UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: March 23, 2023

Commission File Number: **001-40377**

Valneva SE
(Translation of registrant's name into English)

6 rue Alain Bombard
44800 Saint-Herblain, France
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F [ ]

On March 23, 2023, the Registrant issued a press release and a presentation, copies of which are attached hereto as Exhibit 99.1 and Exhibit 99.2 and are incorporated herein by reference. The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-266839).

Exhibits

99.1	Press release dated March 23, 2023
99.2	Analyst Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Valneva SE
(Registrant)

Date: March 23, 2023

/s/ Thomas Lingelbach
Thomas Lingelbach
Chief Executive Officer and President

Valneva Reports Full Year 2022 Results and Provides Corporate Updates

Total revenues of €361.3 million in 2022 compared to €348.1 million in 2021

- Driven by product sales of €114.8 million (82.3% increase compared to 2021), including €85.2 million of travel vaccine sales and €29.6 million of COVID-19 vaccine sales
- €246.5 million of Other Revenues, primarily driven by revenue recognition related to previous COVID-19 vaccine supply agreements

Strong cash position of €289.4 million at December 31, 2022

- Raised over €190 million in equity:
  - €102.9 million of gross proceeds from an upsized global offering[1] in a challenging economic environment
  - €90.5 ($95) million equity investment by Pfizer
- Included drawing a total of $40 million from the Deerfield & OrbiMed loan agreement[2]

2023 financial guidance

- Expected total revenues and other income between €220 million and €260 million:
  - €130 million to €150 million of product sales, including marginal COVID-19 vaccine sales under an existing supply agreement with the Kingdom of Bahrain
  - Between €90 million and €110 million of other income
- R&D expenses expected between €70 million and €90 million

Financial Information
(Audited[3] 2022 results, consolidated per IFRS)

€ in million	**12 months ending December 31**	
	2022	**2021**
Total revenues	361.3	348.1
Product sales	114.8	63.0
Net profit/(loss)	(143.3)	(73.4)
Adjusted EBITDA (loss)	(69.2)	(47.1)
Cash	289.4	346.7

Saint-Herblain (France), March 23, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company, today reported its consolidated financial results for the year ending December 31, 2022[4] and provided corporate updates.

Valneva will provide a live webcast of its full-year 2022 results conference call beginning at 3 p.m. CET/10 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/n2f4om2y

Peter Bühler, Valneva's Chief Financial Officer, commented, "In 2022, Valneva successfully executed on key strategic objectives despite a difficult economic environment. After achieving clinical and regulatory success, we decided to wind-down our COVID-19 activities and focus on our lead programs. We were agile in reactivating production of our commercial vaccines to capitalize on the travel industry recovery. We also managed to strengthen our cash level and shareholder base, attracting leading investors and maintaining the support of existing shareholders. With close to €290 million in cash, we entered 2023 in a strong position to support expected commercial growth and R&D programs."

Clinical Stage Vaccine Candidates

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
FDA Priority Review of vaccine license application granted

VLA1553 is a live-attenuated, single-dose vaccine candidate against the chikungunya virus (CHIKV), a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. The Pan American Health Organization (PAHO) issued an epidemiological alert last month as the number of cases and deaths due to chikungunya continues to rise in the Americas[5]. With no preventive vaccine or specific treatment yet available, chikungunya is considered a major public health threat.

Valneva announced last month that the U.S. Food and Drug Administration (FDA) accepted the filing of a Biologics License Application (BLA)[6] for approval of VLA1553 in persons aged 18 years and above and granted priority review for the application[7]. Under this priority review, VLA1553 has currently been assigned a Prescription Drug User Fee Act (PDUFA) review goal date at the end of August 2023, which is the date by which the FDA intends to take action on the application subject to progress of the BLA review. VLA1553 is currently the only chikungunya vaccine candidate worldwide for which a regulatory review process is underway[8] and, if approved, it could become the first chikungunya vaccine available to address this unmet medical need.

Valneva's BLA application follows final pivotal Phase 3 data in March 2022[9], final lot-to-lot consistency results in May 2022[10] and positive twelve-month persistence data in December 2022[11]. A clinical study of VLA1553 in adolescents is ongoing in Brazil[12], for which Valneva reported enrollment and vaccination completion in February 2023[13]. This trial, conducted by Valneva's partner Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), may support future regulatory submissions in this age group, if VLA1553 is initially approved in adults, as well as licensure of the vaccine in Europe and Brazil, which would be the first potential approval for use in an endemic population. Topline results are expected mid-2023.

The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted PRIority MEdicine (PRIME) designation by the European Medicines Agency (EMA) in 2020. Valneva currently plans to make additional regulatory submissions for VLA1553 in the second half of 2023. The sponsor of the first chikungunya vaccine approved in the U.S. is eligible to receive a Priority Review Voucher (PRV)[14].

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 3 study initiated

Valneva and Pfizer are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in North America and Europe. VLA15 is the only Lyme disease vaccine program in advanced clinical development today and has received Fast Track designation from the FDA.

Valneva and Pfizer reported results for three Phase 2 clinical trials of VLA15 in both adult and pediatric populations, in which high levels of antibodies against all six strains were observed[15,16,17]. In August 2022, the companies initiated a Phase 3 clinical study, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)", to investigate the efficacy, safety and immunogenicity of VLA15 in participants five years of age and older in highly endemic regions in the United States and Europe[18].

In February 2023, Pfizer, as the study sponsor, decided to discontinue half of the total enrolled participants in the trial following violations of Good Clinical Practice (GCP) at certain clinical trial sites run by a third-party clinical trial site operator[19]. The clinical trial remains ongoing at sites not operated by the third party. The companies intend to work with regulatory authorities and, as previously announced, aim for Pfizer to potentially maintain the original submission timelines, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

According to the terms of Valneva's collaboration with Pfizer, Pfizer leads late phase development of VLA15 and, if approved, Pfizer will have sole control over its commercialization with Valneva eligible to receive up to $408 million in milestones, plus royalty payments. In June 2022, the terms of this collaboration were updated, and Pfizer invested €90.5 ($95) million in Valneva as part of an equity subscription agreement[20]. As per the terms of the collaboration agreement, Valneva received a $25 million milestone payment from Pfizer in 2022 following initiation of the Phase 3 study.

Pre-Clinical Vaccine Candidates

Valneva continues to progress select pre-clinical assets and focus on strengthening its future clinical pipeline. The Company is currently focused on VLA2112, a vaccine candidate targeting the Epstein-Barr virus (EBV), which is one of the most common human viruses. EBV can cause infectious mononucleosis[21] and is strongly associated with the development of several types of cancer[22] and multiple sclerosis[23]. Valneva has also been working on a vaccine candidate targeting the human metapneumovirus (hMPV), which is a major worldwide respiratory pathogen that causes acute upper and lower respiratory tract infection[24] and is currently exploring potential partnering opportunities. Additionally, Valneva initiated pre-clinical work on vaccine candidates targeting parvovirus B19, a virus most commonly causing fifth disease[25], and *Campylobacter, a* bacterium often associated with food poisoning[26].

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

IXIARO® is an inactivated Vero cell culture-derived Japanese encephalitis that is the only Japanese encephalitis vaccine licensed and available in the United States, Canada and Europe. IXIARO® is indicated for active immunization against Japanese encephalitis, the most prevalent cause of viral encephalitis in Asia, for adults, adolescents, children and infants aged two months and older.

IXIARO®/JESPECT® sales were €41.3 million in 2022 compared to €45.1 million in 2021. This decrease was the result of lower sales to the U.S. Department of Defense. The significant recovery of the private travel markets partly offset this impact, with IXIARO®/JESPECT® private sales reaching €28.8 million in 2022 compared to €7.1 million in 2021.

CHOLERA / ETEC[27]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by *Vibrio cholerae* and/or heat-labile toxin producing ETEC[28], the leading cause of travelers' diarrhea. DUKORAL® is authorized for use in the European Union and Australia to protect against cholera, and in Canada, Switzerland, New Zealand and Thailand to protect against cholera and ETEC.

DUKORAL® sales increased to €17.3 million in 2022 compared to €2.4 million in 2021, also benefitting from the significant recovery in the private travel markets.

SARS-CoV-2 INACTIVATED WHOLE-VIRUS VACCINE

Valneva's COVID-19 vaccine, VLA2001, is the only inactivated whole-virus COVID-19 vaccine approved in Europe[29] and was the first COVID-19 vaccine to receive a full marketing authorization from the EMA. In addition to its marketing approval in Europe, Valneva's COVID-19 vaccine received conditional marketing authorization in the United Kingdom[30] and emergency use authorization in the United Arab Emirates[31] and the Kingdom of Bahrain[32]. In 2022, sales of VLA2001 to the Kingdom of Bahrain and certain EU Member States amounted to €29.6 million. Valneva will provide additional doses to the Kingdom of Bahrain in 2023 pursuant to the advance purchase agreement signed in December 2021.

In July 2022, Valneva entered into an amendment to the purchase agreement originally entered into in November 2021 with the European Commission.[33] In light of the reduced order volume of 1.25 million doses, which were delivered to Germany, Austria, Denmark, Finland, and Bulgaria in 2022, Valneva suspended manufacturing of the vaccine in August 2022 and has been reshaping the Company to increase efficiency and focus on its operational and strategic business objectives. The Company is continuing to explore potential additional supply agreements to deploy the remaining eight to ten million doses of inventory. However, these inventories were fully written down as of December 31, 2022. Earlier this month, Valneva provided clinical and regulatory updates for VLA2001[34]. VLA2001's shelf life was notably extended to 21 months compared to 18 months previously. The Company will continue to submit data to further extend it.

THIRD-PARTY DISTRIBUTION

Valneva distributes certain third-party vaccines in countries where it operates its own marketing and sales infrastructure. In September 2022, Valneva announced a partnership with VBI Vaccines for the marketing and distribution of the only 3-antigen Hepatitis B vaccine, PreHevbri®, in select European markets[35].

In 2022, Valneva's third party product sales increased by 72.1% to €26.5 million from €15.4 million in 2021.

Full Year 2022 Financial Review

(Audited[36], consolidated under IFRS)

Revenues

Valneva's total revenues were €361.3 million in 2022 compared to €348.1 million in 2021, an increase of 3.8%.

Valneva's total product sales reached €114.8 million in 2022 compared to €63.0 million in 2021, an increase of 82.3%. This was driven by a continued recovery of travel vaccine sales that surpassed expectations (€85.2 million versus guidance of €70 to €80 million) complemented by COVID-19 vaccine sales in Europe and Bahrain (€29.6 million). On a constant exchange rate (CER) basis, product sales increased by 66.7% in 2022 as compared to 2021.

IXIARO®/JESPECT® sales were €41.3 million in 2022 compared to €45.1 million in 2021, a decrease of 8.4% (18.6% at CER), driven by lower sales to the U.S. Department of Defense. This decrease was partly offset by the significant recovery of the private travel markets, with IXIARO®/JESPECT® private sales reaching €28.8 million in 2022 compared to €7.1 million in 2021.

DUKORAL® sales were €17.3 million in 2022 compared to €2.4 million in 2021, an increase of 610.3% (629.2% at CER), also benefitting from the significant recovery in the private travel markets.

Third-party product sales grew to €26.5 million in 2022 compared to €15.4 million in 2021, an increase of 72.1%. This increase was primarily due to the marketing and distribution partnership with Bavarian Nordic.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €246.5 million in 2022 compared to €285.1 million in 2021. These were mainly driven by revenue recognition related to previous COVID-19 vaccine supply agreements.

Operating Result and adjusted EBITDA

Costs of goods and services sold (COGS) were €324.4 million in 2022. The gross margin on commercial product sales amounted to 45.5% compared to 36.5% in 2021. COGS of €15.6 million related to IXIARO® product sales, yielding a product gross margin of 62.2%. COGS of €14.2 million related to DUKORAL® product sales, yielding a product gross margin of 18.2%. The DUKORAL® gross margin was impacted by €8.3 million of impairment charges for Valneva Sweden's manufacturing facilities following suspension of the COVID-19 vaccine fill and finish activities at that site. Of the remaining COGS in 2022, €16.7 million related to the third-party products distribution business, €267.1 million to the COVID-19 vaccine business and €9.7 million to cost of services. COGS of the COVID-19 vaccine program included effects from the significant reduction of sales volumes to the European Union Member States which resulted in impairment of fixed assets and inventories. In 2021, overall COGS were €187.9 million, of which €162.9 million related to cost of goods and €25.1 million related to cost of services. Research and development expenses amounted to €104.9 million in 2022, compared to €173.3 million in 2021. This decrease was mainly driven by lower clinical trial costs for Valneva's chikungunya vaccine program advancing towards licensure as well as reduced spend on the COVID-19 program. Marketing and distribution expenses in 2022 amounted to €23.5 million compared to €23.6 million in 2021. Marketing and distribution expenses in 2022 notably included €7.3 million of expenses related to launch preparation costs for Valneva's chikungunya vaccine candidate, VLA1553, compared to €3.8 million in 2021. In 2022, general and administrative expenses declined to €34.1 million from €47.6 million in 2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a non-cash accrual adjustment related to the positive effect of the Company's share price development on employee share-based compensation programs. This income compares to an expense in 2021.

Other income, net of other expenses, reduced to €12.2 million in 2022 from €23.0 million in 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending and an increase of other expenses related to the provision for the ongoing Vivalis/Intercell merger litigation proceedings.

Valneva recorded an operating loss of €113.4 million in 2022 compared to an operating loss of €61.4 million in 2021, of which the COVID-19 program contributed a loss of €42.8 million in 2022 and a profit of €3.9 million in 2021. The other segments represented an operating loss of €70.6 million in 2022 compared to an operating loss of €65.3 million in 2021. Adjusted EBITDA (as defined below) loss in 2022 was €69.2 million compared to an adjusted EBITDA loss of €47.1 million in 2021.

Net Result

In 2022, Valneva generated a net loss of €143.3 million compared to a net loss of €73.4 million in 2021.

Finance expense and foreign currency effects in 2022 resulted in a net finance expense of €31.4 million, compared to a net finance expense of €8.6 million in 2021. This was mainly a result of a foreign exchange loss amounting to €12.6 million in 2022, primarily driven by non-cash revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €8.1 million in 2021. Interest expenses net of interest income were €18.8 million in 2022 compared to €16.7 million in 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €245.3 million in 2022 compared to €76.9 million of cash generated by operating activities in 2021. Cash outflows in 2022 were mainly related to the operating loss generated in the period and non-cash revenues (cash received in previous periods), while during 2021 cash inflows mainly resulted from pre-payments received under the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €29.1 million in 2022 compared to €93.1 million in 2021, both mainly a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €215.1 million in 2022, which was mainly a result of proceeds from the equity subscription agreement with Pfizer, proceeds from a global offering as well as a draw-down of the credit facility provided by Deerfield Management Company & OrbiMed[37]. Cash inflows in 2021 amounted to €154.5 million which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement in May as well as an additional global offering in November 2021.

Cash and cash equivalents amounted to €289.4 million as at December 31, 2022, compared to €346.7 million as at December 31, 2021. This included €102.9 million of gross proceeds from an upsized global offering completed in October 2022, €90.5 ($95) million from an equity investment by Pfizer completed in June 2022 as well as drawing of a total $40 million from the Deerfield Management Company & OrbiMed loan agreement.

Non-IFRS Financial Measures

Management uses and presents IFRS results, as well as the non-IFRS measure of Adjusted EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Valneva's current performance, performance trends, and financial condition.

Adjusted EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provides additional analytical tools. Adjusted EBITDA is defined as earnings (loss) for the period before income tax, finance income/expense, foreign exchange gain/(loss), results from investments in associates, amortization, depreciation, and impairment.

A reconciliation of Adjusted EBITDA to net loss for the period, which is the most directly comparable IFRS measure, is set forth below:

€ in million	**Twelve months ending December 31**	
(consolidated per IFRS)	**2022**	**2021**
Loss for the period	(143.3)	(73.4)
Add:		
Income tax expense	(1.5)	3.4
Total Finance income	(0.3)	(0.2)
Total Finance expense	19.1	17.0
Foreign exchange gain/(loss) – net	12.6	(8.1)
Result from investments in associates	-	-
Amortization	7.0	6.6
Depreciation	14.0	7.7
Impairment	23.2	-
Adjusted EBITDA	**(69.2)**	**(47.1)**

About Valneva SE

Valneva is a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease and the chikungunya virus.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to expected total revenues and product sales for full fiscal year 2023. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of future results. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, including but not limited to the HMG Supply Agreement, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Annex

1. CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)

1.1 Consolidated Statements of Income (Loss)

(€ in thousand)

(except per share amounts)	**Year ended December 31,**		
	2022	**2021**	**2020**
Product sales	114,797	62,984	65,938
Other revenues	246,506	285,101	44,383
REVENUES	**361,303**	**348,086**	**110,321**
Cost of goods and services	(324,441)	(187,920)	(54,302)
Research and development expenses	(104,922)	(173,283)	(84,454)
Marketing and distribution expenses	(23,509)	(23,643)	(18,264)
General and administrative expenses	(34,073)	(47,606)	(27,539)
Other income and expenses, net	12,199	22,976	19,117
OPERATING LOSS	**(113,443)**	**(61,390)**	**(55,120)**
Finance income	260	249	516
Finance expenses	(19,054)	(16,964)	(10,738)
Foreign exchange gain/(loss), net	(12,587)	8,130	173
Result from investments in associates	9	(5)	(133)
LOSS BEFORE INCOME TAX	**(144,815)**	**(69,979)**	**(65,302)**
Income tax benefit/(expense)	1,536	(3,446)	909
LOSS FOR THE PERIOD	**(143,279)**	**(73,425)**	**(64,393)**
Losses per share for loss for the period attributable to the equity holders of the Company (expressed in € per share)			
Basic	**(1.24)**	**(0.75)**	**(0.71)**
Diluted	**(1.24)**	**(0.75)**	**(0.71)**

"Foreign exchange gain/(loss), net" was reclassified from the categories "Finance income" and "Finance expenses" for period starting January 1, 2022. The comparable periods were adjusted accordingly to maintain the comparability.

1.2 Comprehensive Income (Loss)

€ in thousand	Year ended December 31,		
	2022	2021	2020
Loss for the period	**(143,279)**	**(73,425)**	**(64,393)**
Other comprehensive income/(loss)			
Items that may be reclassified to profit or loss			
Currency translation differences	(73)	(2,877)	2,438
Items that will not be reclassified to profit or loss			
Defined benefit plan actuarial gains/(losses)	178	205	(78)
Other comprehensive income/(loss) for the year, net of tax	**105**	**(2,672)**	**2,360**
TOTAL COMPREHENSIVE LOSS FOR THE YEAR ATTRIBUTABLE TO THE OWNERS OF THE COMPANY	**(143,174)**	**(76,097)**	**(62,033)**

1. **CONSOLIDATED BALANCE SHEETS**

(In € thousand)	As at December 31,	
	2022	2021
ASSETS		
Non-current assets	**196,685**	**231,520**
Intangible assets	28,711	32,700
Right of use assets	41,603	48,285
Property, plant and equipment	112,435	125,545
Investments in associates	—	2,124
Deferred tax assets	5,637	3,582
Other non-current assets	8,299	19,282
Current assets	**424,660**	**585,832**
Inventories	35,104	124,098
Trade receivables	23,912	44,013
Other current assets	74,079	71,036
Cash and cash equivalents	289,430	346,686
Assets classified as held for sale	2,134	—
TOTAL ASSETS	**621,344**	**817,352**
EQUITY		
Capital and reserves attributable to the Company's equity holders	**219,797**	**170,581**
Share capital	20,755	15,786
Share premium	594,043	409,258
Other reserves	55,252	52,512
Retained earnings/(Accumulated deficit)	(306,974)	(233,549)
Loss for the period	(143,279)	(73,425)
LIABILITIES		
Non-current liabilities	**124,156**	**277,791**
Borrowings	87,227	50,726
Lease liabilities	28,163	53,687
Contract liabilities	—	4,741
Refund liabilities	6,635	158,970
Provisions	1,320	8,308
Deferred tax liabilities	694	1,290
Other liabilities	116	69
Current liabilities	**277,392**	**368,979**
Borrowings	11,580	7,107
Trade payables and accruals	41,491	68,119
Income tax liability	532	83
Tax and Employee-related liabilities	15,738	17,249
Lease liabilities	25,411	3,135
Contract liabilities	9,411	124,017
Refund liabilities	136,450	95,611
Provisions	31,257	48,708
Other liabilities	5,523	4,950
TOTAL LIABILITIES	**401,547**	**646,771**
TOTAL EQUITY AND LIABILITIES	**621,344**	**817,352**

1. **CONSOLIDATED STATEMENTS OF CASH FLOWS**

€ in thousand	Year ended December 31,		
	2022	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss for the year	(143,279)	(73,425)	(64,393)
Adjustments for non-cash transactions	44,070	56,476	37,941
Changes in non-current operating assets and liabilities	(147,713)	59,353	88,472
Changes in working capital	1,732	36,127	77,740
Cash generated from operations	**(245,189)**	**78,532**	**139,759**
Income tax paid	(154)	(1,631)	(2,021)
NET CASH GENERATED FROM OPERATING ACTIVITIES	**(245,343)**	**76,901**	**137,738**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(29,246)	(92,229)	(18,936)
Proceeds from sale of property, plant and equipment	8	—	—
Purchases of intangible assets	(76)	(942)	(535)
Proceeds from sale of intangible assets	—	—	24
Interest received	260	54	107

NET CASH USED IN INVESTING ACTIVITIES	**(29,054)**	**(93,116)**	**(19,340)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common stock, net of costs of equity transactions	189,837	166,614	75
Disposal of treasury shares	—	209	215
Proceeds from borrowings, net of transaction costs	39,331	859	50,266
Repayment of borrowings	(1,793)	(1,956)	(21,995)
Payment of lease liabilities	(3,048)	(2,805)	(2,111)
Interest paid	(9,211)	(8,417)	(4,711)
NET CASH GENERATED FROM/(USED IN) FINANCING ACTIVITIES	**215,116**	**154,504**	**21,740**
NET CHANGE IN CASH AND CASH EQUIVALENTS	**(59,282)**	**138,288**	**140,138**
Cash and cash equivalents at beginning of the year	346,642	204,394	64,439
Exchange gains/(losses) on cash	(828)	3,960	(183)
Restricted cash	2,898	44	41
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	**289,430**	**346,686**	**204,435**

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1 Valneva Announces Closing of Upsized €102.9 Million Global Offering - Valneva
2 Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed - Valneva
3The audit procedures on the consolidated financial statements have been performed. The audit report will be issued upon finalization of procedures regarding the filing.
4 The audit procedures on the consolidated financial statements have been performed. The certification report is in the process of being issued.
5https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas
6 FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva
7 FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva
8 Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate - Valneva
9 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
10 Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate
11 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
12 Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva
13 Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva
14 Tropical Disease Priority Review Voucher Program | FDA
15 Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate - Valneva
16Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva
17 Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate - Valneva
18 Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15 - Valneva
19 Pfizer and Valneva Issue Update on Phase 3 Clinical Trial Evaluating Lyme Disease Vaccine Candidate VLA15 - Valneva
20 Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15
21 https://www.cdc.gov/epstein-barr/index.html#:~:text=EBV%20can%20cause%20infectious%20mononucleosis,common%20among%20teens%20and%20adults.
22 https://www.cancer.org/healthy/cancer-causes/infectious-agents/infections-that-can-lead-to-cancer/viruses.html#:~:text=EBV%20infection%20increases%20a%20person's,some%20cases%20of%20stomach%20cancer.
23 https://www.nih.gov/news-events/nih-research-matters/study-suggests-epstein-barr-virus-may-cause-multiple-sclerosis#:~:text=Infection%20with%20Epstein%2DBarr%20virus,could%20help%20prevent%20multiple%20sclerosis
24 https://www.cdc.gov/ncird/human-metapneumovirus.html
25 Parvovirus B19 and Fifth Disease | CDC
26https://www.cdc.gov/campylobacter/faq.html#:~:text=Campylobacter%20infection%2C%20or%20campylobacteriosis%2C%20is,year%20for%20every%20100%2C000%20people.
27 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.
28 Enterotoxigenic Escherichia coli (ETEC) is a type of Escherichia coli and one of the leading bacterial causes of diarrhea in the developing world, as well as the most common cause of travelers' diarrhea.
29 Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001
30 Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva
31 Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine
32 Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva
33 Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine - Valneva
34Valneva Provides Clinical and Regulatory Updates for its COVID-19 Vaccine VLA2001 - Valneva
35 Valneva and VBI Vaccines Announce European Partnership for Marketing and Distribution of PreHevbri® - Valneva
36 The audit procedures on the consolidated financial statements have been performed. The audit report will be issued upon finalization of procedures regarding the filing.
37 Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed - Valneva

valneva

A LEADING SPECIALTY
VACCINE COMPANY

FULL YEAR 2022 RESULTS & CORPORATE UPDATE

ANALYST PRESENTATION

MARCH 23, 2023

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Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including statements with respect to revenue guidance, the progress, timing, completion, and results of research, development, regulatory milestones, and clinical trials for product candidates and estimates for future performance of both Valneva and certain markets in which it operates. 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.

This presentation presents information about VLA1553, an investigational vaccine candidate that has not been approved for use and has not been determined by any regulatory authority to be safe or effective.

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Valneva Reports Full Year 2022 Results and Provides Corporate Updates

Continued progress across R&D Pipeline

- **Chikungunya**: BLA under review
- **Lyme disease**: Phase 3 VALOR study with Pfizer ongoing
- **COVID-19:** First full MAA by EMA; No further investments
- **Acceleration of pre-clinical activities**: Building R&D pipeline

Significant rebound of commercial business

- Capitalized on strong recovery in the travel segment
- Additional third-party sales

Strong full-year 2022 revenues and cash position

- Total revenues of €361.3m (82.3% product sales increase)
- Cash position of €289.4m (Year-end)

Strengthened shareholder base with successful upsized follow-on offering; new major long-term shareholders including Pfizer

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Most advanced Chikungunya program in development worldwide

VLA1553 - Live-attenuated CHIKV vaccine candidate targeting long-lasting, high sero-response with a single shot

CHIKV Vaccine Candidate VLA1553

- **Live-attenuated**, **single** dose
- Based on **La Reunion strain** of East Central South African genotype
- **Attenuation by reverse genetics,** 60aa deletion within the non-structural nsP3 protein

Development Status – Under FDA Review

- **Pivotal** Phase 3 Trials met **Primary Endpoints:**
  - Sero-response rate
  - Lot-to-Lot consistency
- Positive **12-month antibody persistence** reported; long-term persistence trial ongoing
- Adolescents trial fully enrolled; **first data expected mid-2023**

Regulatory Milestones

- **Priority Review** of biologics license application (BLA) ongoing; **PDUFA action date** currently assigned for **end of August 2023**
- Expect to commence **other regulatory processes** in H2 2023, incl. EMA
- Granted FDA **Fast Track and Breakthrough;** EMA **PRIME** designations

Target Populations & Geographic Reach

- **Non-endemic** countries: travelers / military / outbreak preparedness in U.S., EU, CAN
- **Endemic** use: Partnered with CEPI and Instituto Butantan, including local manufacturing

*VLA1553 is an investigational chikungunya vaccine candidate and is not approved for use in the United States or any other jurisdiction

VLA1553: Clinical Highlights[1,2]

Key data

Immunogenicity Data

- Seroresponse[3] Rate (SRR) in 99% of participants after a single vaccination
- Immunogenicity profile maintained over time: 99% SRR after 12 months[4]
- Older adults (≥ 65 years) achieved similar SRR and neutralizing antibody titers as younger adults (<65 years)[1,4]
- 100% seroconversion after 14 days and sustained to Month 12 in preceding trial[2]

Safety Data[1]

- VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety
- Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia
- Majority of solicited adverse events mild or moderate. 2.0% of study participants reported severe solicited adverse events, most commonly fever.

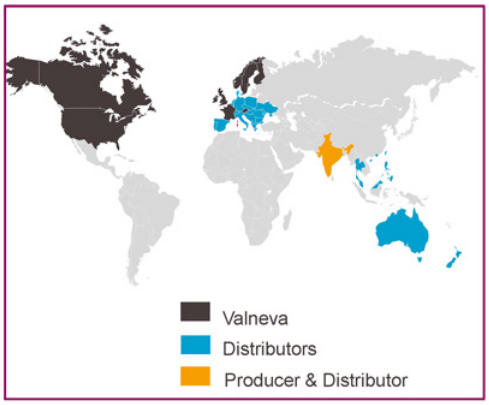
1 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; 2 Wressnigg et al, Lancet ID: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext; 3 CHIKV neutralizing antibody titer of ≥150 by $\mu PRNT_{50}$ (Micro Plaque Reduction Neutralization Test), agreed with regulators to be used as a surrogate endpoint in Phase 3; 4 Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate

VLA1553 Fits Perfectly Within our Existing Commercial Infrastructure

High-caliber team with significant experience in the vaccine space

- **Highly experienced teams with deep expertise in vaccine commercialization**
- **Commercial infrastructure established in most key travel markets; footprint extended through distribution partners**
- **Integrated sales, marketing, medical and government affairs capabilities focused on unlocking brand potential**
- **Data driven insights and digital tools to enhance commercial capabilities**

Commercial Footprint



Only Lyme Disease Vaccine in Advanced Clinical Development Today

VLA15: multivalent recombinant protein vaccine candidate

1. Phase 3 study initiated by Pfizer[1] supported by positive results for three Phase 2 clinical trials[2,3,4], including first pediatric data[5]; Trial design and timelines under review after uncovering GCP violations by 3rd-party operator[6]
2. Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 ($95) million equity investment in Valneva[7]
3. Investigational multivalent vaccine (six serotypes) designed to protect against Lyme disease in the United States and Europe
4. Follows established mechanism of action for a Lyme disease vaccine candidate
5. Fast Track Designation granted by U.S. FDA in July 2017

1 Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; **2** Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate; **3** Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. **4** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate ; **5** Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate/; **6** Pfizer and Valneva Issue Update on Phase 3 Clinical Trial Evaluating Lyme Disease Vaccine Candidate VLA15; **7** Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15;

Strong Immunogenicity Shown in More Than 1000 People

Key data across adult and pediatric trial participants

VLA15-221: First positive pediatric data (April 2022[1])

- Strong immunogenicity profile in adult [2] (ages 18-65) and pediatric participants (ages 5-17)
- More immunogenic in pediatric participants than in adults, with both two-dose and three-dose vaccination schedules; three-dose schedule selected for all ages in Phase 3
- Antibody levels remained above baseline six months after primary vaccination[3]

VLA15-202: First positive booster data (September 2021)[4]

- High antibody responses confirmed across all serotypes and dose groups after primary vaccination series (primary endpoint)[5]
- 12-month booster dose elicited strong anamnestic response

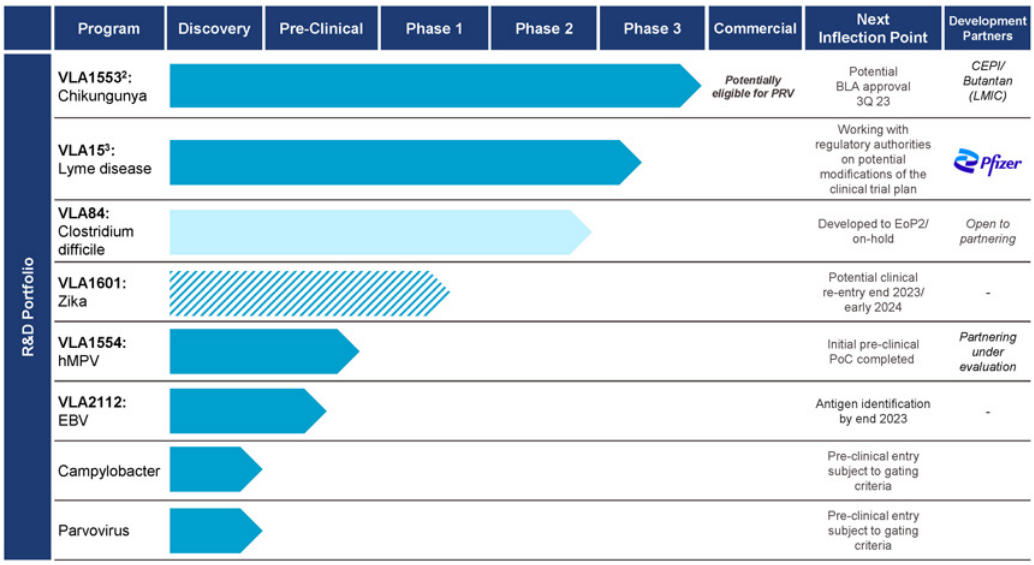
VLA15-201: First positive immunogenicity data (July 2020)[6]

- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Immunogenicity profile confirmed, including in older adults (ages 50-65)

1 Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate; **2** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; **3** Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate; **4** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate, **5** Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15 **6** Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate

Advanced, Focused and Differentiated Clinical Pipeline and promising early stage targets

R&D pipeline overview



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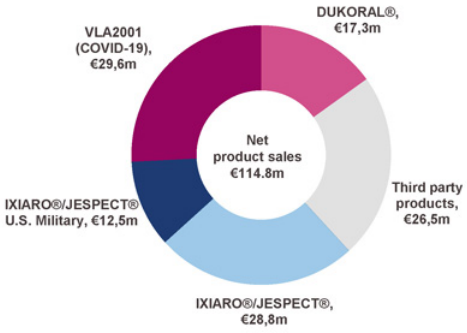
Full Year 2022 Financials: Total Revenues of €361.3 million

Growth driven by significant increase in product sales

Total Revenues²
+3.8%

Product sales
+82.3%



Direct sales
91.1%

1 Third party products sold by Valneva, 2 YoY comparison for same period

Full Year 2022 Financials: Product Sales of €114.8m

Strong growth driven by recovery of travel segment and performance of 3rd-party products

€m (unaudited)	FY 2022	FY 2021	FY 2021 at CER*	%	% at CER
IXIARO®/JESPECT®	41.3	45.1	50.8	-8.4%	-18.6%
DUKORAL®	17.3	2.4	2.4	+610%	+629%
Third party products	26.5	15.4	15.7	+72.1%	+69.2%
COVID-19 vaccine	29.6	-	-	-	-
Total product sales	**114.8**	**63.0**	**68.9**	**+82.3%**	**+66.7%**
IXIARO®/JESPECT® (excluding US Military)	*28.8*	*7.1*	*7.3*	*+307%*	*+292%*

* FY 2021 recalculated at constant exchange rate (CER; actual average FY 2022 exchange rates)

Full year 2022 Income Statement
Adjusted EBITDA of - €69.2m

€m (2022 audited)	FY 2022	FY 2021
Product sales	114.8	63.0
Other Revenues	246.5	285.1
Revenues	**361.3**	**348.1**
Cost of goods and services	(324.4)	(187.9)
Research and development expenses	(104.9)	(173.3)
Marketing and distribution expenses	(23.5)	(23.6)
General and administrative expenses	(34.1)	(47.6)
Other income / (expense), net	12.2	23.0
Operating loss	**(113.4)**	**(61.4)**
Finance, investment in associates & income taxes	(29.8)	(12.0)
Profit/loss for the period	**(143.3)**	**(73.4)**
Adjusted EBITDA[1]	**(69.2)**	**(47.1)**

1 FY 2022 Adjusted EBITDA was calculated by excluding €74.1 million (FY 2021: €26.3 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment from the €143.3 million (FY 2021: €73.4 million) loss for the period as recorded in the consolidated income statement under IFRS.

Full Year 2022 Financials: Impact of COVID-19 Program on P&L

COVID-19 reported as separate segment as of 2021

€m (2022 audited)	FY 2022 Group	FY2022 COVID only	FY 2022 excl. COVID
Product sales	114.8	29.6	85.2
Other Revenues	246.5	280.0	(34.3)
Revenues	**361.3**	**309.6**	**51.7**
Cost of goods and services	(324.4)	(267.1)	(57.3)
Research and development expenses	(104.9)	(72.8)	(32.2)
Marketing and distribution expenses	(23.5)	(2.8)	(20.7)
General and administrative expenses	(34.1)	(19.4)	(14.7)
Other income / (expense), net	12.2	9.6	2.6
Operating loss	**(113.4)**	**(42.8)**	**(70.6)**
Finance result and income taxes	(29.8)	-	(29.8)
Profit/loss for the period	**(143.3)**	**(42.8)**	**(100.4)**
Adjusted EBITDA[1]	**(69.2)**	**(15.2)**	**(54.0)**

1 FY 2022 Adjusted EBITDA was calculated by excluding €74.1 million of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment from the €143.3 million loss for the period as recorded in the consolidated income statement under IFRS.

Full Year 2022 Financials: Balance Sheet 2021/2022

Net assets impacted by COVID write-downs

€m (2022 audited)	December 31st, 2022	December 31st, 2021
NON-CURRENT ASSETS	***196.7***	***231.5***
- Property, Plant & Equipment	112.4	125.5
- Other Non-current Assets	84.2	106.0
CURRENT ASSETS	***424.7***	***585.8***
- Inventory	35.1	124.1
- Trade Receivables & Other current assets	100.1	115.0
- Cash & Cash Equivalents	289.4	346.7
TOTAL ASSETS	***621.3***	***817.4***

Full Year 2022 Financials: Balance Sheet 2021/2022 (cont.)

Liabilities and equity impacted by COVID/Lyme contracts and public offering

€m (2022 audited)	December 31st, 2022	December 31st, 2021
EQUITY	***219.8***	***170.6***
NON-CURRENT LIABILITIES	***124.2***	***277.8***
- Refund Liabilities	6.6	159.0
- Borrowings and Other Non-Current Liabilities	*117.5*	*118.8*
CURRENT LIABILITIES	***277.4***	***369.0***
- Trade Payables & Accruals	41.5	68.1
- Contract Liabilities	9.4	124.0
- Refund Liabilities	136.5	95.6
- Provisions	31.3	48.7
- Other Current Liabilities	58.8	32.5
TOTAL EQUITY AND LIABILITIES	***621.3***	***817.4***

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Valneva 2023 Financial Guidance

Substantial growth expected from anticipated COVID business

Total revenues and other income expected between €220 to €260 million, including:

- €130 to €150 million of product sales, including marginal COVID-19 vaccine sales under the Bahrain supply agreement
- €90 to €100 million of other income

R&D investments expected between €70 million and €90 million

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Key Upcoming Catalysts and News Flow in 2023

Chikungunya vaccine candidate VLA1553

- First adolescent study results mid-2023
- Potential BLA approval and first launch, Potential PRV sale
- Additional ex-U.S. regulatory submissions in H2

Lyme disease vaccine candidate VLA15

- Clarity on Phase 3 clinical study plans in H1; continued trial execution
- Additional antibody persistence results in H2

Additional news flow

- Potential DoD contract for IXIARO® in H1
- Progression of selected pre-clinical programs towards clinical entry
- Potential augmenting clinical pipeline through program acquisition or partnering

Valneva is Poised for Substantial Growth

Led by potential new product launches

Additional potential growth drivers:

- Continued recovery of travel market to pre-COVID levels and beyond
- New U.S. DoD contract for IXIARO® expected 2023
- Further expansion of 3rd-party distribution segment
- Potential in-licensing or acquisition of additional clinical and/or commercial-stage product(s)


Thank you
Merci
Danke
Tack