Valneva SE

France / Biotechnology
Euronext Paris
Bloomberg: VLA FP
ISIN: FR0004056851

Update

RATING	**BUY**
PRICE TARGET	**€ 8.90**
Return Potential	83.1%
Risk Rating	High

PROSPECTIVE LYME AND CHIKUNGUNYA VACCINE MARKET LEADER

2023 guidance for revenue and other income of €220-260m is below the equivalent 2022 figure of €373.5m. However, over €200m of last year's number was non-cash, mainly related to the COVID-19 vaccine agreements with the UK and the EU. 2023 guidance is all-cash. Disruption to the phase 3 trial of the Lyme disease vaccine candidate VLA15 has created uncertainty whether Pfizer can keep to the original schedule of regulatory submissions to the FDA and EMA in 2025 and also whether Valneva will face any additional financial obligations. However, we think the exact timing of submissions is secondary in comparison with VLA15's overall prospects for success. These remain very good. VLA15 demonstrated strong immunogenicity in both adults and pediatric patients at the phase 2 stage and is the only Lyme disease vaccine candidate currently in clinical development. Pfizer and Valneva also look set to avoid the pitfalls which led to the 2002 withdrawal of GSK's LYMErix, the only previously commercially available Lyme disease vaccine. The Lyme disease vaccine market is expected to be worth USD1bn by 2030. Meanwhile, we expect FDA approval of VLA1553 by the end of August this year. VLA1553 is so far the only chikungunya vaccine candidate to have met its phase 3 trial endpoint. The value of the chikungunya vaccine market is put at USD500m by 2032 (not including potential government stockpiling for outbreak preparedness). 2022 cashflow from operations of €-245.3m was heavily influenced by spending on the now halted manufacturing of the VLA2001 COVID-19 vaccine. YE/22 cash was €289.4m. Assuming no additional VLA15 phase 3 trial obligations and excluding pipeline acquisitions, we expect reduced cash consumption going forward. With these caveats, management believes the current cash position is sufficient to fund operations through at least the end of 2024. We raise our recommendation from Add to Buy but lower the price target from €12.00 to €8.90 to reflect the rise in interest rates since our last study of 18 August 2022, a higher share count, the company's lower net cash position as well as the uncertainty surrounding VLA15 phase 3 disruption. **(p.t.o.)**

FINANCIAL HISTORY & PROJECTIONS

	2020	2021	2022	2023E	2024E	2025E
Revenue (€ m)	110.32	348.09	361.30	146.80	225.41	322.78
Y-o-y growth	-12.6%	215.5%	3.8%	-59.4%	53.5%	43.2%
EBIT (€ m)	-55.12	-61.39	-113.44	9.96	-45.22	10.71
EBIT margin	n.a.	n.a.	n.a.	6.8%	n.a.	3.3%
Net income (€ m)	-64.39	-73.43	-143.28	-5.00	-54.15	5.18
EPS (diluted) (€)	-0.71	-0.75	-1.24	-0.04	-0.39	0.04
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	118.27	-16.27	-274.67	-128.05	-70.25	-5.64
Net gearing	-127.8%	-136.0%	-62.4%	0.6%	67.2%	95.8%
Liquid assets (€ m)	204.44	346.69	289.43	160.88	80.80	35.85

RISKS

Risks include, but are not limited to development, partnering, regulatory, competition and retention of key personnel.

COMPANY PROFILE

Valneva is a specialty vaccine company which develops and commercialises prophylactic vaccines for infectious diseases with significant unmet medical need. Valneva has successfully commercialised two vaccines and has successfully advanced several vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19. Valneva is incorporated in France and had 719 employees at end December 2022.

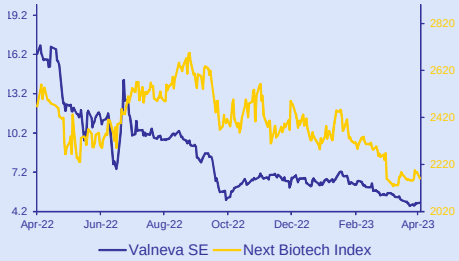
MARKET DATA

As of 03 Apr 2023

Closing Price	€ 4.86
Shares outstanding	138.35m
Market Capitalisation	€ 672.37m
52-week Range	€ 4.63 / 16.89
Avg. Volume (12 Months)	544,119

Multiples	2022	2023E	2024E
P/E	n.a.	n.a.	n.a.
EV/Sales	1.5	3.7	2.4
EV/EBIT	n.a.	54.0	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2022

Liquid Assets	€ 289.43m
Current Assets	€ 424.66m
Intangible Assets	€ 28.71m
Total Assets	€ 621.34m
Current Liabilities	€ 277.39m
Shareholders' Equity	€ 219.80m

SHAREHOLDERS

Groupe Grimaud La Corbière	9.9%
CDC	8.9%
Deep Track Capital	7.6%
Pfizer Inc.	6.9%
Free Float and other	66.7%

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Figure 1: FY/22 results

€m	2022A	2022 consensus*	2021A
Product sales	114.8	114.8	63.0
Other revenues	246.5	246.5	285.1
Total revenue	361.3	361.3	348.1
Operating loss	-113.4	-32.9	-61.4
Cash	289.4	289.4	346.7
2023 guidance			
Product sales	130-150		
Other income	90-110		
Total revenue	220-260		
R&D expenses	70-90		

*Source: Valneva,*Bloomberg*

2022 EBIT below consensus due COVID-19 vaccine fixed asset/inventory writedown Valneva published final 2022 results on 23 March as shown in figure 1 above. The company had already reported 2022 product sales, total revenue and cash on 16 February. On 16 February Valneva also gave guidance for 2023 product sales of €130-150m. FY/22 EBIT was well below consensus mainly because of impairment taken in Q4/22 for fixed assets and inventories in relation to the COVID-19 vaccine programme. Additional 2023 guidance given for the first time on 23 March was for other income of €90-110m, total revenue of €220-260m and R&D expenses of €70-90m. The other income of €90-100m relates to the expected proceeds from the priority review voucher sale following the expected late summer FDA approval of VLA1553.

Figure 2: Product revenue breakdown

	2022A	2021A	Δ
Product sales	114.8	63.0	82.2%
of which:			
Ixiaro	41.3	45.1	-8.4%
of which:			
Private	28.8	7.1	305.6%
US Department of Defense	12.5	38.0	-67.1%
Dukoral	17.3	2.4	620.8%
COVID-19	29.6	0.0	n.a.
Third party products	26.5	15.4	72.1%

Source: Valneva

Vaccine sales to travellers' market recovered strongly in 2022… Product revenue jumped 82.2% to €114.8m (2021: €63.0m). The increase was driven by the first sales of Valneva's COVID-19 vaccine, a post-pandemic recovery in sales of the travel vaccines Ixiaro and Dukoral to private customers, as well as increased sales of third party products.

…Ixiaro sales to the US military should rebound this year Ixiaro sales to the US Department of Defense (DoD) fell by two thirds last year because the DoD decided not to exercise the second option year of a contract for supply of the vaccine originally signed in September 2020. The DoD declined to exercise the contract's second option year because COVID-19 reduced usage of Ixiaro. Private market demand for Ixiaro and Dukoral is recovering quickly and we gather that the same is true for military demand. Valneva has stated it expects that a new contract will be negotiated with the DoD around mid-year. Valneva's third party product business also benefitted from post-pandemic recovery in travel.

Sales jumped 72.1% to €26.5m. The most important third party products marketed by Valneva are Bavarian Nordic's vaccines for rabies and tick-borne encephalitis.

2022 other revenues included over €200m of non-cash items Other revenues fell 13.5% to €246.5m (2021: €285.1m). In 2022, other revenues included €89.4m of non-cash released refund liability as a result of the settlement following the termination of Valneva's COVID-19 vaccine supply agreement with the UK government. Other revenues further included the non-cash release of non-refundable advance payments from EU Member States of over €150m following the European Commission's reduction in its firm order volume for Valneva's COVID-19 vaccine from 24.3m doses to 1.25m doses which prompted Valneva to wind down the COVID-19 vaccine business.

These sums were partially offset by €36.1m of non-cash negative revenue resulting from an increase in the refund liability linked to the amendment to the VLA15 collaboration and license agreement with Pfizer. The €285.1m of other revenues booked in 2021 were attributable to revenues recognised in relation to the terminated UK COVID-19 vaccine supply agreement for non-refundable payments received up to 31 December 2021.

We estimate total 2023 R&D spend at €226m, of which €80m through the P&L and €146m only through the cashflow statement Valneva raised a net €190m through equity issuance in 2022 while gross debt also rose. However, the cash position fell by €57.3m to €289.4m (2021: €346.7m) mainly, as discussed above, because of the high costs associated with the COVID-19 vaccine programme and because other revenue booked in connection with the COVID-19 vaccine supply agreements was non-cash. Nevertheless, the cash position is ample to finance ongoing R&D programmes and support the expected US launch of the Chikungunya vaccine VLA15 later this year. Valneva is guiding towards R&D expenditure of €70-90m this year. This is down on last year's €105m because the chikungunya vaccine candidate VLA1553, is nearing expected approval. R&D expenditure on the COVID-19 vaccine, VLA2001, will also be much lower than last year, but not zero, because Valneva will conclude some ongoing studies. Valneva also plans to invest in preclinical programmes such as VLA1554 (hMPV) and VLA2112 (Epstein-Barre virus) with a view to expanding the product pipeline. At the end of 2022 Valneva had current contract and refund liabilities of €146m. Most of this figure relates to Valneva's obligations towards Pfizer under the terms of their collaboration and license agreement for the Lyme disease vaccine candidate VLA15. Valneva has stated that the corresponding cash outflow will not be taken through the P&L but only through the cashflow statement. Assuming that no further obligations arise in consequence of possible revisions to the VLA15 phase 3 trial design, Valneva will have only a single digit €m obligation to Pfizer at the end of this year. Management has stated that Valneva is also open to acquisitions should suitable opportunities arise.

Valneva and Pfizer announced the initiation of the VLA15 programme's phase 3 trial on 8 August, 2022. The trial design stipulated the enrolment of 6,000 participants ≥ 5 years of age split 2:1 between the US and Europe. Half the participants were to receive injections of VLA15 and the other half placebo. The trial encompassed the 2023 and 2024 tick seasons with participants receiving three primary shots at months 0 and 2 and 5-9 and a booster at month 18. Enrolment was originally scheduled to complete in Q2/23.

Removal of VLA15 phase 3 participants due to 3rd party GCP violations However, on 17 February Pfizer and Valneva announced that half of the 6,000 participants had been removed from the trial because of good clinical practice violations at US trial sites run by a third party. The loss of 3,000 participants in the US equates to three quarters of the country's total participants. The original plan was to submit marketing authorisation applications to the FDA and EMA in 2025 after two tick seasons (2023 and 2024).

Pfizer and Valneva have stated they intend to work with the regulatory authorities with the aim of Pfizer potentially submitting a BLA to the FDA and an MAA to the EMA in 2025 in line with the original schedule.

Clarity on whether 2025 regulatory submission schedule is feasible likely in Q2/23 The loss of three quarters of the US study participants two months before the start of the first of the two tick seasons calls into question whether the 2025 schedule is achievable. Clarity on this issue is likely to be forthcoming in Q2/23 following the conclusion of discussions between Pfizer and the regulatory authorities over proposed modifications to the trial plan.

VLA15 has potentially strong competitive position irrespective of exact submission schedule Irrespective of whether Pfizer makes regulatory submissions in 2025 or 2026, VLA15 potentially has a strong competitive position in a market which is estimated to reach a value of USD1bn by 2030. Lyme disease is the most common tick-transmitted infection in the Northern hemisphere. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 476,000 Americans are diagnosed and treated for Lyme disease each year with at least a further 200,000 cases in Europe. The cost of Lyme disease is estimated at approximately USD1.3 billion each year in direct medical costs in the United States alone. There is currently no vaccine available against Lyme disease and VLA15 is the only vaccine candidate currently in clinical development.

VLA15 effective against all Lyme species most frequently encountered in US and Europe Lyme disease is caused by the borrelia bacterium. It is transmitted to humans from a natural reservoir among small mammals and birds by ticks that feed on both sets of hosts. In the United States transmission is usually through ticks of the ixodes scapularis type and in Europe through ixodes ricinus ticks. There are numerous Lyme-related borrelia species which are collectively known as Borrelia burgdorferi sensu lato. The species most frequently responsible for Lyme disease in the United States are burgdorferi and mayoni and in Europe burgdorferi, afzelii, garinii and bavariensis. In the United States ixodes scapularis ticks must be attached to the human host for at least 36 hours before the bacteria is transmsitted. On the basis of animal studies, it is thought that transmission from ixodes ricinus might occur in under 36 hours. VLA15 is a multivalent vaccine which is effective against all the Lyme-related borelia species most frequently encountered in the US and Europe.

VLA15 mode of action VLA15 provides a potential prophylactic solution to Lyme disease by generating antibodies that target the OspA protein on the surface of Borrelia, killing the bacteria before it can be transmitted from the infected tick to the human host. VLA15's mode of action is summarised in figure 3 below.

Figure 3: VLA15 mode of action summarised

Step 1	Step 2	Step 3	Step 4
Vaccine, when injected, elicits high levels of anti-OspA antibodies	Tick attaches to vaccinated human and begins feeding on blood (24-48-hour attachment needed to transmit B. *burgdorferi)*	Anti-OspA antibodies from vaccine enter tick via consumed blood	Antibodies kill B. *burgdorferi* in midgut, preventing transmission to human host

Source: Valneva

Potential VLA15 competitors include oral lotilaner formulation, antibody treatment As mentioned above, VLA15 is the only Lyme disease vaccine candidate currently in development. However, non-vaccine preparations to prevent Lyme disease are in clinical development. The most advanced of these is Tarsus Pharmaceuticals' TP-05. TP-05 is an oral systemic formulation of lotilaner, an agent whose mode of action is based on selectively inhibiting parasite-specific GABA-CI channels, thereby inducing uncontrolled neuromuscular activity and death in the parasite.

Lotilaner was approved in the EU in 2017 and in the US in Switzerland as a chewable to protect cats and dogs against ticks and fleas. TP-05 is currently undergoing a phase 2a trial with data expected in the second half of this year. Based on preclinical studies, Tarsus claims that TP-05 kills 99% of ticks within 8 hrs. Transmission of the borrelia bacterium, which causes Lyme disease, takes places 24-36 hours after the tick has attached itself to the body. Dosing of TP-05 is expected to be monthly.

The University of Massachusetts Medical School's MassBiologics is the only non-profit FDA-licensed manufacturer of vaccines and biologics in the United States. MassBiologics is developing Lyme PrEP, an antibody treatment intended for yearly administration. Lyme PrEp is based on one of the antibodies, developed by the human body after injections of the LYMErix vaccine (see below). Preclinical trials in animals showed this antibody to be 100% effective. A phase 1 trial ended in August 2022. MassBiologics have stated that the phase 1 trial indicates that the shot will give protection over an entire tick season, but that this will require conformation in subsequent trials. So far MassBiologics has not given a date for the start of a phase 2 trial.

GSK's LYMErix Lyme disease vaccine was available in US from 1998 but withdrawn in 2002 While there is currently no human vaccine against Lyme disease, GSK's LYMErix was approved by the FDA for 15-70 year-olds in 1998 but was later voluntarily withdrawn by GSK because of low public demand and class-action lawsuits. This was the first time in the modern era in which an FDA-licensed vaccine was voluntarily withdrawn. VLA15's mode of action is similar to that of LYMErix which used vaccine-induced OspA antibodies in the tick's human blood meal to neutralise Borrelia Burgdorferi in the tick before transmission to humans.

In the phase 3 trial of LYMErix, the vaccine showed efficacy of 80%. But following LYMErix's launch some patients testified that they had developed arthritis after receiving the vaccine. These patients filed a class action lawsuit against GSK. An FDA panel later concluded that there was no connection between the vaccine and arthritis, but falling sales caused GSK to withdraw the vaccine in 2002.

Besides the groundless association of LYMErix with arthritis, a raft of other factors contributed to the vaccine's failure in the market. The full syndrome now known as Lyme disease was not recognised until the mid-1970's. Understanding of the disease was less well developed in the 1990's and early 2000's than it is today. The incidence of the disease was also much lower. According to the United States Environmental Protection Agency, the incidence of Lyme disease in the United States rose from 3.74 cases per 100,000 people in 1991 to 7.21 reported cases per 100,000 people in 2018. The turn of the millennium was also characterised by above average levels of vaccine hesitancy and anti-vax activism. In 1998 the Lancet published an article falsely claiming that 12 children had acquired bowel symptoms, autism and other disorders after administration of MMR (measles, mumps, rubella) vaccine. However, it was not until 2010 that the General Medical Council found the research underlying the paper to be dishonest and the Lancet retracted it. In 1999 Wyeth withdrew its rotavirus vaccine, RotaShield (launched in 1998), after investigations confirmed that it caused intussusception (bowel obstruction) in some infants.

The lower historic incidence of and knowledge about Lyme disease contributed to the lukewarm recommendations by the regulatory authorities which accompanied LYMErix's approval. The high incidence of Lyme Disease in relatively affluent New England prompted one member of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), which advises the CDC on recommendations for use of vaccines in clinical practice to label LYMErix a "yuppie vaccine."

During the approval process for LYMErix, the Vaccines and Related Biological Products Advisory Committee (VRBAPC) observed that most Lyme diseases were treatable with antibiotics. Visitors to areas with high incidence of Lyme disease were also advised to take preventive measures such as use of DEET repellents, full body tick checks and avoidance of wooded areas with high grass. Recent research (Jutras et al: 2019) has revealed that in ca. 10% of Lyme disease cases, arthritis persists after appropriate antibiotic treatment. Meanwhile the preventive measures outlined above have been shown not to work on a public health scale.

The attitudes of regulators towards LYMErix were also coloured by the fact that GSK was late in starting a pediatric trial for LYMErix. As noted above, the vaccine was approved in 1998 for 15-70 year olds. There was also a lack of clarity at the time of the vaccine's approval as to the duration of immunity and the number of boosters which would be required to maintain a high enough concentration of antibodies in the tick meal to kill Borrelia Burgdorferi.

The FDA approved LYMErix in 1998 after a recommendation for approval by the VRBAPC. However the committee's chair noted that "its rare that a vaccine be voted on with such ambivalence and a stack of provisos." After FDA approval of the vaccine, ACIP also issued a luke warm "should consider" recommendation for people at high risk and a "may be considered" recommendation for individuals "exposed to tick-infested habitats but whose exposure is nether frequent nor prolonged." Along with the, as later became clear, baseless lawsuits, these tepid recommendations also contributed to the low uptake of the LYMErix vaccine and its withdrawal from the market.

Valneva and Pfizer have shown themselves to be very aware of and determined to avoid the pitfalls which prevented the success of LYMErix. In a presentation given at a July 2019 R&D Investor Day Valneva summarised the mistakes made with LYMErix as follows:

By GSK:

- Advertising directly to public, not physicians
- Launching pediatric study too late
- Not engaging patients groups

By CDC:

- Making weak recommendations: "should be considered"

By others:

- Weak support by opinion leaders
- Opposition by patients
- Class action lawsuit

Fast track status for VLA15 programme shows increased seriousness with which FDA takes Lyme disease Valneva and Pfizer are already engaging with the medical community ahead of the potential approval of VLA15. The VLA15 phase 3 trial also incorporates a pediatric population. Furthermore, as a consequence of its increased incidence and the passage of time, the medical community and regulators have a higher degree of knowledge of Lyme disease than at the time of the LYMErix approval in the 1990's. The FDA's decision in July 2017 to grant the VLA15 programme fast track status shows the increasing seriousness with which the regulator now takes Lyme disease.

PDUFA date for VLA1553 is end August The FDA accepted Valneva's Biologics License Application for its chikungunya vaccine candidate VA1553 in February and set a Prescription Drug User Fee Act (PDUFA) review goal date at the end of August this year. VLA1553 is so far the only chikungunya vaccine candidate to have met its phase 3 trial endpoint. Duration of protection is expected to be 3-5 years. The value of the chikungunya vaccine market is put at USD500m by 2032. This figure splits roughly equally between the travel/military market and the endemic market. However, it does not include the value of the market for stockpiling for outbreak preparedness. Given chikungunya's expanding geographic footprint in Asia and the Americas, this could be substantial.

Other companies developing vaccine candidates and non-vaccine treatment prophylactic candidates for chikungunya include Bavarian Nordic, Evotec and Baharat Biotech.

Bavarian Nordic acquired Emergent's chikungunya vaccine candidate in February Valneva markets the Danish company Bavarian Nordic's Rabipur (rabies) and Encepur (tick-borne encephalitis) vaccines in Canada, UK, France and Austria. Both tick-borne encephalitis and Lyme disease are mainly transmitted by ticks. But Lyme disease is caused by a bacterium while a virus causes tick-borne encephalitis. On 15 February Bavarian Nordic announced that it had acquired Emergent BioSolutions' travel vaccine business for up to USD380m. The acquired portfolio includes the chikungunya vaccine candidate, CHIKV VLP. CHIKV VLP is a single-shot aluminium-adjuvanted non-replicating Virus-Like Particle. CHIKV VLP is currently the subject of two phase 3 trials – one in 12 to 64 year olds and the other in participants of 65 years of age and over. Both trials are due to complete in July this year. Duration of protection is expected to be up to 2 years initially with phase III follow-up of 5-year duration. The estimated launch year is 2025 compared with August/September 2022 for Valneva's VLA1553.

Evotec's EVT894 is a monoclonal antibody to treat and potentially prevent chikungunya virus infections. The programme was initially developed by Sanofi as SAR440894. EVT894 is currently the subject of a phase 1 trial which is due to complete in December this year.

Baharat Biotech's BBV87 is an inactivated whole virion chikungunya vaccine candidate. Bharat Biotech and the International Vaccine Institute have sponsored a phase II/III trial. The estimated study completion date was December 2022 but no data has been released so far.

Figure 4 shows changes to our forecasts for 2023. We also inaugurate detailed forecasts for 2024 and 2025. Upward revisions to our 2023 forecasts for Ixiaro and Dukoral reflect a stronger than expected rebound in sales of these vaccines since our last note of August 2022. We now take a more conservative stance on sales of VLA1553 during its launch phase. Valneva now expects only minor sales of VLA2001 in 2023 and we have adjusted our numbers accordingly. Our previous R&D forecast for 2023 was based on the assumption that R&D cost for VLA15 would pass through the P&L. The adjustment to our forecast reflects Valneva's statement that this item will not be taken through the P&L but booked against refund liabilities in the balance sheet and taken through the cashflow statement.

Figure 4: Changes to our forecasts

All figures in EUR '000	Old	2023E New	% Δ	2024E New	2025E New
Product revenues	**140,520**	**136,800**	**-2.6%**	**215,105**	**312,172**
of which:					
Ixiaro	52,000	59,727	14.9%	76,364	79,091
Dukoral	16,000	32,000	100.0%	35,200	36,960
VLA2001	32,000	3,800	-88.1%	0	0
Chikungunya	13,520	7,273	-	68,182	159,347
Third party revenues	27,000	34,000	25.9%	35,360	36,774
Other revenue	34,000	10,000		10,300	10,609
Total revenues	**174,520**	**146,800**	**-15.9%**	**225,405**	**322,781**
Gross profit	90,722	71,666	-21.0%	124,964	195,390
margin (%)	*52.0%*	*48.8%*	-	*55.4%*	*60.5%*
Sales & marketing	-35,000	-42,205	-	-56,187	-68,678
General & administrative	-39,000	-39,000	-	-40,000	-42,000
Research & development	-150,000	-80,000	-	-80,000	-80,000
Other operating items, net	*6,000*	*99,500*	1558.3%	*6,000*	*6,000*
EBIT	-127,278	9,961	n.a.	-45,223	10,712
margin (%)	*-72.9%*	*6.8%*	-	*-20.1%*	*3.3%*
Net financial result	-9,045	-14,952	-	-8,927	-4,959
EBT	**-135,323**	**-4,991**	**n.a.**	**-54,149**	**5,752**
Tax	-5,000	-4	-	0	-575
Net income	**-140,323**	**-4,995**	**n.a.**	**-54,149**	**5,177**
EPS (in EUR)	-1.46	-0.04	n.a.	-0.39	0.04
Adjusted EBITDA	**-107,278**	**28,269**	**n.a.**	**-26,440**	**29,979**

Source: First Berlin Equity Research estimates

Recommendation raised from Add to Buy but price target lowered from €12.0 to €8.9

Our reworked valuation model (see figure 5 overleaf) reflects the rise in the French government 10 year bond yield from 1.8% to 2.8% since our last study of 18 August 2022, a higher share count, the company's lower net cash position as well as the uncertainty surrounding VLA15 phase 3 disruption. We now assume first revenue from VLA15 in 2027 (previously: 2026). These factors outweigh a stronger than expected recovery in sales of the travel vaccines Ixiaro and Dukoral. We have upgraded the recommendation from Add to Buy but lowered the price target from €12.0 to €8.9.

Figure 5: Valuation model

Compound	Project[1)]	Present Value	Market Size 2030	Market Share 2030	Sales 2030	PACME Margin[2)]	Discount Factor	Time to Market
Ixiaro	Japanese Encephalitis	€391.1M	€99.6M	90.0%	€89.6M	40%	9.5%	-
Dukoral	Cholera & ETEC	€153.4M	€171.4M	25.0%	€42.8M	30%	9.5%	-
VLA15	Lyme Disease	€752.0M	€909.1M	70.0%	€636.4M	18%	9.5%	4 Years
VLA 1553	Chikungunya virus	€718.9M	€463.0M	58.9%	€272.7M	45%	9.5%	1 Year
EB66 cell line	Technology Platform	€11.9M			€19.7M	15%	9.5%	-
PACME PV		€2,027.2M						
Costs PV[3)]		€1,182.0M						
NPV		€845.2M						
PV grants, collabs., 3rd party distrib.		€249.0M						
Net cash		€137.0M						
Fair Value		€1,231.3M						
Proforma share count (fully diluted)		138,347K						
Price Target		**€8.90**						

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.
This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research estimates

Figure 6: Changes to our valuation model

	Old	New	Delta
PACME PV	**€1,863.1M**	**€2,027.2M**	**8.8%**
Costs PV	€970.6M	€1,182.0M	21.8%
NPV	**€892.5M**	**€845.2M**	**-5.3%**
PV grants, collabs., 3rd party distrib. milestones	€312.6M	€249.0M	-20.3%
Net cash	€202.7M	€137.0M	-32.4%
Fair Value	**€1,407.9M**	**€1,231.3M**	**-12.5%**
Pro-forma share count	117,352K	138,347K	17.9%
Price Target	**€12.00**	**€8.90**	**-25.8%**

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in EUR '000	2020	2021	2022	2023E	2024E	2025E
Product sales	65,938	62,984	114,797	136,800	215,105	312,172
Other revenue	44,383	285,101	246,506	10,000	10,300	10,609
Total revenues	**110,321**	**348,086**	**361,303**	**146,800**	**225,405**	**322,781**
Cost of materials/goods sold	-54,302	-187,920	-324,441	-75,134	-100,441	-127,392
Gross Profit	**56,019**	**160,166**	**36,862**	**71,666**	**124,964**	**195,390**
Sales & marketing	-18,264	-23,643	-23,509	-42,205	-56,187	-68,678
General & administrative	-27,539	-47,606	-34,073	-39,000	-40,000	-42,000
Research & development	-84,454	-173,283	-104,922	-80,000	-80,000	-80,000
Other operating items, net	19,117	22,976	12,199	99,500	6,000	6,000
Operating income (EBIT)	**-55,120**	**-61,390**	**-113,443**	**9,961**	**-45,223**	**10,712**
Net financial result	-10,222	-16,715	-18,794	-14,952	-8,927	-4,959
Foreign exchange gains/(loss)	173	8,130	-12,587	0	0	0
Associates	-133	-5	9	0	0	0
Pre-tax income (EBT)	**-65,302**	**-69,979**	**-144,815**	**-4,991**	**-54,149**	**5,752**
Income taxes	909	-3,446	1,536	-4	0	-575
Net income / loss	**-64,393**	**-73,425**	**-143,279**	**-4,995**	**-54,149**	**5,177**
EPS	**-0.71**	**-0.75**	**-1.24**	**-0.04**	**-0.39**	**0.04**
Adjusted EBITDA	**-45,200**	**-47,100**	**-69,200**	**28,269**	**-26,440**	**29,979**
Ratios as % of total revenues						
Gross margin	50.8%	46.0%	10.2%	48.8%	55.4%	60.5%
EBITDA margin	-41.0%	-13.5%	-19.2%	19.3%	-11.7%	9.3%
EBIT margin	-50.0%	-17.6%	-31.4%	6.8%	-20.1%	3.3%
Net margin	n.a.	n.a.	n.a.	n.a.	n.a.	1.6%
Expenses as % of total revenues						
Sales & marketing	-16.6%	-6.8%	-6.5%	-28.8%	-24.9%	-21.3%
General & administrative	-25.0%	-13.7%	-9.4%	-26.6%	-17.7%	-13.0%
Research & development	-76.6%	-49.8%	-29.0%	-54.5%	-35.5%	-24.8%
Y-Y Growth						
Product sales	-49.1%	-4.5%	82.3%	19.2%	57.2%	45.1%
Total revenues	-12.6%	215.5%	3.8%	-59.4%	53.5%	43.2%
Operating income (EBIT)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income / loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in EUR '000	2020	2021	2022	2023E	2024E	2025E
Assets						
Current Assets, Total	**308,427**	**585,832**	**424,659**	**256,640**	**231,378**	**254,368**
Cash and cash equivalents	204,435	346,686	289,430	160,880	80,804	35,847
Receivables	19,232	44,013	23,912	34,200	53,776	78,043
Inventories	26,933	124,098	35,104	34,200	53,776	78,043
Other current assets	57,827	71,035	76,213	27,360	43,021	62,434
Non-Current Assets, Total	**140,737**	**231,520**	**196,685**	**217,218**	**259,621**	**311,270**
Property, plant & equipment	34,778	125,545	112,435	119,855	127,342	134,910
Right of use assets	43,374	48,285	41,603	49,577	77,955	113,133
Intangibles	35,409	32,700	28,711	25,733	22,874	20,129
Equity-accounted investees	2,130	2,126	0	0	0	0
Other assets	19,476	19,282	8,299	16,416	25,813	37,461
Deferred tax assets	5,570	3,582	5,637	5,637	5,637	5,637
Total Assets	**449,164**	**817,352**	**621,344**	**473,858**	**490,999**	**565,637**
Shareholders' Equity & Debt						
Current Liabilities, Total	**175,870**	**368,979**	**277,392**	**147,461**	**238,705**	**320,023**
Short-term debt	6,988	7,107	11,580	21,351	50,842	47,385
Accounts payable	36,212	68,119	41,491	34,200	53,776	78,043
Other current liabilities and provisions	13,010	53,658	36,780	34,200	53,776	78,043
Current finance lease liabilities	2,696	3,135	25,411	30,281	47,615	69,101
Tax and employee-related liabilities	13,164	17,249	15,738	20,520	32,266	46,826
Current tax liability	0	83	532	274	430	624
Contract liabilities and refund liabilities	103,800	219,628	145,860	6,635	0	0
Longterm Liabilities, Total	**195,872**	**277,792**	**124,155**	**111,575**	**91,601**	**79,724**
Long term debt	46,375	50,726	87,227	76,951	37,630	1,766
Non-current finance lease liabilities	49,392	53,687	28,163	33,561	52,772	76,585
Other liabilities	2,900	8,378	1,436	390	546	740
Contract liabilities and refund liabilities	97,205	163,711	6,635	0	0	0
Shareholders Equity	**77,422**	**170,581**	**219,797**	**214,822**	**160,693**	**165,890**
Total Consolidated Equity and Debt	**449,164**	**817,352**	**621,344**	**473,858**	**490,999**	**565,637**
Ratios						
Current ratio (x)	1.75	1.59	1.53	1.74	0.97	0.79
Quick ratio (x)	1.60	1.25	1.40	1.51	0.74	0.55
Net gearing	-127.8%	-136.0%	-62.4%	0.6%	67.2%	95.8%
Book value per share (€)	0.85	1.88	2.42	2.36	1.77	1.82
Net debt	-98,984	-232,031	-137,049	1,265	108,054	158,990
Equity ratio	17.2%	20.9%	35.4%	45.3%	32.7%	29.3%

CASH FLOW STATEMENT

All figures in EUR '000	2020	2021	2022	2023E	2024E	2025E
Net income / loss	**-64,393**	**-73,425**	**-143,279**	**-4,995**	**-54,149**	**5,177**
Depreciation and amortization	7,328	11,497	17,880	18,308	18,782	19,267
Impairment	0	0	0	0	0	0
Share-based payments	0	0	0	0	0	0
Tax provision	0	0	0	0	0	0
Adjustments for non-cash transactions	37,941	56,476	44,070	18,308	18,782	19,267
Changes in non-current op. assets/lias.	88,472	59,353	-147,713	0	0	0
Changes in w orking capital	77,740	36,127	1,732	27,253	-4,833	-5,991
Refund liabilities	0	0	0	-145,860	-6,635	0
Other adjustments	0	0	0	0	0	0
Income tax	-2,021	-1,631	-154	0	0	0
Operating cash flow	**137,738**	**76,901**	**-245,344**	**-105,295**	**-46,835**	**18,453**
Property, plant and equipment	-18,936	-92,229	-29,246	-22,000	-22,660	-23,340
Investments in intangibles	-535	-942	-76	-750	-750	-750
Free cash flow	**118,267**	**-16,270**	**-274,666**	**-128,045**	**-70,245**	**-5,637**
Acquisitions & disposals, net	24	0	8	0	0	0
Interest received	107	55	260	0	0	0
Investing cash flow	**-19,340**	**-93,116**	**-29,054**	**-22,750**	**-23,410**	**-24,090**
Debt financing, net	28,271	-1,097	37,538	-505	-9,830	-39,321
Equity financing, net	290	166,823	189,837	0	0	0
Payment of lease liabilities	-2,111	-2,805	-3,048	0	0	0
Interest expense	-4,710	-8,417	-9,211	0	0	0
Cash flow from financing	**21,740**	**154,504**	**215,116**	**-505**	**-9,830**	**-39,321**
Forex & other	-142	3,962	2,026	0	0	0
Net cash flows	**139,996**	**142,251**	**-57,256**	**-128,550**	**-80,075**	**-44,958**
Cash and equivs., start of the year	64,439	204,435	346,686	289,430	160,880	80,804
Cash and equivs., end of the year	**204,435**	**346,686**	**289,430**	**160,880**	**80,804**	**35,847**
Adj. EBITDA/share	**-0.50**	**-0.48**	**-0.60**	**0.20**	**-0.19**	**0.22**
Y-Y Growth						
Operating cashflow	2391.2%	-44.2%	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA/share	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

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Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	26 April 2017	€2.52	Buy	€4.00
2...31	↓	↓	↓	↓
32	22 October 2021	€18.92	Buy	€23.80
33	12 November 2021	€21.60	Add	€23.40
34	16 December 2021	€22.36	Add	€23.40
35	27 January 2022	€15.21	Buy	€23.40
36	10 February 2022	€15.03	Buy	€22.10
37	6 July 2022	€11.12	Add	€12.00
38	26 July 2022	€9.75	Buy	€12.50
39	19 August 2022	€9.91	Add	€12.00
40	Today	€4.86	Buy	€8.90

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