Valneva presents its 9M 2020 financial results

Analyst Presentation
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valneva

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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

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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.

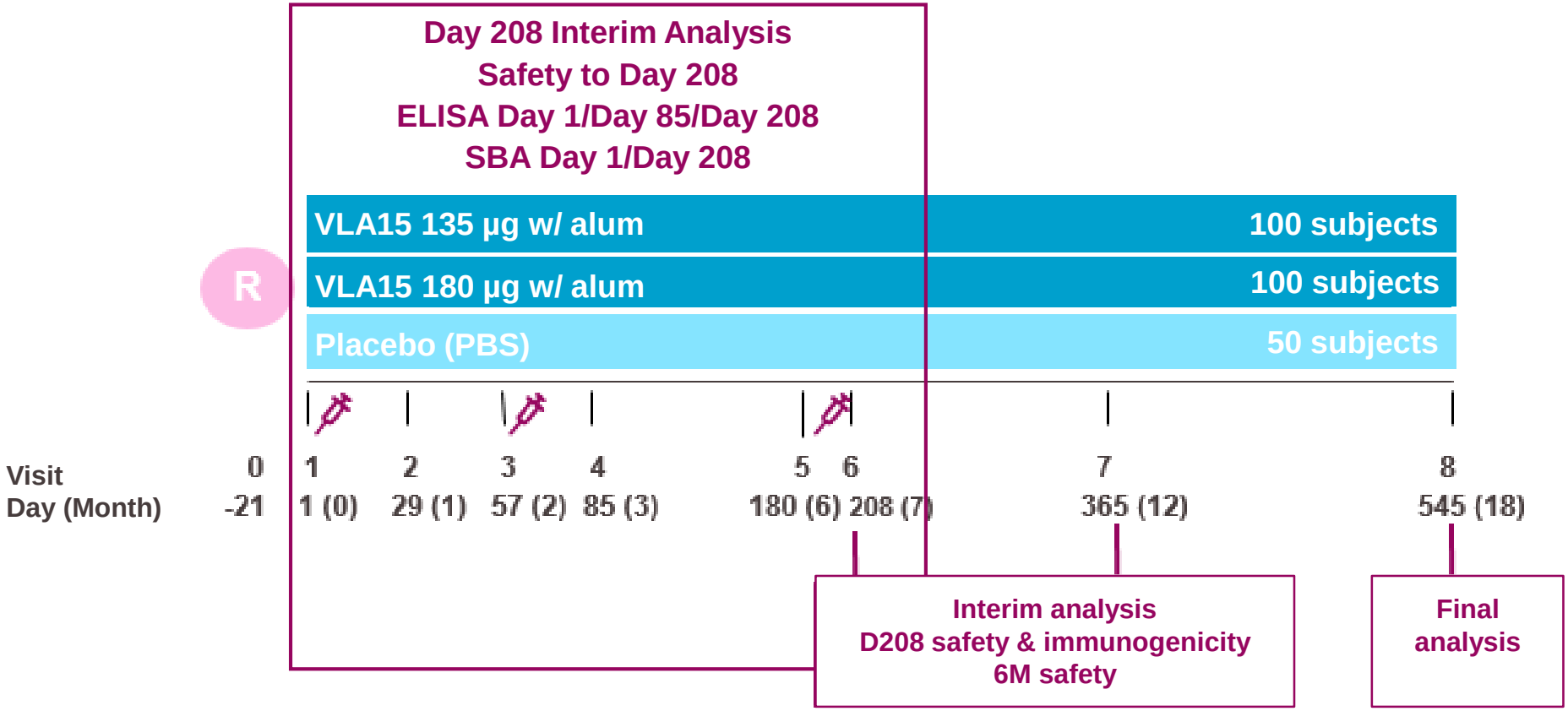
Valneva and Pfizer will prepare for the next development steps in the coming months.

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

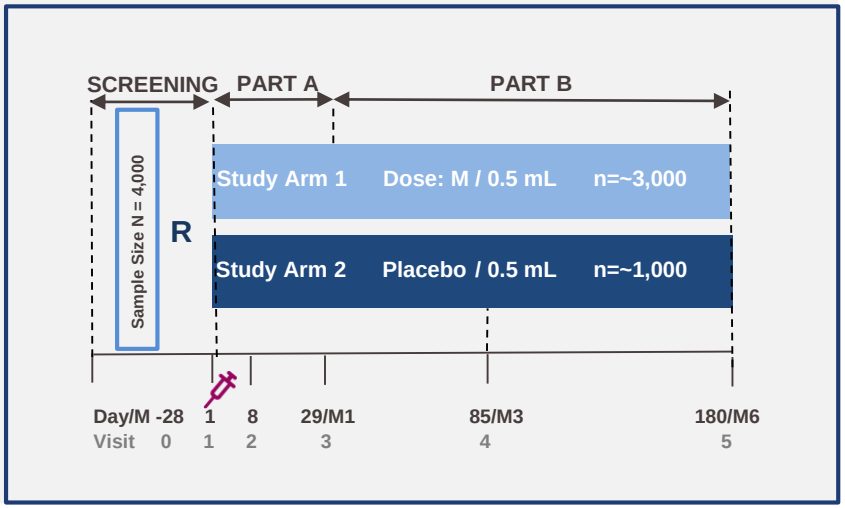
- Awarded by the EMA to promising medicines that demonstrate the potential to address substantial unmet medical need based on initial clinical data
- EMA considers PRIME designations a priority and provides medicine developers with special support, including enhanced interactions and dialogue, as well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

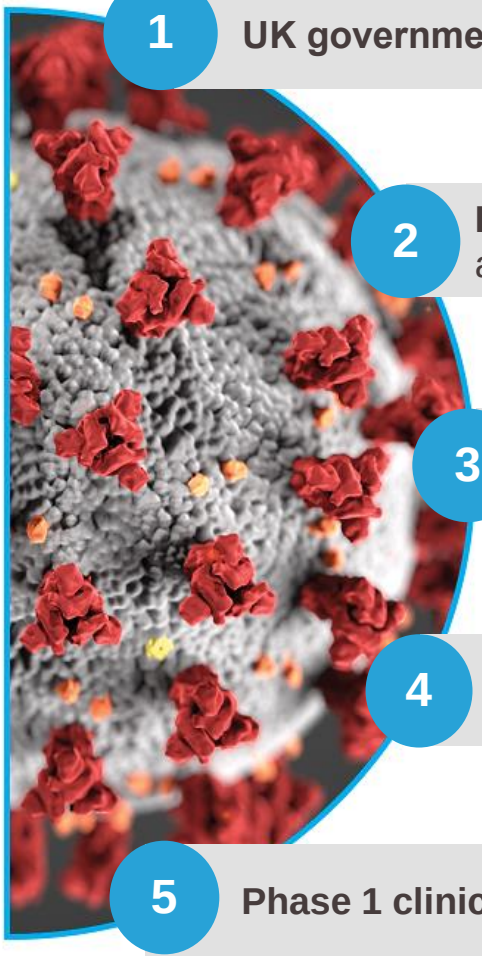
Double-Blinded, Controlled, Randomized Study

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)

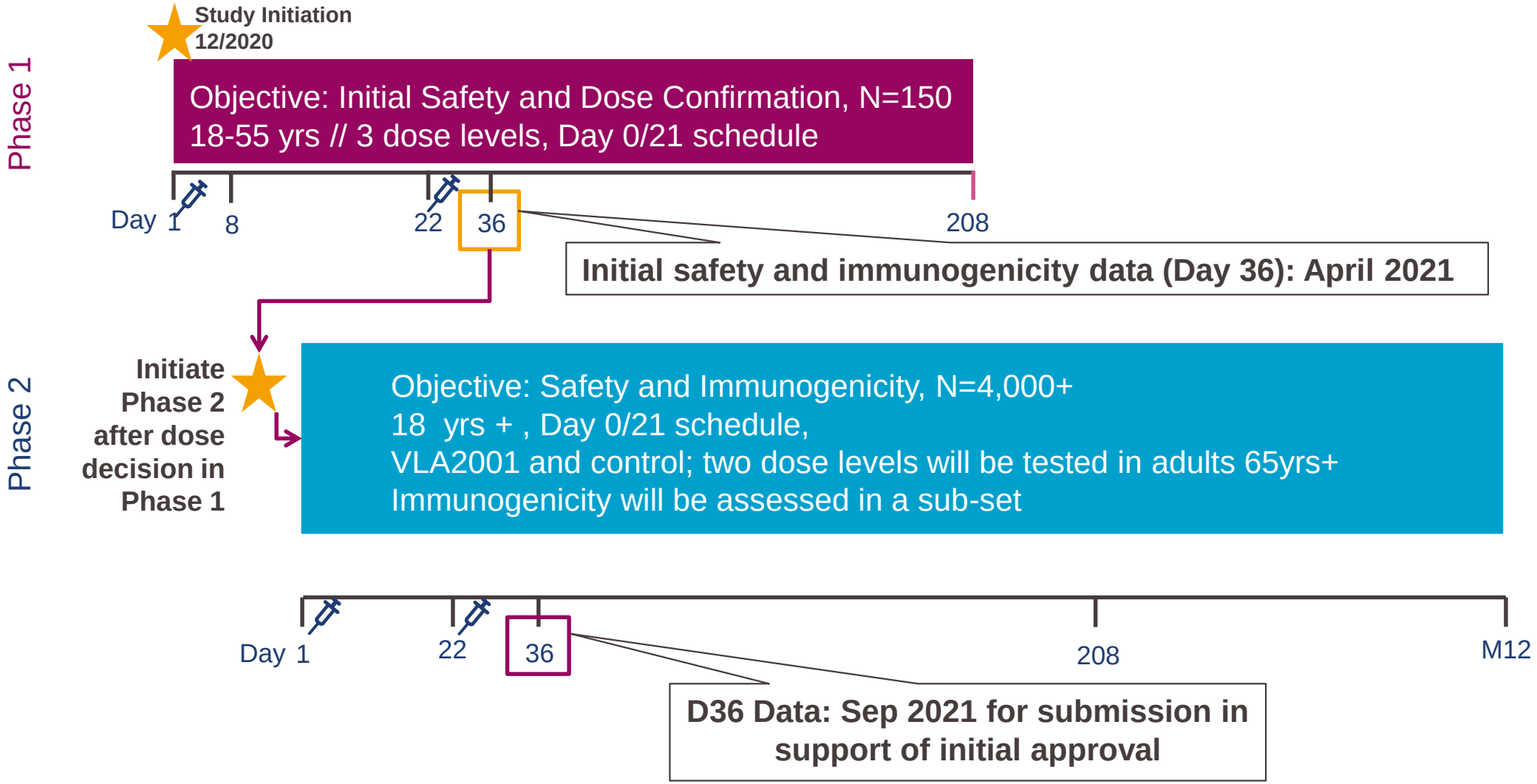
Based on platform experiences, expected to meet preferred/ critical criteria defined in WHO TPP*

	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



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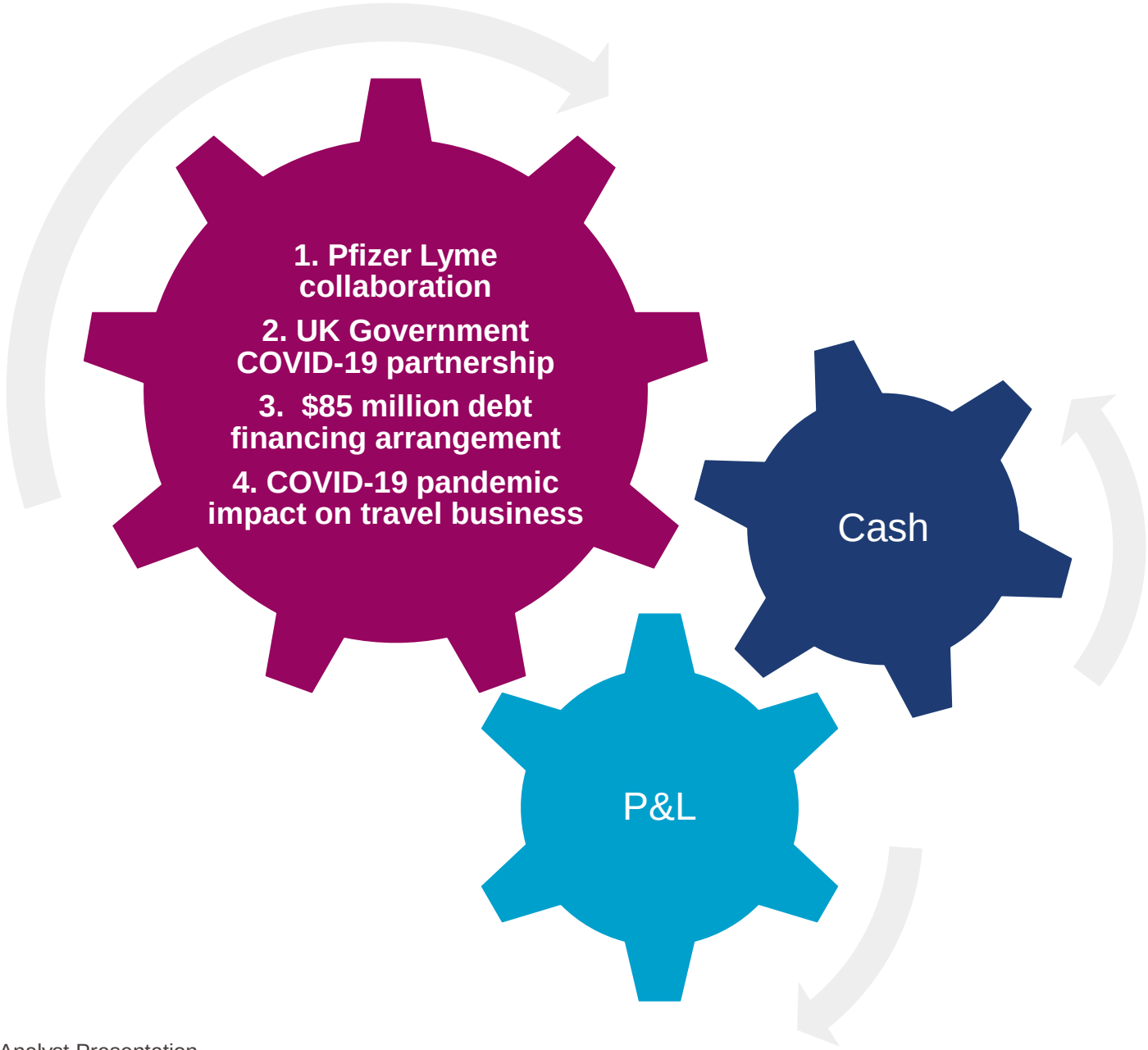
Several Key 2020 Events Affect Cash and P&L



Cash position of €156 million at end of September

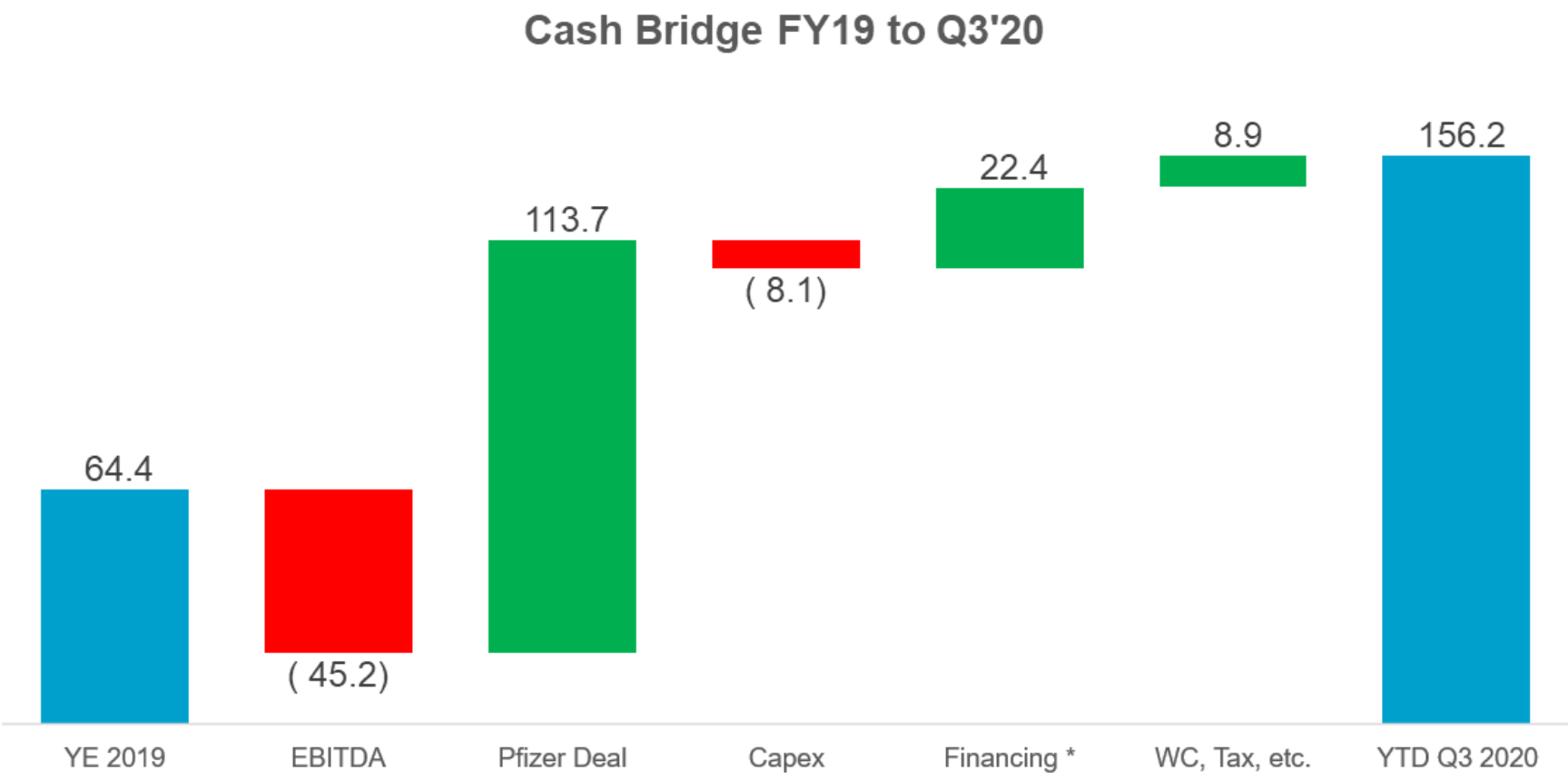
High September Receivables Turning Into Cash in Q4

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

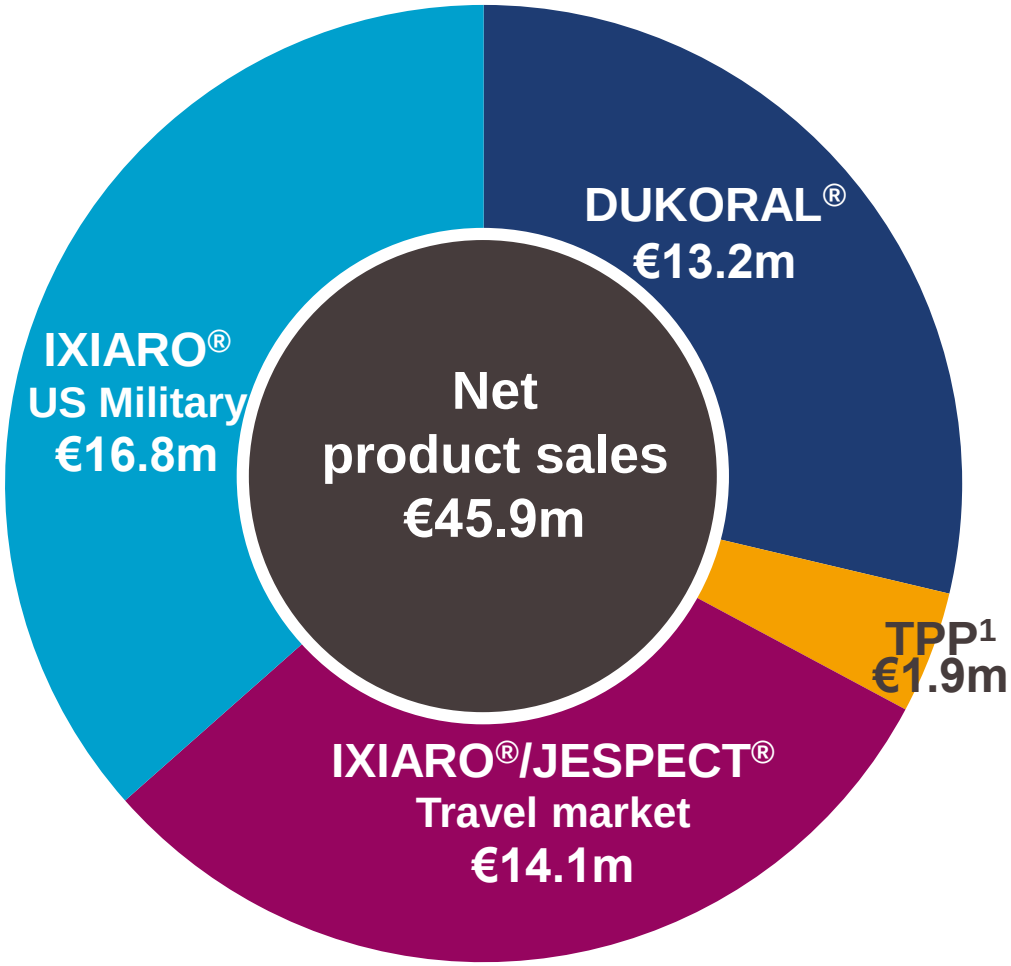
Cash Positively Impacted by Issuance of U.S. loan Facility & Pfizer Deal



* 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

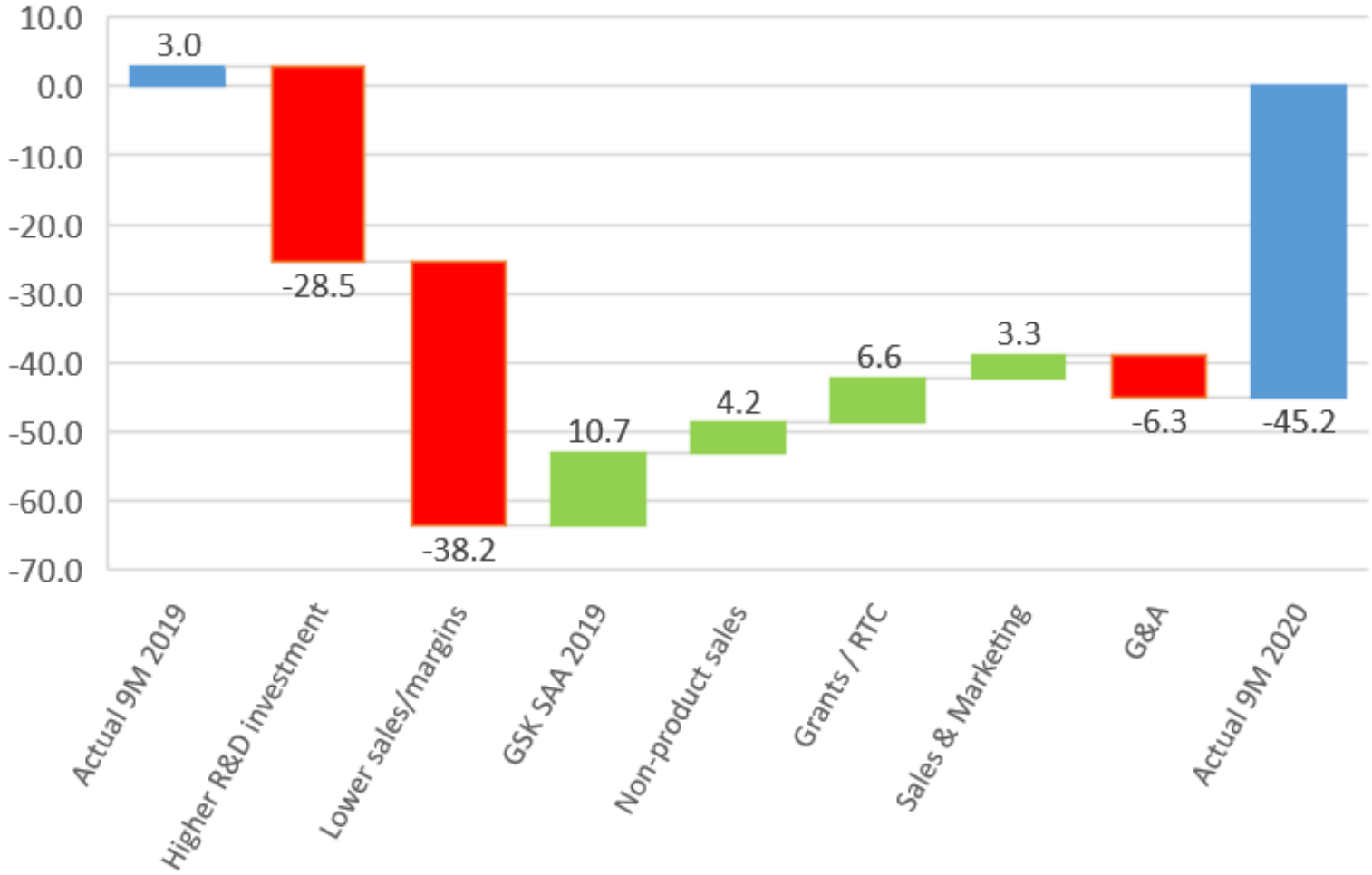
9M 2020 G&A Analysis

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

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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

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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

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Thank you
Merci
Danke
Tack

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