Valneva Presents its 9M 2019 Financial Results

Analyst Presentation
October 31, 2019

valneva

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Agenda

- Introduction
- Key R&D Updates
- Financial Report 9M 2019
- Outlook
- Q&A

Valneva raises FY 2019 product sales guidance following strong nine-month results and R&D execution

Significant R&D milestones announced

- Completion of patient recruitment for Phase 2 studies of Lyme disease vaccine candidate VLA15
- Up to $23.4 million awarded by CEPI for the late-stage development of single-dose chikungunya vaccine VLA1553

FY Product sales guidance raised, EBITDA confirmed

- Product sales rev. of €125 million to €130 million now expected
  - › Overall 2019 revenues of €125m – €135m confirmed[1]
- EBITDA guidance of €5m – €10m confirmed[1]

Strong nine-month financial results reported

- Product sales of €86.4m (+22% / +18% CER[2])
- Gross margin of 65.2%
- EBITDA of €3.0m, EBITDA of €13.7m adjusted[3]
- Cash position of €67.4m

1 Including revenue recognition effects (GSK SAA Termination) **2** CER at constant exchange rates as 9M average Act 2019 **3** Adjusted figure excluding GSK SAA termination recognition effects

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Lyme disease is a serious and growing unmet medical need

VLA15 is the only vaccine candidate in clinical development today

1. Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe
2. Targets OspA of Lyme borrelia, preventing spirochetes from migrating through the tick's mid-gut – an established and proven Mode of Action for a Lyme disease vaccine
3. Safe and immunogenic with excellent boosterability in Phase 1 studies[1]
4. Currently in Phase 2 with clear development path for U.S. and EU licensure; FDA Fast Track Designation granted
5. Semi-generic manufacturing process with three fusion proteins expressed in e. coli – final industrialization for Phase 3 initiated
6. Addressing a very significant unmet medical need and market opportunity

1 Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate.

Lyme disease vaccine candidate VLA15: development on track

Phase 2 well underway

Patient recruitment for both Phase 2 studies completed September 2019

Process for a late stage development & commercialization partner initiated

Phase 2 on track to provide first data by mid 2020

- Initial Data: Day 85 after base immunization schedule expected mid 2020

Phase 3 could be initiated 2021/2022

- Two placebo-controlled Phase 3 efficacy studies are currently planned with 8000 volunteers each, based on current estimates of Lyme incidence rates in order to demonstrate efficacy of the vaccine in Lyme endemic regions in the U.S. and Europe

*Subject to development progress, regulatory concurrence and company funding

Chikungunya is a major public health threat
VLA1553 is a unique, differentiated single-shot vaccine candidate

1. Currently no preventive vaccines or effective antiviral treatments exist for chikungunya
2. VLA1553 is a monovalent, single dose, live attenuated[1] prophylactic vaccine targeting chikungunya virus neutralization
3. Excellent immunogenicity and safety in Phase 1 with first insights on efficacy[2]
4. Currently in Ph 1 (follow-up) – Acceleration directly into pivotal trial under evaluation; non-clinical work ongoing; FDA Fast Track Designation granted; PRV eligible
5. Full-scale drug substance manufacturing process established at in-house FDA licensed facility – additional synergy with existing commercial infrastructure
6. Addressing a significant market opportunity. Up to $23.4 million awarded by CEPI

1 CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; 2 Valneva Reports further Positive Results for its Chikungunya Vaccine Candidate; Photo credit: James Gathany (source)

Chikungunya vaccine candidate VLA1553: progression on track

Status update

Up to $23.4m/ €20.3m awarded by CEPI for late-stage development of VLA1553

- Accelerate regulatory approval for use in regions where outbreaks occur
- Support WHO prequalification to facilitate broader access in lower/middle income countries

Further Phase 1 results for single-shot chikungunya vaccine candidate reported

- Day 28 safety and immunogenicity after single dose
- Viremia data at Days 3, 7 and 14 post-vaccination
- Month 6 safety and immunogenicity data providing information on antibody persistence
- Month 7 re-vaccination safety, immunogenicity and viremia data as early indicator of efficacy

Additional non-clinical experiments ongoing to support EoP2 FDA meeting Q1 2020

- Mosquito transmission studies (complete)
- NHP study addressing biodistribution (complete)
- Passive transfer study in NHPs to develop correlate of protection using human sera from VLA1553-101 (will complete Q4 2019)

Aiming for accelerated pathway into Phase 3 in the U.S., subject to FDA approval*

* Subject to development progress, regulatory concurrence and company funding

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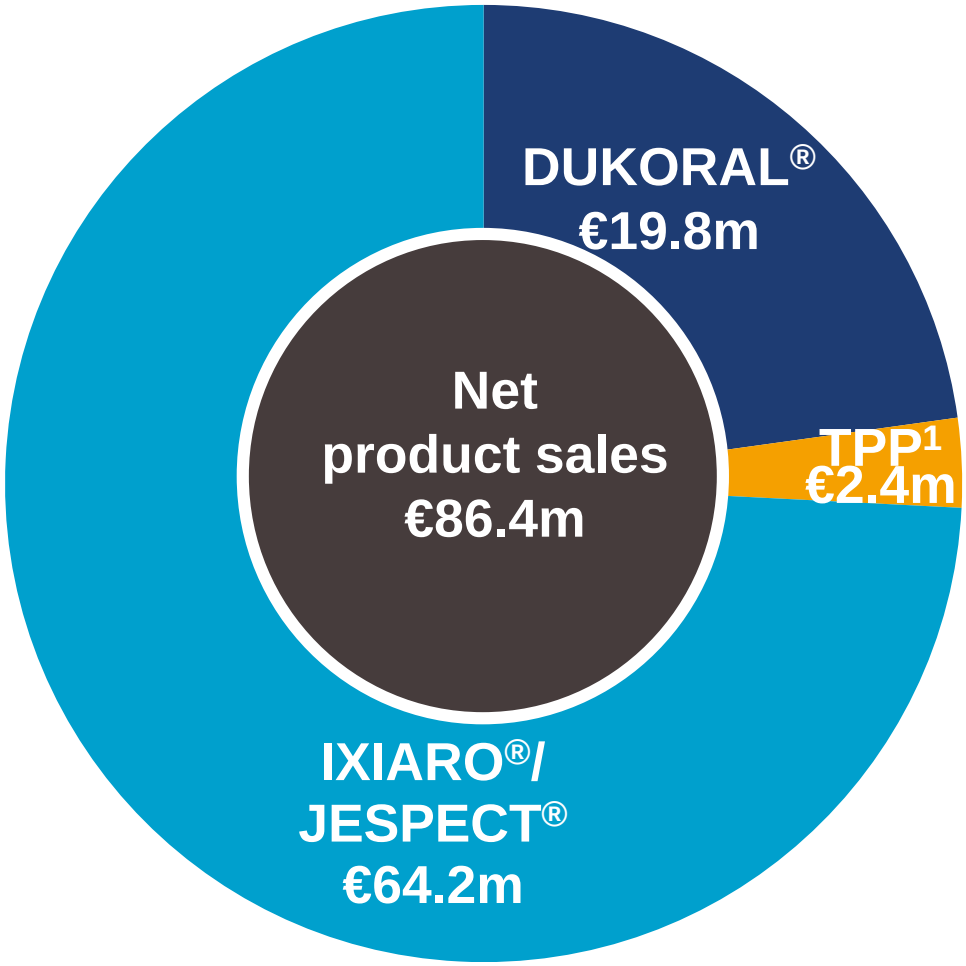
Strong operational performance for 9M 2019



Product sales growth
22% AER / 18% CER

Direct sales
86%

Gross margin[2]
65.2%

CER: at constant exchange rates; **1** Third party products sold by Valneva's commercial organization, **2** Gross margin on product sales

IXIARO® generated > 70% of nine-month sales and continues to be our primary top line growth driver

€m (CER[1])	9M 2019 (unaudited) Actual	9M 2018 CER	CER %	9M 2018 Actual
IXIARO®/JESPECT®	64.2	51.7	**24%**	50.0
DUKORAL®	19.8	18.8	**5%**	18.6
Third party products	2.4	2.5	**-1%**	2.4
Total	**86.4**	**72.9**	**18%**	**71.1**

1 CER at constant exchange rates as 9M average Act 2019,

GSK SAA termination has impacted total revenues by €10.7m

Net revenue effect according to IFRS

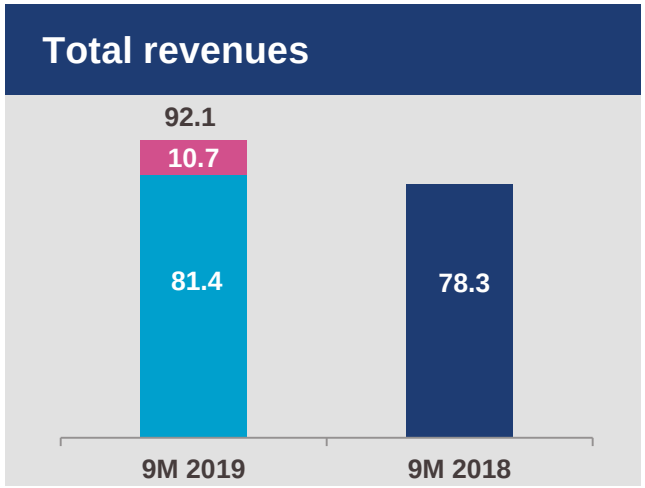
€m	
Total revenues *(excl. effect of GSK SAA termination)*	**92.1**
Settlement Fee (One time, fixed)	(9.0)
Settlement Fee (Milestone related, conditional; discounted)[1]	(6.0)
Release of SAA related contract liability	4.3
Net effect of GSK SAA termination	**(10.7)**
Total revenues *(incl. effect of GSK SAA termination)*	**81.4**

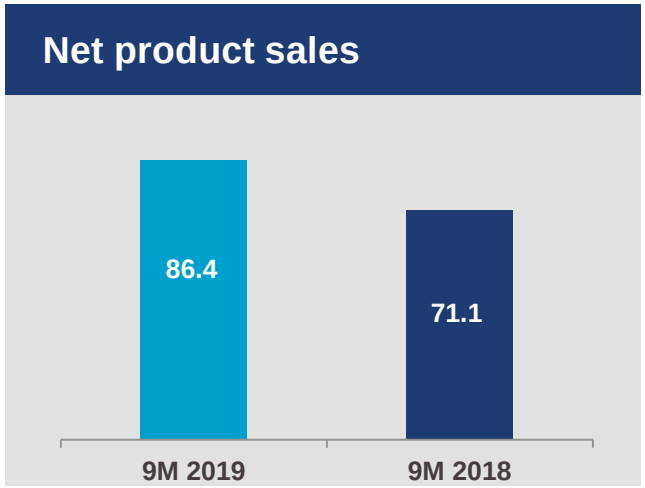
1 €7m Milestone payment valued at fair value applying a 2.98% p.a. incremental borrowing rate under IFRS15

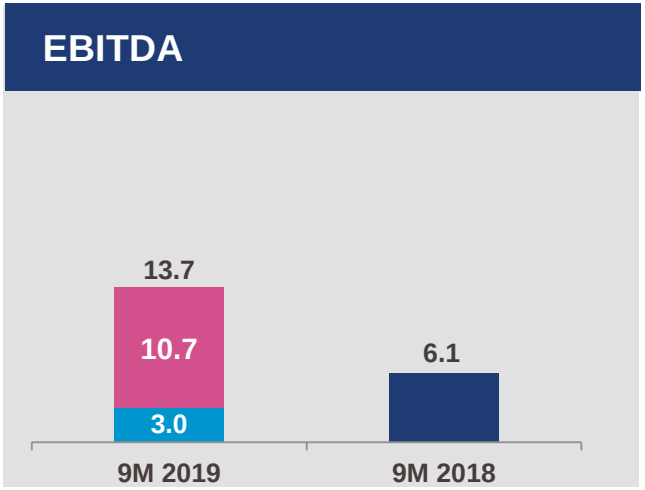
Strong year on year financial performance

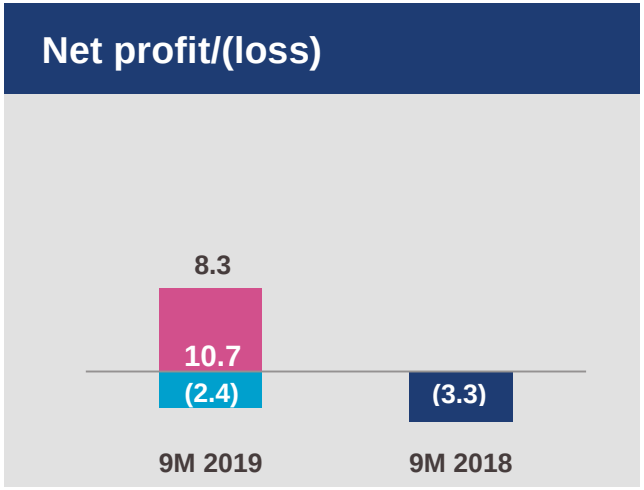
Financial results highlights (IFRS, € million) incl. GSK SAA termination effects

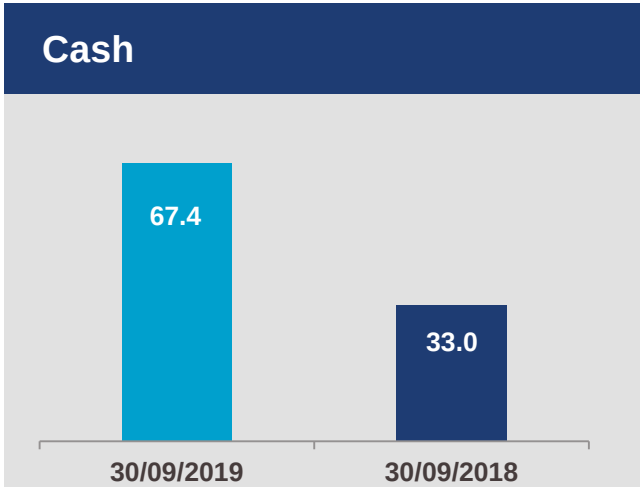
GSK SAA termination effects











Excellent underlying business performance

Profit & Loss Report 9M comparison incl. GSK SAA termination effects (at AER)

* excluding SAA termination accounting / revenue recognition effect

€m	9M 2019 unaudited	9M 2019 excl. SAA effect	9M 2018
Product sales	86.4		71.1
Revenues from collaboration, licensing and services	(5.0)	5.7	7.2
Revenues	**81.4**	**92.1**	**78.3**
Cost of goods and services	(33.4)		(32.3)
Research and development expenses	(23.2)		(18.2)
Marketing and distribution expenses	(17.1)		(15.0)
General and administrative expenses	(13.0)		(12.6)
Other income / (expense), net	4.2		3.1
Amortization and impairment	(2.2)		(2.4)
Operating profit/loss	**(3.2)**	**7.5**	**0.9**
Finance, investment in associates & income taxes	0.8		(4.2)
Profit/loss for the period	**(2.4)**	**8.3**	**(3.3)**
EBITDA[1]	**3.0**	**13.7**	**6.1**

1 9M 2019 EBITDA was calculated by excluding €6.2 million of depreciation and amortization from the €3.2 million operating loss as recorded in the condensed consolidated income statement under IFRS., 9M 2018 EBITDA was calculated by excluding €5.2 million of depreciation and amortization from the €0.9m operating profit.

Gross margin continues to improve

Gross margin on product sales revenues 9M (at AER)

Gross Margins	9M 2019	9M 2018
TOTAL PRODUCT SALES REVENUES *(€m)*	**86.4**	**71.1**
Total Product Sales Gross Margin *(IXIARO®, DUKORAL® and Third Party Products)*	65.2%	59.7%

Net operating margin underpins strong business productivity

Net operating margin 9M (at AER)

€m	9M 2019	9M 2018
Product sales	86.4	71.1
Cost of goods and services	(30.1)	(28.6)
Commercial costs[1]	(28.4)	(28.6)
Net operating margin	**28.0**	**14.0**
as % Revenues	32.4%	19.7%

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

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2019 product sales guidance raised following strong 9M results

All other guidance confirmed despite GSK SAA termination impact

	2018	2019
Product sales revenues	€103.5m	**€125m - €130m**
Total revenues	€113.0m	€125m - €135m
R&D investments	€25.3m	€35m - €40m
Gross margin	60.7%	> 60%
Net operating margin[1]	24.1%	25% - 35%
EBITDA	€13.1m	€5m - €10m

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

Upcoming newsflow

Valneva to attend forthcoming chikungunya VRBPAC[1] meeting

Lyme partnering process

Lyme disease vaccine candidate VLA15: Phase 2 execution on track for initial data mid-2020

Chikungunya vaccine candidate VLA1553: progressing towards potential accelerated development strategy; aiming for EoP2 FDA meeting Q1 2020

New IXIARO® contract with the U.S. Department of Defense in H1 2020

https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-november-8-2019-meeting-announcement

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Thank you
Merci
Danke
Tack

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