

Key Upcoming Newsflow

Lyme disease vaccine candidate VLA15

- Valneva and Pfizer will prepare for next development steps in the coming months

Chikungunya vaccine candidate VLA1553

- Phase 3 recruitment completion expected in Q4 2020

Initiation of Phase 1 COVID-19 vaccine clinical trial

- Top line data end of Q1 2021

Agenda

- Introduction
- R&D Updates
- Financial Report H1 2020
- Financial Outlook
- Newsflow
- Q&A

Thank you
Merci
Danke
Tack

valneva