Valneva Presents its H1 2019 Financial Results

Analyst Presentation
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valneva

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Agenda

- Introduction
- Financial Report H1 2019
- R&D Portfolio Update
- Outlook
- Q&A

Valneva reports H1 2019 marked by strong operational performance and major corporate progress

Strong product sales, improved margins, positive EBITDA	+ Product sales €61.6m, 12% CER[1] growth + Gross margin of 66.1% + EBITDA €2.4m, EBITDA €13.1m adjusted[2]
Key R&D milestones reported	+ VLA15: final Phase 1/first booster data reported + VLA15: successful outcome of Phase 2 run-in and initiation of second Phase 2 study VLA15-202 + VLA1553: further Phase 1 results reported
Control of R&D assets regained	+ Valneva terminated the strategic alliance agreement with GSK to regain full control of its R&D assets
Strengthened financial outlook	+ Up to $23.4 million awarded by CEPI in July for the late-stage development of a single-dose Chikungunya vaccine + Cash position of €69.9m

1 CER at constant exchange rates as H1 average Act 2019, AER at actual exchange rates, **2** Adjusted figure excluding GSK SAA termination effect

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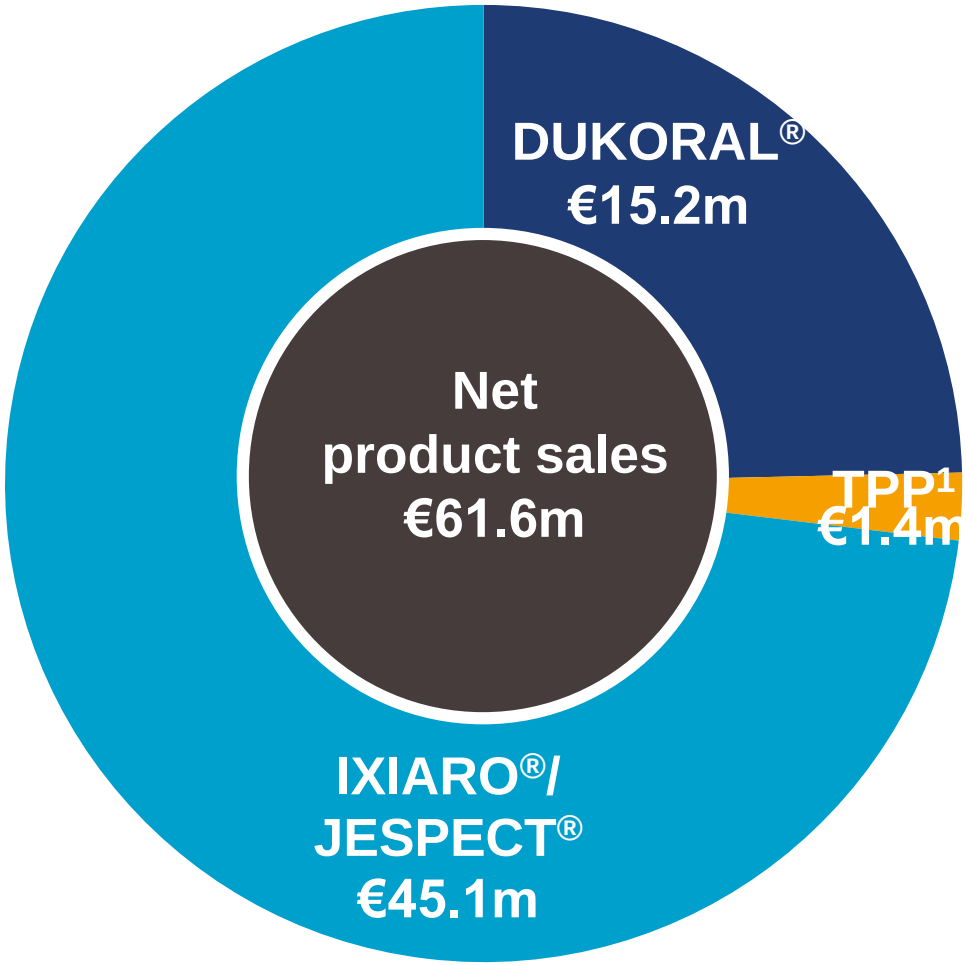
Strong product sales and gross margin
H1-2019



Product sales growth (CER)
12%

Direct sales
88.4%

Gross margin[2]
66.1%

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

IXIARO® contributes > 70% of sales and is the primary sales growth driver

€m (CER[1])	H1 2019 (unaudited) Actual	H1 2018 CER	CER %	H1 2018 Actual
IXIARO®/JESPECT®	45.1	39.1	**15%**	37.6
DUKORAL®	15.2	14.3	**7%**	14.2
Third party products	1.4	1.8	**-23%**	1.7
Total	**61.6**	**55.1**	**12%**	**53.5**

1 CER at constant exchange rates as H1 average Act 2019,

GSK SAA termination reduces revenues by €10.7m

Net revenue effect according to IFRS

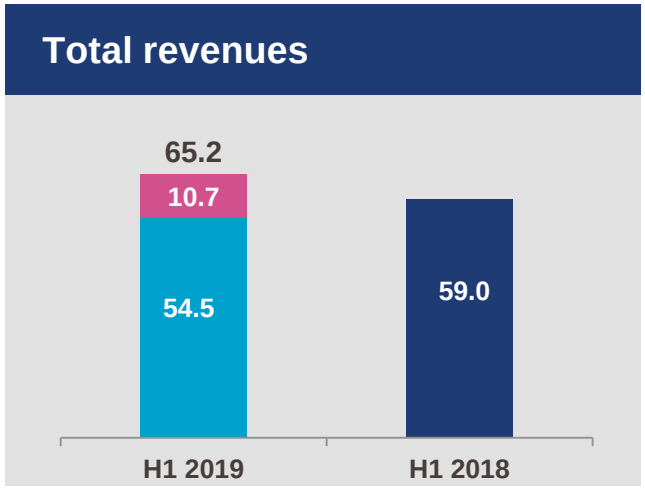
€m	
Total revenues *(excl. effect of GSK SAA termination)*	**65.2**
Settlement Fee (Fixed)	(9.0)
Settlement Fee (Conditional; discounted)[1]	(6.0)
Release of SAA related contract liability	4.3
Net effect of GSK SAA termination	**(10.7)**
Total revenues *(incl. effect of GSK SAA termination)*	**54.5**

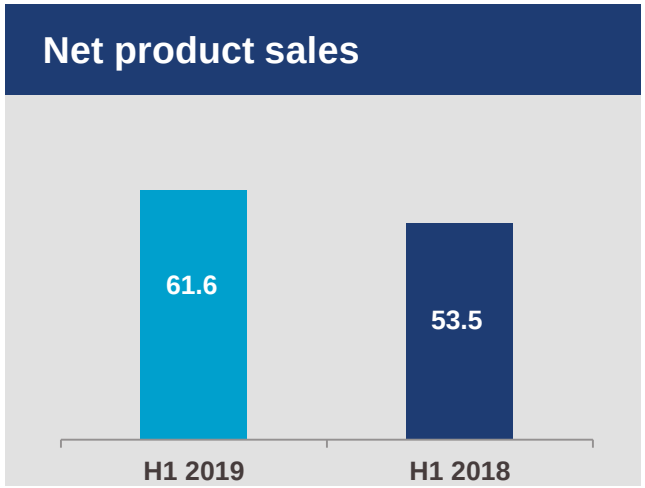
1 €7m Milestone payment valued at fair value applying a 2.98% p.a. incremental borrowing rate under IFRS15

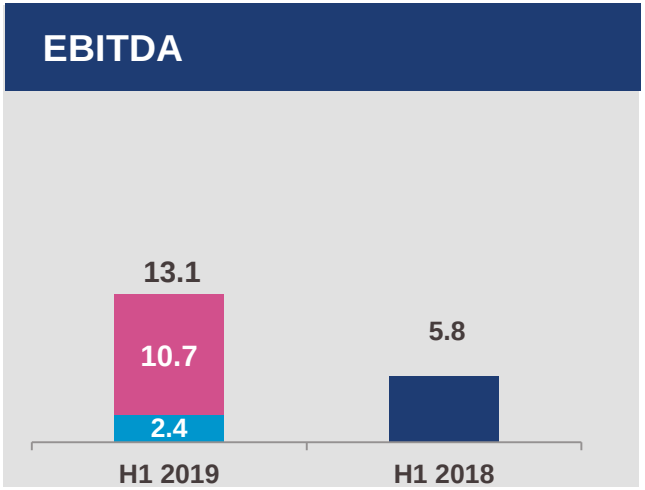
Strong year on year financial performance

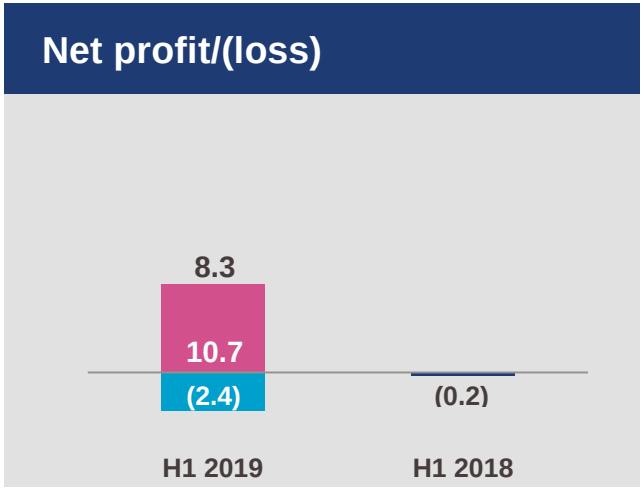
Financial results highlights (IFRS, € million) incl. GSK SAA termination effects

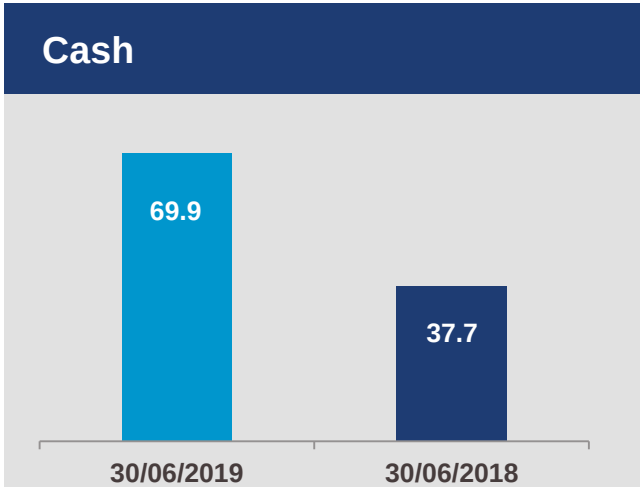
GSK SAA termination effects











On an adjusted* basis, best H1 result in Company´s history

2019 Profit & Loss Report (all figures at AER)

* excluding SAA termination accounting / revenue recognition effect

€m	6 months ended June,		
	2019	2019 excl. SAA effect	2018
Product sales	61.6		53.5
Revenues from collaboration, licensing and services	(7.1)	3.6	5.4
Revenues	**54.5**	**65.2**	**59.0**
Cost of goods and services	(23.1)		(24.0)
Research and development expenses	(14.1)		(12.9)
Marketing and distribution expenses	(11.8)		(10.9)
General and administrative expenses	(8.8)		(8.8)
Other income / (expense), net	3.0		1.6
Amortization and impairment	(1.4)		(1.6)
Operating profit/loss	**(1.7)**	**9.0**	**2.3**
Finance, investment in associates & income taxes	(0.7)		(2.5)
Profit/loss for the period	**(2.4)**	**8.3**	**(0.2)**
EBITDA[1]	**2.4**	**13.1**	**5.8**

1 H1 2019 EBITDA was calculated by excluding €4.1 million of depreciation and amortization from the €1.7 million operating loss as recorded in the condensed consolidated income statement under IFRS., H1 2018 EBITDA was calculated by excluding €3.5 million of depreciation and amortization from the €2.3m operating profit.

ASP and operational efficiency have improved gross margin

Gross margin at AER

Gross Margins	H1 2019	H1 2018
TOTAL PRODUCT SALES REVENUES *(€m)*	**61.6**	**53.5**
Total Product Sales Gross Margin *(IXIARO®, DUKORAL® and Third Party Products)*	66.1%	60.0%

ASP: Average Selling Price

Net operating margin has also improved

All figures at AER excluding GSK SAA termination effects

€m	6 months ended June 30th,	
	2019	2018
Product sales	61.6	53.5
Revenues from collaboration, licensing and services	0.1	0.1
Revenues	**61.7**	**53.6**
Cost of goods and services	(20.9)	(21.4)
Commercial costs[1]	(19.7)	(20.6)
Net operating margin	**21.1**	**11.6**
as % Revenues	34.2%	21.6%

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

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Lyme disease is a serious unmet medical issue

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 already anticipated
6. Addressing a very significant 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: progression on track

Status update

Final Phase 1 data and first booster data for Lyme vaccine candidate reported ✓

Successful outcome of Phase 2 Run-In (June) and initiation of second Phase 2 study VLA15-202

+ Based on DSMB clearance, two lead dosage levels have been selected for ongoing Phase 2 clinical development ✓
+ VLA15-202 evaluates an alternative immunization schedule for two lead dosage levels ✓
+ Patient recruitment ongoing and on track

Phase 2 expected to provide first data by mid-2020

+ Initial Data: Day 85 after short schedule: dose determination
+ Alternative schedule data expected late 2020
+ Booster studies with additional 12 months follow-up

ON TRACK

Phase 3 could be initiated 2021/2022

**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 hints on efficacy[2]**
4. **Currently in Phase 1 (follow-up) – Acceleration directly into pivotal trial under evaluation; FDA Fast Track Designation granted**
5. **Full-scale drug substance manufacturing process established at in-house FDA licensed facility**
6. **Addressing a very significant market opportunity**

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

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

CEPI awarded up to $23.4m for late-stage development of our single-dose vaccine ✓

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

Supporting non-clinical experiments in preparation/process

+ Mosquito transmission studies ✓
+ NHP study addressing biodistribution
+ Passive transfer study in NHPs to develop correlate of protection using human sera from VLA1553-101

ON TRACK

Aiming for accelerated approval procedure at FDA*

* Subject to development progress, regulatory concurrence and company funding

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2019 financial guidance confirmed irrespective of GSK SAA termination effects

	2018	2019
Product sales revenues	€103.5m	€115m - €125m
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®

Important most recent and expected upcoming newsflow

Overview

- **Valneva held its R&D Investor Day in New York**
- **CEPI agreement, award of up to $23.4 million for late-stage development of a single-dose chikungunya vaccine**
- **Establishment of a Scientific Advisory Board announced**
- **On track to deliver 15-20% CER product sales growth expected in 2019**
- **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**

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Thank you
Merci
Danke
Tack

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