# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# WASHINGTON, D.C. 20549

# FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2025**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 13(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report _____

**Commission File Number 001-40377**

# Valneva SE

**(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)**

**France**

(Jurisdiction of incorporation or organization)

**Îlot Saint-Joseph, Bureaux Convergence, Bât. A, 12 ter Quai Perrache**

**69002 Lyon, France**

(Address of principal executive offices)

**Thomas Lingelbach**

**Chief Executive Officer, Valneva SE**

**Îlot Saint-Joseph, Bureaux Convergence, Bât. A, 12 ter Quai Perrache**

**69002 Lyon, France**

**Tel: +33 2 28 07 37 10**

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

**Securities registered or to be registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **American Depositary Shares, each representing two ordinary shares, €0.15 nominal value per share** | **VALN** | **The Nasdaq Global Select Market** |
| **Ordinary shares, €0.15 nominal value per share** | ***** | **The Nasdaq Global Select Market*** |

* *Not for trading, but only in connection with the registration of the American Depositary Shares.*

**Securities registered or to be registered pursuant to Section 12(g) of the Act. None.**

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary Shares: 173,539,745 outstanding as of December 31, 2025**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer, "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that require a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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# INTRODUCTION

Unless otherwise indicated in this Annual Report (this "Annual Report"), "Valneva," "the company," "our company," "we," "us" and "our" refer to Valneva SE and its consolidated subsidiaries.

"Valneva," the Valneva logo, "IXIARO," "JESPECT," "DUKORAL", "IXCHIQ" and other trademarks or service marks of Valneva SE of any of our business partners appearing in this Annual Report are the property of Valneva, its subsidiaries or its business partners, as applicable. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend to use or display other companies' trademarks and trade names to imply any relationship with, or endorsement or sponsorship of us by, any other companies.

Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements are presented in euros, and unless otherwise specified, all monetary amounts are in euros. All references in this Annual Report to "$," "US$," "U.S.$," "U.S. dollars," "dollars" and "USD" mean U.S. dollars and all references to "€" and "euros" mean euros, unless otherwise noted. Throughout this Annual Report, references to ADSs mean American Depositary Shares or ordinary shares represented by such ADSs, as the case may be.

# SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- timing and expected outcomes of clinical trials and pre-clinical studies, particularly with respect to the Phase 3 clinical trial of our Lyme disease vaccine candidate VLA15 as well as the ongoing and planned clinical trials of our chikungunya vaccine VLA1553 (licensed in some territories as IXCHIQ), and the ongoing Phase 2 trials of the shigellosis vaccine candidate S4V2;
- the likelihood, timing, and expected outcomes of regulatory filings and approvals, including, in the short-term, potential approval of the chikungunya vaccine candidate VLA1553 or locally manufactured versions thereof in other markets and the potential filings and approvals of VLA15 and in the mid- to long-term, potential filings and approvals of S4V2;
- the potential safety and effectiveness of our vaccine candidates in development and new safety data related to our approved vaccines, particularly IXCHIQ;
- our ability to successfully market IXCHIQ in Europe, Canada, the UK, and other markets where it is or may be approved and to establish partnerships for the manufacturing, marketing, and distribution of IXCHIQ in endemic or high-risk areas, particularly in Asia;
- our expectations with respect to Pfizer's regulatory and commercialization plans for our Lyme disease candidate;
- our ability to implement effective restructuring and cost-savings measures and maintain business continuity in case of unfavorable Phase 3 data for our Lyme disease vaccine candidate;
- our expectations and forecasts for sales of our approved commercial products and estimates of market opportunity and future revenues for our vaccine candidates;
- our ability to expand, develop, and advance our pipeline of product candidates;
- our ability to supply a sufficient, compliant, and timely quantity of our products and product candidates and to safely and effectively scale up our manufacturing capabilities;
- the effectiveness and profitability of our collaborations and partnerships, our ability to maintain our current collaborations and partnerships and our ability to enter into new collaborations and partnerships, to support our business plans;
- regulatory and political developments in the United States, Europe, and other countries, including in particular regulatory developments relating to tariffs and the review and approval of vaccine candidates in the United States and elsewhere;
- our expectations related to future milestone and royalty payments and other revenue under our collaborations and partnerships, particularly the partnership with Pfizer for VLA15;

- our ability to meet our obligations under our various collaboration, partnership, and distribution arrangements;
- the effects of any pandemics on our sales and operations, including our expectations and assumptions regarding the resumption of travel and the future demand for travel vaccines;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to obtain, maintain, protect and enforce our intellectual property rights and proprietary technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- statements regarding future revenue, cash situation, hiring plans, expenses, capital expenditures, capital requirements, stock performance, and financing opportunities; and
- other risks and uncertainties, including those listed in the section of this Annual Report titled "Item 3.D—Risk Factors."

You should refer to the section of this Annual Report titled "Item 3.D—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this Annual Report.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this Annual Report is generally reliable and is based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the section of this Annual Report titled "Item 3.D—Risk Factors."

## SUMMARY RISK FACTORS

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length in the section below titled "Risk Factors." These risks include, among others, the following:

- Our business is capital intensive, and given our level of planned investments over the medium term, we may not achieve or maintain profitability.
- Our future success is substantially dependent on the successful clinical development, regulatory approval, and commercialization of our product candidates in a timely manner. This risk is heightened in the short-term given that our Lyme disease vaccine candidate is undergoing Phase 3 clinical trials and we plan to seek approval for our chikungunya vaccine in new markets. If we or our partners are not able to obtain or maintain the regulatory approvals we target, whether as a result of clinical trials results or other factors, we will not be able to commercialize our product candidates according to our plans or at all, and our ability to generate product revenue will be adversely affected. Delays in clinical development or delays or changes in regulatory approvals may also lead to delays in our expected commercial timelines, including expected royalties in connection with an approved Lyme disease vaccine candidate, which could materially impact our business plans and our financial projections. In particular, Pfizer has sole discretion over next steps regarding regulatory submissions, marketing, and commercialization of the Lyme disease vaccine candidate and may not undertake any or all of these next steps according to our expectations or at all. Any decisions that Pfizer may take to delay or change these next steps could materially impact our business plans and future financial condition.
- We will require ongoing funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce, or terminate certain of our planned investments, including in-development programs or other parts of our operations, or to undertake restructuring and other cost-saving measures, some of which could be required by law but constitute an event of default under our loan from Pharmakon. This is particularly in the event of negative Phase 3 data for our Lyme disease vaccine candidate. Additionally, the terms of our existing financing arrangements place restrictions on our operating and financial flexibility and in the event of negative data for our Lyme disease vaccine candidate, we may be required by law to initiate restructuring processes that would constitute an event of default under our loan from Pharmakon.
- The regulatory environment in which we operate is and will continue to remain dynamic, particularly in the United States, which could have implications for the development, review, approval, and commercialization of our product candidates and for other aspects of our business operations, including costs that may be impacted by tariffs. We may fail to comply with applicable regulatory obligations, and we may not be able to adapt in a timely manner or at all to regulatory changes applicable to our business, which could have a material impact on our business plans and financial projections.
- Our future growth depends on continuing to build our pipeline of product candidates. If we are unable to progress existing clinical-stage and pre-clinical stage product candidates or to initiate new clinical or pre-clinical programs, including through the potential in-licensing or acquisition of product candidates, this could have a material impact on our business plans and financial projections.
- We depend upon our existing partners and other third parties to advance our business and provide other key services. If we are unable to maintain such existing agreements or enter into additional arrangements as needed, or if such third parties do not provide such services as anticipated, our business could be adversely affected. Our partnerships with Pfizer in connection with our Lyme disease vaccine candidate and with Instituto Butantan in connection with the manufacturing and commercialization of IXCHIQ in low- and middle-income countries are particularly important. Following the termination of our agreement with the Serum Institute of India at the end of 2025, we will also need to identify one or more partners for the manufacturing, marketing, and distribution of IXCHIQ in Asia. Failure to implement such new partnerships could jeopardize the future of the IXCHIQ program as a whole.
- We rely primarily on our manufacturing facilities and rely in part on third parties' manufacturing facilities as the source of manufacturing for our products and for certain of our product candidates. If we are unable to manufacture in order to meet actual or expected demand, including because of challenges related to quality compliance that could impact the quantity and timing of released products or because of actions taken by regulatory agencies, our sales and reputation could be adversely impacted.
- Our products are aimed at diseases that largely threaten travelers. If international travel is substantially disrupted, due to a pandemic or a similar event or to adverse economic conditions, this will significantly adversely affect the sale of these vaccines. Additionally, future outbreaks of disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites, or other business operations, could materially affect our operations globally and at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations, or other third parties with whom we conduct business.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

- We may face competition, and our competitors may have significantly greater resources and experience, which may negatively impact our commercial opportunities.
- We are dependent on single source suppliers for some of the components and materials used in our products.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- Our information systems and data, and those of third-parties connected to us, are vulnerable to cyber attacks and security breaches which could have a material impact on our operations, reputation, and/or financial results.
- There are material weaknesses in our internal controls over financial reporting, and if we are unable to maintain effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence, and depress the market price of our securities.
- The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States. As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

# PART I

## Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

## Item 2. Offer Statistics and Expected Timetable

Not applicable.

## Item 3. Key Information

### A. [Reserved]

### B. Capitalization and Indebtedness

Not applicable.

### C. Reasons for the Offer and Use of Proceeds

Not applicable.

### D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

### Risks Related to Our Financial Position and Capital Needs

***Our business is capital intensive, and given our level of planned investments over the medium term, we may not achieve or maintain profitability.***

We have previously incurred significant net losses, and we might not succeed in becoming profitable over the next several years. As of December 31, 2025, we had an accumulated net loss of €679.1 million. Our planned investments with respect to our approved products and product candidates and to seek and develop additional product candidates are in excess of the revenues that we expect to generate in the short term, and we expect to continue to incur substantial operating losses for the next several years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

To achieve profitability, we would need to generate revenues from sales of our commercial products and other income (such as royalties) exceeding our total expenses, including our planned investments in research and development. We anticipate that if the Phase 3 trial of our Lyme disease vaccine candidate VLA15 is successful, Pfizer will apply for approval in the United States and European Union in 2026 and launch commercialization in 2027 or 2028, depending on the timing of approval. Future revenues from our product candidates, including milestone and royalty revenue, depend on obtaining regulatory approval in multiple markets, generating market acceptance and market share, and obtaining reimbursement from third-party payors. In addition, we also generate revenue from sales of third-party products, licensing and service agreements, and grants.

If our clinical trial plans change, for example because of additional requirements mandated by regulatory authorities or delays in trial execution, our anticipated expenses could increase. Even if a product receives regulatory approval, we may not be able to generate revenue from it, according to the timing or quantities expected or at all. For example, we did not generate expected revenue from sales of IXCHIQ in 2025 due to reports of serious adverse events, or SAEs, and subsequent regulatory action. Additionally, if VLA15 is ultimately approved, there is no guarantee that we will receive any or all of the sales-based milestone payments or royalty payments in the amounts or according to the timing we expect.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we cannot accurately predict when or if we will be able to achieve or maintain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

***We will require additional funding to finance our operations and achieve our strategic ambitions. If we receive unexpected clinical trial results or are unable to raise capital when needed, we could be forced to delay, reduce, or terminate certain of our planned investments, including development programs or other parts of our operations.***

Investment in the development of biopharmaceutical products is highly speculative because it entails substantial expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially successful. We may need to raise additional capital to add to our product pipeline, complete the development and commercialization of our product candidates, and fund certain of our existing manufacturing and other commitments. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding, and marketing and distribution arrangements, as well as other collaborations, strategic alliances, and licensing arrangements, or any combination of these approaches. However, our operating plans and need for additional funds may change due to factors we cannot predict. For example, we are awaiting results from the pivotal, placebo-controlled efficacy clinical study, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)" in the first half of 2026, conducted by our partner Pfizer. If the primary endpoints of the Phase 3 trial are not met, we will be required to undergo restructuring and implement cost-containment measures that would allow us to meet our financial obligations for the foreseeable future but would significantly impact our operations and prospects. These restructuring measures would require alignment with Pharmakon (our lender, as described further below) to avoid an event of default, including potential renegotiation of existing debt terms, and we cannot guarantee that such measures would be sufficient in the long term.

Global financial markets may be negatively impacted by macroeconomic factors including as a result of inflation, changes in interest rates, tariffs, changes in trade policies, and other geopolitical elements, such as conflicts in Europe and the Middle East. If these disruptions persist or deepen, or if other global events have a significant impact on the global financial markets, we could experience an inability to access additional capital or an increase in our costs of borrowing, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. Adequate additional financing may not be available to us when we require it in sufficient amounts or on acceptable terms, or at all. Additionally, investors are using sustainability and environmental, social and governance, or ESG, criteria to evaluate possible investments, and we cannot guarantee that we will be able to implement effective sustainable practices that will make us attractive for such investors, in a timely fashion or at all.

If we are unable to raise capital or refinance existing debt when needed or on attractive terms, we could be forced to delay, reduce, or altogether terminate certain of our research and development programs or future commercialization efforts. We may need to seek funds through arrangements with collaborative partners or otherwise at an earlier stage of product development than otherwise would be desirable, and we may be required to monetize rights to some of our technologies or product candidates at an earlier stage of development or otherwise agree to terms unfavorable to us.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares or the ADSs to decline. The sale of additional equity or convertible securities would dilute our shareholders. Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting on the basis of a report from the Board of Directors. In addition, the French Commercial Code imposes certain limitations on our ability to price certain offerings of our share capital without preferential subscription rights (*droit préférentiel de souscription*), which limitation may prevent us from successfully completing any such offering.

***The terms of our financing arrangements place restrictions on our operating and financial flexibility.***

On October 6, 2025, Valneva Austria GmbH entered into a loan agreement, or the Loan Agreement, with Pharmakon Advisors, LP that provides for a senior term loan facility of an aggregate principal amount of up to $500.0 million, divided into the following tranches, including the $215.0 million tranche that was funded in October and used, together with cash on hand, to repay in full our previous lenders, Deerfield Management and OrbiMed. These loans will mature in October 2030 and bear interest at a fixed rate equal to 9.00% per annum. Our obligations under the Loan Agreement are secured by substantially all of our assets, including our intellectual property, and most of our subsidiaries have provided guarantees. For further information about the terms of the Loan Agreement, including defined events of default, see Item 10C of this Annual Report or the full Loan Agreement, which is filed as Exhibit 4.36 to this Annual Report.

The Loan Agreement contains customary affirmative and restrictive covenants. During the term of the Loan Agreement, we may not, subject to specified exceptions, (i) sell or dispose of assets, (ii) amend, modify, or waive our rights under material agreements, (iii) incur additional indebtedness, (iv) incur non-permitted liens or encumbrances on our or our subsidiaries' assets, or (v) make payments on subordinated indebtedness, among other restrictions. The Loan Agreement also requires that our annual and quarterly financial statements be free of any "going concern" qualification. The Loan Agreement contains customary events of default, including in connection with a material adverse change. The occurrence of an event of default would enable the lender to, among other things, accelerate our obligations under the Loan Agreement, and in case of an event of default relating to certain insolvency, liquidation, bankruptcy or similar events, all outstanding obligations may be immediately accelerated. If we were unable to pay the full amount due in case of an event of default, the lender could exercise its rights to take possession and dispose of the collateral for their benefit. Our business, financial condition, and results of operations would be substantially harmed if this occurs.

Additionally, we announced in February 2022 that Valneva Scotland had received two grants worth up to £20 million (approximately €23.9 million) from Scottish Enterprise, Scotland's national economic development agency, to support research and development relating to the manufacturing processes of our COVID-19 vaccine and our other vaccine candidates. For more information as to the amendment of the grants, see Note 5.8.1 Grants. Valneva SE has provided a parent guarantee in connection with these grants, and if we fail to comply with the terms of the grants, Scottish Enterprise may stop payments under the grants and require repayment of the funds provided to date.

***We market our products primarily to travelers to regions where the targeted diseases are endemic. If international travel is substantially disrupted, this will significantly adversely affect the sale of these vaccines.***

We market IXIARO, DUKORAL, and IXCHIQ primarily to travelers to particular regions. During the COVID-19 pandemic, travel significantly decreased worldwide, and sales of DUKORAL and IXIARO decreased significantly in 2020 and 2021, adversely affecting our financial results. In addition, our failure to correctly forecast the recovery of the travel vaccine market in 2022 and produce sufficient quantities of DUKORAL and IXIARO resulted in a loss of potential sales. Adverse economic conditions may also impact consumer choices related to travel, for example by making people less willing to pay for recommended vaccines, and this could also negatively impact our sales. If another disruption or adverse economic conditions cause a substantial decrease in international travel, our revenues will be significantly adversely affected, and we may not be able to finance our operations and continue the development of one or more of our vaccine candidates without additional financing.

## Risks Related to the Development and Commercialization of Our Product Candidates

***Our future success is substantially dependent on the successful clinical development, regulatory approval, and commercialization of our product candidates in a timely manner, which may be impacted by decisions of regulatory authorities or our partners.***

Only a small percentage of products in development in our industry successfully complete regulatory authorities' approval processes and are commercialized. The regulatory approval or marketing authorization process for our product candidates takes many years and depends on numerous factors outside of our control, including the unpredictability of future clinical trial results and the discretion and priorities of regulatory authorities. Even if we believe that the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support initial or continued approval by the regulatory authorities, or our partners may nonetheless choose not to apply for regulatory approval at the time expected or at all. Regulatory authorities may make approval contingent on the performance of additional clinical trials, including post-marketing clinical trials that require additional coordination and expense. For example, the continued approval of IXCHIQ is conditioned upon the completion of certain post-marketing clinical trials, including Phase 3 and 4 trials. Regulatory authorities may also provide approval for a product candidate for a more limited indication or patient population than we originally request and may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Approval by one regulatory authority does not guarantee approval by another regulatory authority, with the same scope or at all, on the basis of the same data, and regulatory authorities may suspend, withdraw, or vary a product's license following approval or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS, or foreign equivalent. Any prolonged approval suspension, delay in obtaining, or inability to obtain and maintain, applicable or anticipated regulatory approval would delay, inhibit, or prevent commercialization of that product candidate and would adversely impact our business and prospects. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. These and other factors discussed below may impact our or our partners' decisions regarding commercialization of an approved product, as originally planned or at all. Generally, failure to develop a vaccine that we or our partners can successfully commercialize could result in the total loss of our investment in its development and consequently could have a significant impact on shareholder value.

In particular, regulatory authorities have taken different decisions regarding our chikungunya vaccine, IXCHIQ.

- In the first half of 2025, following reports of serious adverse events primarily involving elderly individuals, certain regulatory authorities implemented temporary age-related restrictions on IXCHIQ.
- Additionally, on August 22, 2025, the U.S. Food and Drug Administration's ("FDA") Center for Biologics Evaluation and Research ("CBER") suspended the biologics license application ("BLA") for IXCHIQ due to serious safety concerns. According to CBER's formal suspension letter, FDA's review of post-marketing safety data, including reports submitted to the Vaccine Adverse Event Reporting System ("VAERS") as of August 15, 2025, identified over 20 serious adverse events consistent with chikungunya-like illness following vaccination, including 21 hospitalizations and three deaths. FDA determined that one fatal case of encephalitis was directly attributable to the vaccine, supported by detection of the vaccine-strain virus in cerebrospinal fluid. CBER's benefit–risk assessment concluded that, under most plausible scenarios, the vaccine's risks outweighed its benefits and that continued administration posed a risk to public health. Although we submitted a written response to FDA providing additional clinical and epidemiological information regarding the reported SAEs, including our conclusion that the two other deaths were unlikely to be causally related to vaccination, the suspension remained in effect. On January 19, 2026, we announced that we voluntarily withdrew the BLA and the associated investigational new drug application ("IND") for IXCHIQ in the United States.
- In contrast, the European Medicines Agency ("EMA") completed an Article 20 safety procedure under Regulation (EC) No 726/2004 and concluded that the overall benefit-risk balance of IXCHIQ remained positive. Further,

public communications by French health authorities similarly indicated that, of the three reported deaths, a causal link to vaccination was considered likely for one case and not established for the other two. The EMA lifted its temporary restriction on the use of IXCHIQ in elderly individuals but required updates to the product information to include strengthened warnings and precautions, particularly for individuals aged 65 years and older and frail elderly individuals. We implemented similar label updates in other jurisdictions where IXCHIQ is approved.

- In February 2026, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") further revised its recommendations to restrict use of IXCHIQ to adults aged 18 to 59 or in case of specific comorbidities, and MHRA now recommends administration at least 30 days prior to potential exposure. Brazil's Agência Nacional de Vigilância Sanitária ("ANVISA") also announced a restriction of use to adults aged 18 to 59 in February 2026.
- Additionally, on March 9, 2026, Health Canada issued an alert indicating that individuals 65 years of age and older who are medically frail with multiple chronic medical conditions may be at an increased risk of serious and life-threatening adverse reactions following recent vaccination with IXCHIQ. The Canadian Product Monograph for IXCHIQ has been updated to reflect this safety information.

We cannot exclude the possibility that one or more regulatory authorities may take actions towards IXCHIQ that are consistent with, or more restrictive than, those previously implemented. In addition, certain of our funding agreements, including those with the Coalition for Epidemic Preparedness Innovations ("CEPI"), may permit modification or termination if safety, regulatory, or ethical concerns arise. Any such action could adversely affect our financial position, results of operations and development strategy.

Additional serious adverse event reports could prompt further regulatory review and reduce product demand. Any suspension, withdrawal, narrowing of indication, labeling modification, or other restriction or requirement could materially and adversely affect our ability to commercialize IXCHIQ or another product and could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, regulations and policies may be added or revised in the EU, the U.S., or other jurisdictions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain regulatory approvals, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we may have obtained. Furthermore, the U.S. Supreme Court's June 2024 decision in *Loper v. Bright Enterprises v. Raimondo* (overturning the longstanding Chevron doctrine), could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, and in increased regulatory uncertainty and other impacts which could adversely impact our business and operations. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***Successful initial and continued commercialization of our products depends on numerous factors, some of which may be outside of our control.***

Our business is substantially dependent on our ability to commercialize our products in a timely manner in the markets in which they are approved. To successfully commercialize our products, we need to accomplish a number of tasks, including the following:

- Obtaining and maintaining desired regulatory approvals and recommendations from local immunization recommendation bodies, such as the U.S. Centers for Disease Control's Advisory Committee for Immunization Practices, for use of products;
- Developing the commercial organization to support commercialization of the product or entering into partnerships for commercialization in certain geographies, particularly in the case of our chikungunya vaccine;
- Establishing a commercially viable pricing structure, which may require geographic differentiation;
- Obtaining approval for coverage and potential and adequate reimbursement from third-party and government payors, including government health administration authorities, including through the dissemination of recommendations from regulatory bodies such as ACIP;
- Generating knowledge of and demand for our products, including through government or other large-scale contracts; and
- Manufacturing and distributing, either directly or through partners, sufficient quantities of product to meet such demand.

If we or our partners are unable to accomplish any of the above, it could affect our ability to generate sales and other revenues, such as royalties from sales of our Lyme disease vaccine, if approved. Additionally, further developments related to IXCHIQ's safety profile, product label, or recommended use or difficulties in establishing new partnerships for its manufacturing and commercialization in LMICs could result in a decision to discontinue the product.

In addition, we supply the U.S. Department of Defense with IXIARO, our vaccine against Japanese encephalitis. Contracts with the U.S. government are subject to extensive regulations that are subject to change. The U.S government may also modify or terminate its contracts with us, without prior notice and at its convenience. Funding may be reduced or withheld as part of its annual U.S. Congressional appropriations process due to fiscal constraints, changing priorities, or other

reasons. As a result, we could face increased compliance costs, withheld payments and/or reduced future business, which could have an impact on our operating results.

If we are unable to successfully commercialize our product candidates and maintain such commercialization as planned, including through contracting with third parties, we may not generate significant product revenue, which could threaten our financial sustainability and potential investments in R&D.

***If the market opportunities for our products and product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.***

We currently focus our efforts on commercialization of our approved products for prevention of chikungunya, Japanese encephalitis, and cholera. Our estimated market opportunity, pricing estimates, and available coverage and reimbursement may differ significantly from the actual market addressable by our products and product candidates.

Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting, and the number of people impacted may turn out to be lower than expected. In addition, the disease for which we are developing a product vaccine may cease to be a public health concern. Our efforts to educate physicians, patients, third-party payors, and others in the medical community on the benefits of our product candidates require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complex and distinctive nature of our product candidates.

Likewise, the potentially addressable patient population for each of our products or product candidates may be limited or may not be receptive to receiving our vaccines or vaccine candidates, and new patients may become increasingly difficult to identify or access. This may be due in part to reputational challenges that the vaccine industry is facing related to the growing momentum of the anti-vaccine movement in some regions, including in the United States, or to a distrust of certain types of vaccines, of vaccines against certain diseases, or of the adjuvants contained in our vaccines. For example, the FDA has raised questions about the use of aluminum-based adjuvants in vaccines. IXIARO and VLA15 contain such adjuvants and may be subject to further scrutiny in the United States as a result. Developments related to vaccines in the United States could impact regulatory action or vaccine sales in other jurisdictions. Additionally, the more reactogenic nature of live-attenuated vaccines such as IXCHIQ may change the benefit/risk profile of such vaccines in a non-endemic context, where the risk of contracting the targeted disease is lower. Finally, there has been some negative public perception of Lyme disease vaccines as a result of the Lyme disease vaccine LYMErix, which was marketed by Smith Kline Beecham Biologicals and discontinued due to lack of market access and safety concerns, although its benefit/risk profile was confirmed by an FDA advisory committee even post-approval.

If the market opportunities for our products or product candidates are or become smaller than expected, this could have a significant adverse effect on our business, financial condition, results of operations, and prospects. Similarly, if the estimates and forecasts of investment analysts regarding the market for one of our product candidates differ significantly from the actual addressable market, there could be an impact on the trading price of our ordinary shares and ADSs.

***Success in pre-clinical studies or earlier clinical trials may not be indicative of results in future clinical trials, and any ongoing, planned, or future clinical trials might not produce results sufficient for the necessary regulatory approvals.***

Success in pre-clinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Pre-clinical and proof-of-concept studies and Phase 1 clinical trials for vaccines are primarily designed to evaluate safety and immunogenicity. Our ongoing clinical trials, including the Phase 3 clinical trial for our Lyme disease vaccine candidate, might not produce data consistent with those of prior trials. There can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the trial participants, adherence to the dosing regimen and other trial protocols, and the rate of dropout among clinical trial participants. In a late-phase clinical trial with multiple end points, we may not achieve a statistically significant result, even with a large sample size. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain or maintain regulatory approval, despite positive results in pre-clinical studies, successful advancement through earlier clinical trials, or initial data that we may publish, which may materially change as clinical trials progress. A number of companies in the biotechnology and product development industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

A trial design that is considered appropriate for regulatory approval includes an adequate sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The required sample size also depends on the type of vaccine candidate, type of clinical trial design, and regulatory pathway agreed with regulatory agencies. In a late-phase clinical trial with multiple end points, we may not achieve a statistically significant result, even with a large sample size.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we may be unable to design and execute a clinical trial to support regulatory approval, including conditional approval or emergency use authorization for any given current or future product candidate. Data obtained from pre-clinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy, including changes in requirements for clinical trials, or results of audits of clinical trial partners by regulatory authorities during the period of our product candidate development.

***Clinical product development is uncertain and time consuming, and we may incur additional costs or encounter substantial delays or difficulties in our clinical trials.***

Clinical testing is expensive, lengthy, difficult to design and implement, and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. If we or our partners experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed. Any changes or delays to clinical trials would delay the regulatory approval process, increase development costs, and potentially lead to a negative perception of Valneva or the product candidate.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following:

- We may be unable to generate sufficient pre-clinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials.
- We may struggle to reach a consensus with regulatory authorities on the design or implementation of our clinical trials, or any modification thereto.
- Regulators or institutional review boards and ethics committees may prevent us or our investigators from commencing a clinical trial or conducting a clinical trial at a prospective trial site.
- We may experience delays in reaching agreement on acceptable terms with prospective clinical research organizations, or contract research organizations, or CROs, and clinical trial sites.
- We or our manufacturing partners may experience delays or fail to comply with current Good Clinical Practice, or GCP, good manufacturing practices, or cGMP, or other applicable regulations.
- Subject enrollment and retention in clinical trials depends on many factors outside of our control.
- The number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for follow-up, or we may fail to recruit suitable subjects to participate in a trial. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both.
- We may have difficulty collaborating with investigators.
- We or our CROs, partners, other third parties may fail to adhere to clinical trial requirements.
- Clinical trials for our product candidates may have inconclusive or other results that could require additional studies or changes to the development plan, including delays of planned trials.
- Regulatory authorities may impose a clinical hold on our trials, as a result of a serious adverse event or concerns with a class of product candidates, after an inspection of our clinical trial operations, trial sites, or manufacturing facilities, after review of an investigational new drug application, or IND, or IND amendment, after an application for the authorization of a clinical trial or related amendment, or equivalent application or amendment, or after the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives.
- We may need to amend or submit new clinical protocols due to changes in regulatory requirements or guidance.
- We may need to run new or additional trials due to changes in the standard of care on which a clinical development plan was based.
- We may decide or be required by regulators to conduct additional clinical trials or abandon product development programs.
- We may decide to delay previously planned trials due to unforeseen developments with the product or product candidate.
- We may face clinical trial disruptions caused by man-made or natural disasters, public health pandemics or epidemics, global instability, or other business interruptions.

For example, we experienced clinical trial disruptions and delays including the following:

- In August 2025, the FDA suspended the biologics license for IXCHIQ due to serious safety concerns and in January 2026, we announced that we voluntarily withdrew the biologics license and IND for IXCHIQ in the United States, all of which had adverse impacts on the timely initiation of our planned post-marketing clinical trials.
- We experienced a delay in receiving all the required regulatory approvals to initiate the Phase 2 pediatric study for S4V2, the vaccine candidate for shigellosis that we have in-licensed from LimmaTech Technologies.
- Following Pfizer's decision in February 2023 to discontinue approximately half of the participants then enrolled in the Phase 3 trial of our Lyme disease vaccine candidate as a result of violations of GCP at certain trial sites run by a third party, the target for submission of a BLA shifted from 2025 to 2026.

In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. This includes our Lyme disease vaccine candidate partnered with Pfizer in connection with ongoing Phase 3 trials and development activities.

***We depend on strategic collaborations with partners, which may require us to relinquish rights to and control over the development and commercialization of our product candidates or to make payments upon achievement of milestone events.***

We have in the past and may in the future enter into agreements or engage in strategic collaborations in order to advance our business strategy. For example, in April 2020 we entered into a research collaboration and license agreement with Pfizer in connection with VLA15, our Lyme disease vaccine candidate. Pursuant to this agreement, Pfizer is leading late-stage development of the vaccine candidate, including conducting the ongoing Phase 3 clinical trials, and, if the Phase 3 data are positive, will have sole control over the timing and nature of its commercialization, which will have a significant impact on Valneva's financial condition for the foreseeable future. In addition, in July 2024, we entered into a development, collaboration, license and commercialization agreement with LimmaTech Biologics in connection with S4V2, their shigellosis vaccine candidate, pursuant to which we have assumed development of the product candidate and will be responsible for commercializing the product. Under this agreement, we will be required to make milestone payments to LimmaTech Biologics at various stages of product development, regardless of our ability to ultimately successfully commercialize the product.

In addition, we may in the future explore strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates. We cannot predict what form such strategic collaborations or licenses might take in the future. If we do seek additional strategic collaborations, we are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses that we have deemed important for the development and commercialization of any of our product candidates could delay or limit those processes in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including the following:

- Collaborators and partners have significant discretion in determining the efforts and amount and timing of resources that they devote to the development or commercialization of our product candidates, and their priorities may differ from ours.
- Business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to devote resources and complete its obligations under any arrangement.
- A collaborator or partner may not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization of our products or product candidates based on clinical trial results or delays, changes in their strategic focus, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities.
- Disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources.
- Strategic collaborators may select indications or design clinical trials in a way that does not optimize timing, success, or value.
- Strategic collaborators may delay or encounter unanticipated problems with clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing.
- Strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products.
- We may be required to undertake the expenditure of substantial operational, financial, and management resources, including expenditure beyond the amount originally agreed.
- We may not have the right to control the preparation, filing, prosecution, and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent

applications will be prepared, filed, prosecuted, and maintained in a manner consistent with the best interests of our business.

- We may fund additional collaborations by issuing equity securities that would dilute our shareholders' percentage ownership of our company.
- We may acquire and develop product candidates that fail to receive market approval or gain commercial approval.
- We may be required to assume substantial actual or contingent liabilities.
- Strategic collaborators may experience financial difficulties.
- Strategic collaborators may not properly maintain, enforce, or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.
- Strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

***Our product candidates and approved products may cause undesirable side effects or have other properties that could impact or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval.***

During clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their physician. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. If subjects in our clinical trials experience any side effects, and if regulatory authorities determine that such side effects are being caused by our vaccine candidates, they may require additional testing to confirm these determinations.

In addition, it is possible as we test our product candidates in larger, longer, and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, that illnesses, injuries, discomforts, and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked or limited or require labeling updates.

Notably, sales of IXCHIQ were negatively impacted during 2025 as a result of reports of serious adverse events, including one death, following administration of the vaccine to mainly elderly people, as described further above in "Our future success is substantially dependent on the successful clinical development, regulatory approval, and commercialization of our product candidates in a timely manner, which may be impacted by decisions of regulatory authorities or our partners". Any additional SAEs may result in further action from regulators or Valneva, including further changes to the product label. We cannot exclude the possibility that one or more additional regulatory agencies may suspend or withdraw the product's license as a result of safety concerns. Additionally, our grants from CEPI may be terminated if CEPI determines that there are safety, regulatory, or ethical concerns associated with continuing funding for IXCHIQ market access. For further information, please refer to "Item 10C—Material Contracts" of this Annual Report and note 5.8.1 to our consolidated financial statements.

Additionally, if IXCHIQ is used in future outbreak situations, such as the outbreak on the French island of La Réunion in 2025, there is a greater risk that the vaccine may not be administered in accordance with the label, which increases the risk of potential adverse events. We believe that some of the SAEs observed in 2025 resulted from such off-label use of the product. Further, although outbreak responses represent a potential business opportunity, our ability to respond to future outbreaks will depend on the availability of doses and the speed at which required contracts and approvals can be obtained. We cannot guarantee that we will be able to respond effectively to any future outbreak or that such a response will not have unintended negative consequences.

In addition, we are currently conducting a technology transfer of the drug product manufacturing process for our chikungunya vaccine with our strategic partner in Brazil and may enter into a similar arrangement with another strategic partner in Asia following the termination of our agreement with the Serum Institute of India in December 2025. While we are not responsible for the clinical trials conducted by our partners, we have input on the clinical design and must ensure that all relevant pharmacovigilance and safety monitoring is conducted according to ICH guidelines. If the results of these trials are not favorable, or if the vaccine candidate causes serious side-effects not seen in our own clinical trials, this may have reputational consequences for our vaccine, may require us to expend our resources to establish that such side-effects were not caused by our drug substance, or may cause regulators in countries where our vaccine has been approved to raise additional questions or require further post-approval trials, which would have a material impact on our business.

Further developments related to IXCHIQ's safety profile, product label, or recommended use or related to its manufacturing and commercialization in LMICs could result in a decision to discontinue the product. This would have a significant adverse effect on the Group's financial condition, results of operations, and business prospects.

***The development of additional product candidates is risky and uncertain, and we might not be able to successfully develop additional vaccines for other diseases.***

A core element of our business strategy, particularly in case of positive Phase 3 data for our Lyme disease vaccine candidate, is to expand our product pipeline. In August 2024 we acquired the exclusive worldwide license for LimmaTech Biologic's S4V2 Shigella vaccine candidate, which is currently in Phase 2 development. We also continue to evaluate the possibilities for the other clinical and preclinical candidates in our pipeline as well as the possibilities for acquiring candidates from third parties or partnering with third parties to co-develop candidates. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified, and there are a limited number of third-party programs to evaluate for this purpose. Our efforts may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development, approved products, or commercial revenue for many reasons, some of which are outside our control, including the following:

- Our methodology may not be successful in identifying potential product candidates.
- Competitors may develop alternatives that render any product candidates we develop obsolete.
- A product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise fail to meet applicable regulatory criteria, or limit its commercial potential.
- A disease we may target may cease to be a public health concern or a priority for organizations providing necessary funding for vaccine development.
- A product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.
- A product candidate may not be accepted as safe and effective by physicians, patients, the medical community, or third-party payors.

We have limited financial, manufacturing, and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business and shareholder value may be harmed.

***Our current products are, and any future product candidates for which we obtain regulatory approval will be, subject to ongoing regulatory oversight.***

Our currently approved products, and any future products we commercialize, if any, are subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping, applicable product tracking and tracing requirements, and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS or foreign equivalents or contain requirements for potentially costly post-marketing testing, including Phase 4 trials (such as those required for IXCHIQ), and surveillance to monitor the quality, safety, and efficacy of the product. Such regulatory requirements may differ from country to country depending on where we receive regulatory approval. Regulators may also subsequently limit or revise the indicated uses for which the product was originally marketed, which could significantly impact our sales. For example, the agency supervising pharmaceutical products in Canada, which is our principal market for DUKORAL, contacted us in July 2021 to request further information in support of DUKORAL's indications and labeling. While this matter has been resolved, if DUKORAL's indications or labeling were to change significantly in Canada or elsewhere in the future, this could have a significant negative impact on our sales which in turn could result in the product no longer being economically viable.

Our products are subject to ongoing review by regulatory authorities. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, a regulatory authority may limit the circumstances in which the product may be used, require a recall or withdrawal of product from the market, amend the product label, or suspend or withdraw the product's license. For example, in 2025 reports of serious adverse events following administration of IXCHIQ resulted in regulatory action which included the temporary (and now lifted) suspension of the use of IXCHIQ in people ages 65 and over by the certain regulatory agencies, the revision of the prescribing information in all jurisdictions where IXCHIQ was approved, and the complete suspension of the product license by the FDA in August 2025.

In addition, biopharmaceutical manufacturers and their facilities are subject to ongoing review and periodic inspections by the competent authorities of individual EEA countries, FDA, or other comparable regulatory authorities for compliance with applicable regulatory requirements, including with cGMP requirements and with commitments made in the

application for regulatory approval. If we, or a regulatory authority, discover previously unknown problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to that facility, including suspension of manufacturing.

If we fail or if a third party fails to comply with applicable regulatory requirements for our products or any of our product candidates that receive regulatory approval in the future, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil, or criminal penalties or monetary fines;
- suspend, vary, or withdraw regulatory approval;
- suspend or vary any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign application for regulatory approval or any supplements thereto submitted by us or our partners;
- restrict the labeling, distribution, marketing, or manufacturing of the product or clinical trial material;
- seize or detain the product or otherwise require the withdrawal of the product from the market or product recalls;
- require additional post-marketing studies or clinical trials;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations, and prospects. The serious adverse events reported in connection with IXCHIQ, the subsequent changes to the product label in different markets, and the FDA's suspension of the BLA for IXCHIQ significantly impacted sales in 2025 and may continue to effect the commercialization of IXCHIQ in existing or new markets.

Regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. In addition, we cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action in any geography where we market a product.

It is difficult to predict how these executive actions, including any executive orders, will be implemented and the extent to which they will affect the regulatory authorities' ability to exercise their authority. If these executive actions impose constraints on the regulatory authorities' ability to engage in oversight and implementation activities in the normal course, our business, financial condition, results of operations, and prospects may be negatively impacted.

***If we are unable to maintain and expand our sales and marketing capabilities on our own or with others, we may not be successful in increasing sales of our current products and commercializing future products, if approved.***

To increase sales of our current products and third-party products pursuant to distribution agreements, as well as successfully commercialize any product candidate that may result from our development programs, we will need to maintain and continue to build out our sales and marketing capabilities, either on our own or with others. In particular, the distribution of IXCHIQ and other products we may in the future commit to providing in LMICs will require collaboration with regional or local partners. The continued development of our sales and marketing team will be expensive and time-consuming and could delay any product launch. We compete with many companies that currently have extensive, experienced, and well-funded marketing and sales operations to recruit, hire, train, and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train, and retain any of our own marketing and sales personnel. If we are unable to sustain and expand our sales and marketing team, we may be unable to compete successfully against these more established companies. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. For further information about risks related to collaborations with partners, see "—Risks Related to Our Reliance on Third Parties".

***We may be liable if regulatory enforcement agencies determine we engaged in the off-label promotion of our products, pre-approval promotion of our product candidates, or dissemination of false or misleading labeling, advertising, or promotional materials.***

Our promotional activities, materials, and training methods are strictly regulated, with prohibitions on marketing claims that promote the off-label use of our products or that omit material facts or make false or misleading statements about the safety or efficacy of our products. Pre-approval promotion of product candidates is also prohibited. However, in the United States and certain other countries, the FDA or the equivalent regulatory authority does not restrict or regulate a physician's

choice of treatment within the practice of medicine. Therefore, physicians may use our products off-label if deemed appropriate in their independent medical judgment.

A regulatory authority could disagree with the manner in which we advertise and promote our products or communicate about our product candidates. It could conclude that a claim is misleading if it determines that there are inadequate non-clinical and/or clinical data supporting the claim, or if a claim fails to reveal material facts about the safety or efficacy of our products, or claim that we have engaged in pre-approval promotion of a product candidate.

If a regulatory authority determines that our promotional activities or advertising materials promote an off-label use or make false or misleading claims, or that our communications about product candidates constitute pre-approval promotion, it could request that we modify our promotional materials, training content, or other communications or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. In the case of a claim of pre-approval promotion, these consequences could result in a delay in the review of any dossiers we have submitted for regulatory review and approval.

In the United States, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which may lead to costly penalties and may adversely impact our business. Recent court decisions in the United States have impacted FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations such that companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling; however, there are still significant risks in this area, in part due to the potential for False Claims Act exposure.

In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

***Our future growth depends, in part, on our ability to penetrate multiple markets, in which we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability will depend, in part, on our ability to continue to commercialize our products and, if approved, our product candidates in markets in Europe, the United States, and other countries where we maintain commercialization rights. As we continue to commercialize our products and begin to commercialize our product candidates, if approved, in multiple markets, we are subject to additional risks and uncertainties, including:

- foreign currency exchange rate fluctuations and currency controls;
- tariffs, trade barriers, import or export licensing requirements, or other restrictive actions;
- economic weakness, including inflation and rising interest rates, or political instability in particular economies and markets;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- the burden of complying with complex and changing regulatory, tax, accounting. and legal requirements, many of which vary between countries;
- different medical practices and customs in multiple countries affecting acceptance of drugs in the marketplace;
- differing payor reimbursement regimes, governmental payors, or patient self-pay systems and price controls;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- reduction or loss of protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics; and
- becoming subject to the different, complex, and changing laws, regulations, and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties, and regulations.

Future sales of our products or our product candidates, if they are approved, will be dependent on purchasing decisions of and recommendations from government health administration authorities. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, armed conflict, wars, or otherwise, these organizations may defer purchases or may be unable to satisfy their purchasing or reimbursement obligations, which may affect milestone payments or royalties for our products or any of our product candidates that are approved for commercialization in the future. These and other risks associated with international operations may adversely affect our ability to attain or maintain profitable operations.

***Our failure to obtain marketing approval in jurisdictions other than the United States and the European Union would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and the European Union would not assure approval of product candidates in other jurisdictions.***

In order to market and sell our product candidates in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals in such jurisdictions and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing aside from that which is required to obtain such approval in the United States and the European Union. The time required to obtain approval may differ from that required to obtain approval from the FDA or regulatory authorities in the European Union. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA approval or approvals from regulatory authorities in the European Union. In addition, some countries outside the United States and the European Union require approval of the sales price of a product before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement, and a product may not be approved for sale in the country until it is also approved for reimbursement. We may not obtain marketing, pricing, or reimbursement approvals outside the United States and the European Union on a timely basis, if at all. Approval by the FDA or regulatory authorities in the European Union does not ensure approval, with the same scope or at all, by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and the European Union does not ensure similar approval by regulatory authorities in other countries or jurisdictions or by the FDA or regulatory authorities in the European Union. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and the European Union do not ensure pricing approvals in those countries or in any other countries where such approvals are required, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities, damage our reputation, and limit commercialization of any product candidate that we may develop as well as continued commercialization of our current products.***

We face an inherent risk of product liability exposure related to the sale and use of our products and the testing of our product candidates in clinical trials. Side effects of, or manufacturing defects in, products that we develop could result in injury or even death. For example, our liability could be sought after by subjects participating in the clinical trials in the context of the development of the vaccine candidates tested and unexpected side effects resulting from the administration of these products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by subjects, regulatory authorities, biopharmaceutical companies, and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees, and subcontractors over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy, result in withdrawal of clinical trial participants, result in decreased demand for our products, and may be costly and time-consuming to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities, may be forced to limit or forgo further development or commercialization of the affected products, and may suffer damage to our reputation.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our products or our product candidates.

To date, we have obtained product liability insurance with a coverage amount of €40 million per claim, up to 1.5 times per year. Our product liability insurance will need to be adjusted in connection with the commercial sales of our products and our product candidates or our strategic partnerships, and may be unavailable in meaningful amounts or at a reasonable cost. Our insurance coverage may not be sufficient to cover any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

In addition, product liability claims relating to our own or similar products may result in increases in insurance premiums or deductibles that may make insurance coverage more costly or prohibitively expensive. Additionally, insurance providers may refuse to provide coverage for a category of related products if one such product is removed from the market for safety reasons. We cannot guarantee that we will be able to maintain product liability insurance coverage for all of our products. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we would incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of our product programs. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

***Interim, topline, and preliminary data from clinical trials of our product candidates that we or our collaborators publicly disclose from time to time may change as more patient data become available and are subject to audit, review, and/or verification procedures that could result in final clinical data that is materially different and unfavorable.***

From time to time, we or our collaborators conducting clinical trials of our product candidates may publicly disclose interim, preliminary or topline data from those clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of

the data related to the particular trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data at the time of initial disclosure. As a result, preliminary and topline results reported for clinical trials of our product candidates may differ from final results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously disclosed by us or a collaborator. As a result, preliminary and topline data should be viewed with reservation until the final data are available. From time to time, we or a collaborator may also disclose interim data from clinical trials of our product candidates. Interim data from clinical trials of our product candidates are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects.

If the topline data reported by us or a collaborator differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability, or that of a collaborator, to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

## Risks Related to Competition

***We operate in a highly competitive industry, and our competitors may have significantly greater resources and experience, which may negatively impact our commercial opportunities.***

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial and technical resources, as well as experience and expertise across a wide range of capabilities, which are required in our industry.

Large and more established companies compete in the general vaccine market. In particular, these companies may have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products.

Smaller or early-stage companies and research institutions also may prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies and research institutions develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. These companies may also render our product candidates obsolete or non-competitive through advances in existing technological approaches or the development of new or different approaches, such as using artificial intelligence (AI) and machine learning, potentially eliminating the advantages in our drug discovery process. If any of our competitors succeed in obtaining approval from regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, or if the scope of approval for a competing product is broader than an approval granted for our product, our commercial opportunity could be significantly reduced. Mergers and acquisitions, including of specific assets, in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors and in changes to the competitive landscape in regions where we market and distribute our products.

***Some of our competitors have developed or are developing vaccines for the same diseases that we are targeting, and we may not be able to compete effectively or may lose market share to these products.***

We are aware of companies with competing products or product candidates for Japanese encephalitis, cholera (one of which is currently available in the U.S. and a limited number of European markets) and chikungunya (including one that is now available in the U.S., Europe, and the UK and is expected to become available in Canada in 2026). If and as these vaccines become available in the markets in which we compete, sales of our vaccines may be adversely affected. In particular, the launch of the second chikungunya vaccine has impacted sales of IXCHIQ in the markets we share.

We may not be successful in gaining significant market share for any approved product candidate and may not continue to be successful maintaining or gaining market share for our currently marketed products if competing products enter the market. Our technologies and vaccines also may be rendered obsolete or non-competitive because of products introduced by our competitors to the marketplace more rapidly and at a lower cost.

## Risks Related to Our Reliance on Third Parties

***We are dependent on single-source suppliers for some of the components and materials used in our products.***

In certain cases, we rely on single suppliers for all of our requirements for some of our materials or components. In most cases we do not have long term contracts with these suppliers, and even in the cases where we do the contracts include significant qualifications that would make it extremely difficult for us to force the supplier to provide us with their services, materials, or components should they choose not to do so. We are therefore subject to the risk that these third-party suppliers will not be able or willing to continue to provide us with materials and components that meet our specifications, quality standards, and delivery schedules. Factors that could impact our suppliers' willingness and ability to continue to provide us with the required materials and components include disruption at or affecting our suppliers' facilities, such as

work stoppages or natural disasters, adverse weather or other conditions that affect their supply, the financial condition of our suppliers, and deterioration in our relationships with these suppliers. In addition, we cannot be sure that we will be able to obtain these materials and components on satisfactory terms. Any increase in material and component costs could reduce our sales and harm our gross margins. In addition, any loss of a material supplier may permanently cause a change in one or more of our products that may not be accepted by our customers or that may cause us to eliminate that product altogether.

For example, we rely on a single-source supplier for fetal bovine serum, a critical and scarce raw material which is only available from our supplier and is used in the manufacturing of IXIARO. We also rely on a single-source supplier for the adjuvant contained in certain vaccine candidates. A loss of the supplier or any shortages of these or other materials for which we rely on a single supplier could adversely affect our ability to manufacture our products and significantly raise our cost of production.

We have not qualified secondary sources for all materials or components that we source through a single supplier, and we cannot assure investors that the qualification of a secondary supplier would prevent future supply issues. Disruption in the supply of materials or components, or changes to these materials or components that may unexpectedly impact our products, would impair our ability to sell our products and meet customer demand and also could delay the launch of new products, any of which could harm our business and results of operations. If we were to have to change suppliers, the new supplier may not be able to provide us materials or components in a timely manner and in adequate quantities that are consistent with our quality standards and on satisfactory pricing terms. In addition, alternative sources of supply may not be available for materials that are scarce or components for which there are a limited number of suppliers.

If we experience shortages in the supply of our marketed products, our results could be materially impacted.

***The marketing and distribution of our products and the late-stage development of our product candidates may depend on our ability to establish and maintain collaborations with biopharmaceutical companies.***

We rely on collaboration, research, and license agreements with other biopharmaceutical companies to assist us in the marketing and distribution of our products and the development of product candidates and the financing of their development.

Our collaborations may be amended or terminated for various reasons. On December 31, 2025, we announced the mutual termination of our agreements with the Serum Institute of India, or SII, relating to the manufacturing and distribution of IXCHIQ in Asia. This will delay the supply of IXCHIQ in Asia, and we cannot guarantee that we will be able to find one or more new partners to facilitate that supply. Additionally, as a result of Bavarian Nordic's acquisition of another cholera vaccine, we terminated our previous agreements that provided for Bavarian Nordic's distribution of our vaccines in certain countries and our distribution of Bavarian Nordic's vaccines in certain countries.

We may fail to maintain or find collaboration partners and to sign new agreements for our other product candidates and programs. The competition for partners is intense, and the negotiation process is time-consuming and complex. If a collaboration relates to the manufacture of one of our products, the transfer of our technology to the new partner also requires significant time. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain a collaboration if, for example, development or approval of a product candidate is delayed, actual or expected sales of an approved product candidate do not meet expectations, or the collaborator terminates the collaboration, including because of changes in the collaborator's business. Any collaboration, or other strategic transaction, may also require us to incur non-recurring or other charges, increase our near- and long-term expenditures, and pose significant integration or implementation challenges or disrupt our management or business. However, the failure to explore or enter into a collaboration or other strategic cooperation might also cause us to forego beneficial opportunities to develop and commercialize our product candidates.

As we continue to commercialize our products and identify new product candidates, we will determine the appropriate strategy for development and marketing, which may result in the need to establish additional collaborations with other biopharmaceutical companies. We may also enter into agreements with institutions and universities to participate in our other research programs and to share intellectual property rights.

***We rely on third parties to supply key materials used in our research and development, to manufacture our products and product candidates, to provide services to us, and to assist with clinical trials.***

We make considerable use of third-party suppliers for the key materials used in our business, such as the adjuvant used in certain vaccine candidates. We also rely upon several, and in the future may rely on additional, third-party contract manufacturing organizations, or CMOs, for the manufacture and supply of components and substances for all of the product candidates we are developing. For example, we have outsourced an important step in the manufacturing of IXCHIQ to a third party, and another third party performs the filling process for IXIARO and the filling of IXCHIQ diluent. In the biopharmaceutical industry, supplier changes require lengthy validation and regulatory approval processes. A loss of any CMO or component supplier and delay in establishing a replacement could delay our clinical development and regulatory approval process or interrupt supply. Notably, the termination of our agreements with SII at the end of 2025 will delay supply of IXCHIQ in Asia.

The failure of third-party suppliers to comply with regulatory standards could result in the imposition of sanctions on us. These sanctions could include fines, injunctions, civil penalties, refusal by regulatory organizations to grant approval to conduct clinical trials or marketing authorization for our products, delays, suspension, variations or withdrawal of approvals, license revocation, seizure or recalls of our products, operating restrictions, and legal proceedings. Furthermore,

the presence of non-conformities, as may be detected in regulatory toxicology studies, could result in delays in the development of one or more of our product candidates or in the supply of a commercial product and would require further tests to be financed. Although we are involved in establishing the protocols for the production of these materials, we do not control all the stages of production and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations or that we will be informed in a timely manner of any non-conformities or other failure to comply with obligations. In particular, a partner's failure to comply with protocols or regulatory constraints, or repeated delays by a partner, could compromise the development or manufacturing of our products. Such events could also inflate our product development or manufacturing costs.

We also use third parties to provide certain services such as scientific, medical, or strategic consultancy services. These service providers are generally selected for their specific expertise, as is the case with the academic partners with whom we collaborate. We face intense competition to build and maintain such a network under acceptable terms. Such external collaborators may terminate their involvement at any time, and we can exert only limited control over their activities. We may not be able to obtain the intellectual property rights to the product candidates or technologies developed under collaboration, research, and license agreements under acceptable terms or at all. Moreover, our scientific collaborators may assert intellectual property rights or other rights beyond the terms of their engagement.

Finally, we use third parties to assist with conducting clinical trials. All clinical trials are subject to strict regulations and quality standards. Should any of these risks materialize, as in the case of the Phase 3 trial of VLA15 involving GCP violations by a third party engaged by Pfizer to conduct certain clinical trial sites, this could have a material adverse effect on our business.

## Risks Related to Our Business Operations, Employee Matters and Managing Growth

***We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, and scientific personnel, our business will be harmed.***

We are highly dependent on our management, scientific, and medical personnel, particularly our Chief Executive Officer Thomas Lingelbach, who we heavily rely on for a variety of matters. Our key personnel may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or other employees.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel, and commercialization, manufacturing, and sales and marketing personnel will be critical to our success. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies, as well as universities and research institutions, for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We also rely, and for the foreseeable future will continue to rely, in part, on certain independent organizations, advisors, and consultants to provide certain services. Such assistance might not continue to be available to us on a timely or cost-effective basis when needed, and we might not find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired staff, particularly at the senior level. Failure to do so could result in inefficiencies in the development and commercialization of our product candidates and other aspects of our business, which could negatively impact our results of operations.

***We may encounter difficulties in managing our growth, which could disrupt our operations.***

Our strategy involves continuing to grow our business organically. However, we may also grow through selective acquisitions of complementary products and technologies, or of companies with such assets. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs, and sales, marketing and distribution for our approved products. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and recruit and train additional qualified personnel. Due to our limited financial resources and the extent of our anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing organic or inorganic growth. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure and give rise to operational errors, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected

growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy.

If we were to acquire assets or companies, the success of such an acquisition would depend on our capacity to carry out such acquisitions and to integrate such assets or companies into our existing operations.

In addition, an acquisition could result in shareholder litigation, which could be costly and time consuming and divert management's attention and resources. For example, following the merger between Vivalis SA and Intercell AG in 2013, certain former Intercell shareholders initiated legal proceedings to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used for the non-departing shareholders who received Valneva shares in the merger. On December 1, 2025, we were informed that the Vienna Commercial Court had confirmed that 1) the exchange ratio was adequate, meaning no additional compensation is required in connection with the conversion of Intercell shares, 2) shareholders are entitled to an additional cash compensation of EUR 3.52 plus interest per share (in line with our expectations), and 3) the Court's decision on costs is reserved until final conclusion of the proceedings. On January 16, 2026, the Commercial Court informed us of two appeals of this initial decision. The first appeal was filed by the common representative of the plaintiffs and challenges the exchange ratio. The second appeal was filed by two shareholders and challenges both the exchange ratio and the amount of cash compensation. The Company has submitted a response to these appeals and is now awaiting further information from the Commercial Court. We are not obligated to make any payments to litigants until a final judgment is available.

The results of this litigation or any other legal proceedings are inherently uncertain, and adverse judgments or settlements in some of these legal disputes may result in adverse and potentially substantial monetary damages, penalties, or injunctive relief against us.

***We have engaged and may in the future engage in strategic transactions, such as acquisitions or investments in other companies or technologies or product in-licensing, which could divert our management's attention and in some cases result in dilution to our shareholders and otherwise disrupt our operations and adversely affect our operating results.***

We have engaged and may in the future engage in strategic transactions that may divert the attention of management and incur various expenses in identifying, investigating, and pursuing suitable transactions, whether or not they are consummated. For example, we may seek to acquire or invest in additional businesses and/or technologies that we believe complement or expand our current products or product candidates, enhance our technical capabilities, or otherwise offer growth opportunities in the United States and internationally. We may also consider divestment of specific assets to support different strategic objectives.

Realizing the benefits of acquisitions or in-licensing depends upon the successful integration of the acquired technology into our existing and future product candidates, including via effective collaboration with the selling or licensing party. Furthermore, we may not be able to integrate the acquired personnel, operations, and technologies successfully, or effectively manage the combined business following the acquisition. We also may not realize the anticipated benefits from any acquired business. The risks we face in connection with acquisitions and investments, whether or not consummated, include the following:

- unanticipated costs or liabilities associated with the acquisition;
- diversion of management's attention from other business concerns;
- adverse effects on our existing strategic collaborations as a result of the acquisition;
- assimilation of operations, intellectual property, and products of an acquired company;
- the potential loss of key employees;
- difficulty integrating the accounting systems, operations, and personnel of the acquired business;
- the assumption of additional indebtedness or contingent or unknown liabilities, or adverse tax consequences or unfavorable accounting treatment;
- claims and disputes by shareholders and third parties, including intellectual property claims and disputes;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- increased operating expenses and cash requirements; and
- use of substantial portions of our available cash to consummate the acquisition.

A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations, and prospects.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial

condition, results of operations, and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations, and prospects. Further, if we are unable to identify suitable product candidates for potential in-licensing or acquisition, we may fail to generate additional shareholder value.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our CMOs, CROs, and other contractors and consultants, could be subject to cybersecurity attacks, earthquakes, power shortages, information technology or telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, armed conflict, wars, public health pandemics or epidemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our business has been and could in the future be materially adversely affected by the effects of pandemics or epidemics. COVID-19 adversely affected economic activity across virtually all sectors and industries on a local, national, and global scale. We are unable to accurately predict the impact that a similar event would have on our business or those of our manufacturers, CROs, and related third parties due to numerous uncertainties, including the duration of the outbreak, the result of vaccination efforts, resurgence of the virus including any new variants, actions that may be taken by governmental authorities, impacts on international travel, the impact on the business of our service providers and partners, and the impact on the global financial markets, which could limit our access to capital and affect our liquidity. These and similar, and perhaps more severe, disruptions in our operations could materially impact our business, operating results and financial condition.

***We may be negatively impacted by volatility in the political and economic environment across the markets in which we operate, including as a result of tariffs, changes in regulatory practice or policy that apply to our industry, military conflicts, elections and changes in leadership, economic downturns, increases in interest rates, and sustained inflation. Any of these could result in higher operating costs and may negatively impact our business and financial performance, including because of similar impacts on our business partners.***

Our business could be adversely affected by changes in the political and economic environment. These conditions include:

*Tariffs and Trade Restrictions*. We could be affected by substantial new and increased tariffs and other restrictive trade policies between the United States and other countries, and any retaliatory tariffs by those other countries. If our activities, or those of our current or future service providers, manufacturers, suppliers and other partners, fall within the scope of any of these or other tariffs, our costs may increase significantly. We or these parties may experience supply chain disruptions as a result of increased costs and uncertainty, including risks to their long-term viability, which may impact our ability to meet customer demand or cause reputational harm if we are unable to deliver our products on expected timelines.

*Regional and Global Conflicts*. Global or regional conflicts, such as the military conflicts between the U.S., Israel, and Iran and between Russia and Ukraine, could cause global security concerns that could disrupt the global supply chain and energy markets and adversely impact our business. Concerns about security and any increase in the cost of travel resulting from an increased cost of fuel could impact the travel industry, which is a key component of demand for our products.

*Capital Markets Volatility*. The U.S. Federal Reserve and European Central Bank have raised interest rates multiple times in response to concerns about inflation, among other things, and they may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and contribute to volatility in the price of our ordinary shares and ADSs. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, including relative to cost or dilution.

*Government Funding, Disruptions, Policy Changes and Shutdowns*. Disruptions at governmental agencies such as the FDA, CDC, and SEC, or similar agencies outside the United States, resulting from funding or staffing cuts, changes in leadership or priorities, or other actions of the executive or legislative branches of the U.S. or other governments may have a significant and negative impact on our business. Similarly, legislative changes may be instituted, or enforcement priorities may shift, creating uncertainty about the regulatory environment in which we operate. Such disruptions may affect an agency's ability to perform routine functions, thereby extending the time necessary for review of new product candidates or previously approved products. The FDA may operate with fewer resources and otherwise adapt its practices moving forward in ways that could hinder review of product candidates or result in changes to prior product approvals, notably of vaccines. Efforts to reduce regulations and expenditures across the U.S. government, presently directed by executive orders or memoranda from the Office of Management and Budget, may lead to proposed or actual policy changes that create additional uncertainty for our business and could affect the FDA's relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of vaccines and other prescription drugs, which could have a material adverse effect on our business. If funding for the FDA or other regulatory authorities is reduced, priorities change, a prolonged government shutdown occurs, or current or future global health concerns prevent the FDA or other regulatory authorities from conducting regulator inspections, reviews or other activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similar disruptions may occur in other markets where we operate, including less familiar markets where we have established strategic collaborations with local partners. Further, in our operations as a

public company, future government disruptions or shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

*Inflation*. Rising inflation may adversely affect us by increasing our costs, including labor and employee benefit costs, and could also adversely affect our customers, which could reduce demand for our products. While we would take actions, wherever possible, to mitigate the impact of the effects of inflation, in the case of sustained inflation across several of the markets in which we operate, it could become increasingly difficult to effectively mitigate the increases to our costs. If we are unable to take actions to effectively mitigate the effect of the resulting higher costs, our profitability and financial position could be negatively impacted.

***Our IT systems and data, and those of our collaborators, consultants, service providers, and other contractors, are vulnerable to cyberattacks and security breaches, which could significantly disrupt our core operations, product development programs, and overall business and adversely affect our business strategy, financial condition, results of operations, and prospects.***

Our computer and information technology systems, networks, infrastructure, hardware, software, and cloud-based computing services, collectively referred to as IT Systems, and those of our current and future collaborators, service providers, and other contractors or consultants are vulnerable to malware (such as ransomware), malicious code (such as computer viruses and worms), data corruption, cyber-based attacks (including attacks enhanced or facilitated by AI), malfeasance by insiders, human error, natural disasters, public health pandemics or epidemics, terrorism, war, and telecommunication and electrical failures, all of which threaten the confidentiality, integrity, and availability of our IT Systems, key business processes, and intellectual property, proprietary business information, personal information, and other important data we process or maintain, collectively referred to as our Confidential Information.

We and certain of our third-party providers have in the past experienced cyberattacks and other security incidents, and we expect that to continue in varying degrees in the future. We expect cyberattacks to accelerate on a global basis in both frequency and magnitude as threat actors are increasingly sophisticated in using techniques and tools – including artificial intelligence – that can circumvent controls, evade detection, and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate, or recover from future attacks or incidents or to avoid a material adverse impact on our IT Systems, Confidential Information, or business. Cybersecurity threats are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, insiders and other personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Remote and hybrid working arrangements at our company (and at many third-party providers) also increase cybersecurity risks due to the challenges associated with managing remote computing assets and the security vulnerabilities that are present in many non-corporate and home networks. In addition, we cannot comprehensively identify all misconfigurations, "bugs", or vulnerabilities in proprietary or third-party systems or software used by our business or guarantee that patches or compensating controls will be applied before vulnerabilities can be exploited by a threat actor. Moreover, any use or integration of generative or other artificial intelligence in our, or any third parties', operations, products, or services will pose new and/or unknown cybersecurity risks and challenges. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our IT Systems and Confidential Information. Any significant system failure, accident, attack, or security breach could have a material adverse effect on our business, financial condition, and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, and security vulnerabilities or to respond to or recover from a cyberattack or security incident could be significant and could result in unexpected interruptions, delays, cessation of service, and other harm to our business and our competitive position, as well as regulatory investigations, litigation (including class action suits), reputational impacts, and the loss of partners, collaborators, and customers. If such an event were to occur and cause interruptions in our operations, it could also result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our product candidates, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our product candidates could be delayed.

In addition, our IT Systems and those of our current and any future collaborators, service providers, and other contractors or consultants are potentially vulnerable to data security breaches, whether by employees, contractors, consultants, malware, phishing attacks, or other cyberattacks, that may expose Confidential Information to unauthorized persons. For example, we have experienced phishing attacks in the past, and we expect to be a target of phishing attacks and other cyberattacks in the future. The risk of such attacks is higher in the context of the anticipated results of the Phase 3 clinical trial of our Lyme disease vaccine candidate and may remain at the same level for a period following the announcement of these results. In addition, our IT Systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. Consequently, successful cyberattacks that disrupt or result in unauthorized access to third-party IT Systems can materially impact our operations and financial results. If a data security breach affects our systems, corrupts our data, or results in the unauthorized disclosure or release of personally identifiable information, for example, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, or individuals pursuant to various data protection, privacy, and security laws, regulations, and guidelines, as applicable, such as the EU and UK GDPR (as defined below). Accordingly, a data security breach or privacy violation that leads to unauthorized

access to, disclosure, or modification of personal information (including protected health information), that prevents access to personal information, or that materially compromises the privacy, security, or confidentiality of the personal information, could result in fines, increased costs, or loss of revenue, and we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Furthermore, laws and regulations around the globe, such as the EU and UK GDPR, can expose us to enforcement actions and investigations by regulatory authorities and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail and if we fail to disclose any material cybersecurity incident in an adequate and timely manner. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees' or vendor's use of generative AI technologies.

***Our current and potential future use of AI may not be successful and presents new risks and challenges to our business.***

We currently integrate AI in certain of our activities and are seeking to further integrate AI throughout our business. Such efforts may not be successful and may generate additional risks. Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues.

As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business. Developing, testing, and deploying AI systems may also increase our operating costs due to the nature of the computing costs involved in such systems, which could adversely affect our business, financial condition, and results of operation. The use of AI by us and our business partners may lead to novel and urgent cybersecurity risks, which could have a material adverse effect on our operations and reputation as well as the operations of any of our business partners. We may also face increased competition from other companies that are using AI, some of whom may develop more effective methods than we have, which could have a material adverse effect on our business, results of operations, or financial condition. In addition, our efforts to develop, acquire, or integrate these technologies will involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing on other elements of our strategy. Furthermore, uncertainties regarding developing legal and regulatory requirements and standards may require significant resources to modify and maintain business practices to comply with U.S. and foreign laws concerning the use of AI, the nature of which cannot be determined at this time.

***Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct, or unauthorized activities that violate any of the following:

- the laws and regulations of the EEA countries, FDA, and other regulatory authorities, including those laws requiring the reporting of true, complete, and accurate information to competent regulatory authorities,
- manufacturing standards,
- federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations in the EEA, the United States, and elsewhere, and
- laws that require the true, complete, and accurate reporting of financial information or data.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, and the curtailment or restructuring of our operations.

***Our business may be exposed to foreign exchange risks.***

We operate internationally and are exposed to foreign exchange risks arising from various currencies, primarily with respect to the Euro (EUR), the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK), and the U.S. Dollar (USD). As we grow and as a result of our strategic collaborations, for example in Brazil with Instituto Butantan, our exposure to foreign exchange risks will increase. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations. Because a substantial part of sales of IXIARO are generated in the United States, with a significant part of production costs in GBP, and in Canada for DUKORAL, with production costs in SEK, we are exposed to foreign exchange risks, principally with respect to the USD, GBP, SEK, and CAD. However, our results of operations continue to be impacted by exchange rate fluctuations. For example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euro at a reduced value. While we entered into currency option contracts in 2020 to limit the risk of foreign exchange losses, we cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Our ADSs are quoted in U.S. dollars on Nasdaq, while our ordinary shares trade in euro on Euronext Paris. Our financial statements are prepared in euro. Therefore, fluctuations in the exchange rate between the euro and the U.S. dollar will also affect, among other matters, the value of our ordinary shares and ADSs. We could also sign contracts denominated in other currencies, which would increase our exposure to currency risk. In accordance with our business decisions, our exposure to this type of risk could change depending on:

- the currencies in which we receive our revenues;
- the currencies chosen when agreements are signed, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on product candidates; and
- our policy for insurance coverage.

In addition, in light of the ongoing military conflict between Russia and Ukraine and the resulting tensions between the European Union, the United Kingdom, the United States and other countries with Russia, any resulting material change to the valuation of European and U.S. currencies could adversely impact our operating results.

## Risks Related to the Manufacture of Our Products and Product Candidates

***We may be unable to successfully manufacture our products or product candidates in sufficient quality and quantity, which would impact commercialization of our products and delay development of our product candidates.***

We perform most of the manufacturing of our products and our product candidates in-house. Delays in manufacturing or inability to manufacture sufficient doses of a product or product candidate could adversely affect our business, financial condition, prospects, and results of operations. If we, or any third-party manufacturing partners, are unable to manufacture sufficient quantities of any vaccine, we may not be able to meet demand or fulfill our obligations under any agreements, or we may be forced to forego additional partnerships or supply agreements which would be advantageous for our business. We may encounter unexpected challenges relating to manufacturing efficiency, quality control, or stability profile that could impact the quantity of products or product candidates manufactured, the consistency of quantity across batches, or the length of time that manufactured material can be used. These problems could impact our supply of the market and require us to manufacture more than previously expected, leading to delays and added costs. We have previously experienced supply shortages for both IXIARO and DUKORAL, including in 2023 and 2024 due primarily to the faster than expected recovery of the travel market from the COVID-19 pandemic and delays in internal processes. Additionally, any supply shortages due to an inability to manufacture sufficient doses could result in fines.

Our manufacturing facility in Livingston, Scotland is the sole source of drug substance of our Japanese encephalitis vaccine IXIARO and our chikungunya vaccine IXCHIQ. Our manufacturing facility in Solna, Sweden, is the sole source of DUKORAL. Our Vienna facility is involved in the product release process for products manufactured in Livingston. Anything that would prevent any aspect of the production process in these facilities, including decisions of regulatory authorities or an event such as a fire or pandemic, would prevent us from manufacturing the relevant product and supplying our customers or clinical trial centers, which could lead to significant delays and shortages.

We may be required to increase our manufacturing capacity to meet demand for approved products, and we may be unable to do this in a timely or cost-effective manner, or at all. We do not have experience manufacturing on the scale that would be required for a large-scale commercialization of vaccine candidates that may receive approval in the future. The process of developing additional manufacturing capacity is complex and affected by multiple external factors, many of which are beyond our control.

We, our contract manufacturers, any future collaborators, and their contract manufacturers could be subject to periodic announced or unannounced inspections by the FDA or other comparable regulatory authorities to monitor and ensure compliance with cGMP or other applicable regulations. Despite our efforts to audit and verify regulatory compliance, we or one or more of our third-party manufacturing vendors may be found on regulatory inspection by the authorities to be noncompliant with cGMP or other applicable regulations, as discussed further below, and this may significantly impact our ability to supply and market our drug products.

We have outsourced to third parties certain manufacturing steps for our commercial products and for clinical trial material. Outsourcing of manufacturing could result in delays, concerns about manufacturing consistency, or other manufacturing failures. Per the standard industry practice, we rather than the third-party provider would bear the risk of such problems.

Any of these factors impacting manufacturing quantity or quality could delay or impact clinical trials, regulatory submissions, and/or commercialization of our products, interfere with current sales, entail higher costs, and result in our inability to effectively sell our products.

***We rely upon third parties to manufacture and supply components necessary to manufacture our products and product candidates.***

We currently rely upon several, and in the future may rely on additional, third-party CMOs for the manufacture and supply of components necessary to manufacture all of the product candidates we are developing. Additionally, certain component materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to manufacture these materials for us. We cannot assure you that, if required, we will be able to identify alternate sources with the desired scale and capability and establish relationships with such sources. Additionally, in the biopharmaceutical industry, supplier changes require lengthy validation and regulatory approval processes. A loss of any CMO or component supplier and delay in establishing a replacement could delay our clinical development and regulatory approval process and interrupt supply. Further, changes made to supplied components could have an unexpected impact on our products that could require time to investigate and resolve.

***Manufacturing facilities and clinical trial sites are subject to significant government regulations and approvals. If we or any third parties fail to comply with these regulations or maintain these approvals, our business could be materially harmed.***

Our manufacturing facilities and those of our third-party partners are subject to ongoing regulation and periodic inspection by national authorities, including the competent authorities of EEA countries, the FDA, and other regulatory bodies to ensure compliance with cGMP and other applicable regulations when producing batches of our products and product candidates for clinical trials. CROs and other third-party research organizations must also comply with Good Laboratory Practice, or GLP, when carrying out regulatory toxicology studies. Any failure to follow and document our or their adherence to such cGMP and GLP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, may delay or prevent filing or approval of marketing applications for our products, or may cause us to not meet our obligations under our commercial agreements.

Failure to comply with applicable regulations at our manufacturing sites or at clinical trial sites could also result in national authorities, the competent authorities of EEA countries, the FDA, or other applicable regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring us to suspend or put on hold one or more of our clinical trials;
- requiring an additional audit or validation of clinical trial data;
- suspending, varying, or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us to suspend manufacturing activities or product sales, imports, or exports;
- requiring us to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to our reputation, business, financial condition, or operating results. Furthermore, we or our key suppliers and partners may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all, or in delays to our clinical trials. In addition, before any additional products would be considered for marketing authorization in the EEA, the United States, or other jurisdictions, the relevant manufacturer will have to pass an inspection by the applicable regulatory authorities, and the inspections and any necessary remediation may be costly. Failure to pass such inspections by us or any of our suppliers would adversely affect our ability to commercialize our products or product candidates in the EEA, the United States, or other jurisdictions. Moreover, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Following an inspection of our Livingston manufacturing site by the FDA in February 2026, we received a Form 483 letter with 11 observations. We submitted a response letter to the FDA confirming corrective actions. The FDA has since informed the Company that it is unable to grant approval of the BLA supplement related to manufacture of IXIARO at the Almeida facility due to outstanding compliance issues associated with the inspection and has issued a complete response

letter. As a result, we are currently unable to use the Almeida facility to produce doses of IXIARO intended for distribution in the United States. The Almeida facility is approved by EMA and Health Canada and operates under a manufacturers license from MHRA. Therefore, IXIARO doses produced at this facility will be sold in regions outside the United States. The Manson facility remains licensed under the FDA BLA for IXIARO and hence can be used for potential supplies of IXIARO to the U.S. As a result of the overall situation, we may experience supply constraints for IXIARO in the U.S. market and are assessing appropriate mitigation measures.

***Our production costs may be higher than we currently estimate.***

Our products and our product candidates are manufactured according to manufacturing best practices applicable to drugs for clinical trials and to specifications approved by the applicable regulatory authorities. If any of our products were found to be non-compliant, we would be required to manufacture the product again, which would entail additional costs and may prevent delivery of the product on time.

Other risks inherent in the production process may have the same effect, such as:

- contamination of the controlled atmosphere area;
- unusable premises and equipment;
- new regulatory requirements requiring a partial and/or extended stop to the production unit to meet the requirements;
- unavailable qualified personnel;
- power failure of extended duration; and
- logistical error.

Additionally, we could experience higher production costs as the result of the degree to which we utilize our manufacturing facilities, including if we externalize any aspect of manufacturing that we have historically performed internally

Overproduction leading to higher levels of inventory could also result in a higher cost of goods sold in the context of lower than forecasted sales, as in the case of IXCHIQ in the second half of 2025.

Should any of these risks materialize, this could have a material adverse effect our business, prospects, financial condition, and results of operations.

***We use hazardous chemicals and biological materials in our business and any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly.***

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We also handle genetically recombined material, genetically modified species, and pathological biological samples. Consequently, in France, Austria, Sweden, and Scotland where we have research and production facilities and in the jurisdictions where we conduct clinical trials, we are subject to environment and safety laws and regulations governing the use, storage, handling, discharge, and disposal of hazardous materials, including chemical and biological products. We impose preventive and protective measures for the protection of our workforce and waste control management in accordance with applicable laws, including part four of the French Labor Code, relating to occupational health and safety.

If we fail to comply with applicable regulations, particularly those applicable to all BSL classifications, we could be subject to criminal prosecutions, fines, damages, and the suspension of all or part of our operations. Compliance with environmental, health, and safety regulations involves additional costs, and we may have to incur significant costs to comply with future laws and regulations in relevant jurisdictions. Compliance with environmental laws and regulations could require us to purchase equipment, modify facilities, and undertake considerable expenses. We do not have insurance that specifically covers liability relating to hazardous materials and could be liable for any inadvertent contamination, injury, or damage, which could negatively affect our business and engage the civil and/or criminal liability of the Company and/or its representatives.

## Risks Related to Our Intellectual Property

***If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.***

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in Europe, the United States and other jurisdictions related to our product candidates and our technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity,

enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some countries do not protect intellectual property rights to the same extent as European laws and federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the EEA or the United States, or from selling or importing products that infringe our patents in and into the EEA or the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in EEA countries, the United States, and other jurisdictions. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or could limit the duration of the patent protection of our technology and product candidates. For example, one of our patents that relates to VLA84 has been limited in scope in opposition proceedings in 2022 in Europe. In another case in 2023, we decided to withdraw a patent covering IXIARO following an opposition proceeding in Europe. More recently in 2025, we have also received a further opposition by a third party against a European patent that is directed at IXIARO, and our Zika Product candidate, VLA1601. The proceeding started in June 2023, and an interlocutory decision of the Opposition Division at the EPO, published on 19 December 2025, has maintained claims in amended form which are still directed to IXIARO and VLA1601. We may face similar proceedings in the future that could have a significant effect on our ability to commercialize our products. We have also recently received an opposition by a third party against a European patent that is directed to our Zika product candidate, VLA1601. In the interlocutory decision of the Opposition Division at the EPO, published on 14. November 2025, claims still directed to VLA1601 have been maintained in amended form and no appeal has been filed. A further opposition by a third party against a European patent that is directed at VLA15 was made on January 2025 with the EPO.

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. As a result, such third parties, including governments and non-for-profit organizations, may have certain rights, including "march-in" rights, to such patent rights and technology. When new technologies are developed with such partners, they generally obtain certain rights in any resulting patents, including a nonexclusive license authorizing the party to use the invention for noncommercial purposes. These rights may permit the funding partner to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our licensed technology. The funding partner can exercise its "march-in" rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. or other country industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States or other countries. Any exercise by the funding partners of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

***Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our

owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

***Patent terms may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in the United States a patent's life can be extended based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations could be adversely affected.

Given the amount of time required for the development, testing, and regulatory review of our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. The Hatch-Waxman Act in the United States, and similar legislation in the European Union, permit a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable in the U.S. for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, in the United States, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. In the EEA, supplementary protection certificates, or SPCs, provide protection for the active ingredient of a patented and authorized medicinal product, which may extend for up to five years beyond the normal patent expiry date (providing together with the patent up to 15 years exclusivity from the first EU marketing authorization). In some cases an additional six months of SPC protection may be obtained by performing pediatric trials of the product. The protection afforded by an SPC extends only to the active ingredient of the authorized medicinal product, within the scope of the granted base patent. However, the applicable authorities may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data and may be able to launch their product earlier than might otherwise be the case.

***Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.***

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market, and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U.S.- and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk may increase that our product candidates may give rise to claims of infringement of the patent rights of others. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is

no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we have in the past and may in the future decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in Europe, the United States, and other jurisdictions could uphold the validity of any such patent. For example, we initiated an *inter partes* review proceeding before the U.S. Patent and Trademark Office against a Takeda U.S. patent no. 11,730,802 in 2025. This proceeding ended as the Patent Trial and Appeal Board decided to grant Institution for this proceeding following Takeda's withdrawal of some of the claims. The remaining claims do no longer cover a VLA1601 target product profile. Even if we are successful in obtaining a first-instance judgement from a court or patent office that such patents are invalid, such judgements may be subject to appeal procedures which suspend revocation of the patent until a final appeal judgment is reached. This may result in many years of uncertainty and could ultimately lead to reversal of the original judgment and the patent being upheld. Furthermore, because patent applications can take many years to issue and are typically confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate or technology platform infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties, or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or any return on our investment at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or may require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ordinary shares and ADSs.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects.

***We may be subject to claims asserting that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.***

Certain of our employees, consultants, or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may

lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications as a result of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

In some countries, the national law may stipulate that certain inventions made by an employee belong to the employer or employee and may restrict the ability of employment or other contracts to define which inventions belong *ab initio* to the employer. Thus in some countries employees could claim ownership of inventions by operation of national law and assignments may not be enforceable. Inventors may also assert additional rights relating to their inventive contribution, without necessarily claiming ownership. For instance, in some countries inventors are entitled to adequate remuneration or other benefit from an invention, even if the invention belongs by law to their employer. In some cases employee-inventors may also be entitled to pursue patent applications that the employer decides to abandon. Inventors claiming such rights may require us to pay additional compensation or might bring claims against us using the patent applications they acquire.

***We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors, or our other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.***

Competitors may infringe, misappropriate, or otherwise violate our patents, the patents of our licensors, or our other intellectual property rights, or may allege that we have infringed on their intellectual property rights. To counter infringement or unauthorized use or defend against such claims, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. For example, Takeda initiated an *inter partes* review proceeding before the U.S. Patent and Trademark Office on our Zika U.S. PATENT NO. 11,219,681. This proceeding ended as the Patent Trial and Appeal Board decided to deny Institution for this proceeding following our withdrawal of some of the claims. The remaining claims continue to cover VLA1601.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO or similar foreign authorities or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

***Developments in patent law could have a negative impact on our business.***

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, from time to time, the U.S. Congress, the USPTO, or similar foreign authorities may change the standards of patentability, and any such changes could have a negative impact on our business. In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process, such as allowing third-party submission of prior art to the USPTO during patent prosecution. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. Under a first-to-file system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor made the invention earlier. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective in March 2013. Substantive changes to patent law associated with the America Invents Act, or any subsequent U.S. legislation regarding patents, may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our U.S. patent applications, our ability to obtain U.S. patents based on our discoveries, and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, prospects, financial condition, and results of operations.

In addition, changes to or different interpretations of patent laws in the United States and other countries may permit others to use our or our partners' discoveries or to develop and commercialize our technology and product candidates without providing any compensation to us, or may limit the number of patents or claims we can obtain. The patent positions of companies in the biotechnology and pharmaceutical market are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of U.S. patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In Europe, the Enlarged Board of Appeal of the EPO has recently indicated that it is prepared to apply a "dynamic" interpretation of certain patent law provisions in view of political developments and thus could reverse previously pro-patentee positions relating to biotechnological and pharmaceutical inventions. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO, and the EPO, as well as similar bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future, which could have a material adverse effect on our business, prospects, financial condition, and results of operations.

***We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.***

Filing, prosecuting, and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, including certain developing countries such as Brazil and India, where we have transferred certain technology in the context of strategic collaborations, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, such a license may be issued in circumstances where demand for a product cannot be met by the patent holder in cases of a public health emergency, such as the COVID-19 pandemic. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we rely on third parties to help us discover, develop, and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing, or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements, or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. We also enter into invention or patent assignment agreements with our employees, advisors, and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

In addition, our competitors may independently develop knowledge, methods, and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations, and prospects.

We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by our collaborators, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. Our collaborators also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize our proprietary information or invalidate our intellectual property.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

***Any trademarks we have and that we may obtain may be infringed or successfully challenged, resulting in harm to our business.***

We rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. We entered into a co-existence agreement with respect to the VALNEVA trademark. The agreement places restrictions on how we can use this mark and how we can seek trademark protection for this mark.

In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

***Intellectual property rights do not necessarily address all potential threats to our business.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- others may be able to develop technologies that are similar to our technology platforms but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that are covered by a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

***If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.***

We have in-licensing agreements relating to certain of our products and product candidates, including with LimmaTech Biologics for S4V2 (Shigella).

If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the license agreement and other issues relating to interpretation of the relevant agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license granted to us;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, on the one hand, and us and our sublicensees, on the other hand.

## Risks Related to Regulatory Compliance

***Accelerated regulatory review and approval procedures do not guarantee faster development, review, or approval or that approval will ultimately be granted.***

Regulatory authorities such as the EMA and FDA offer various options for accelerated review and approval of product candidates, such as the EMA's PRIME designation for priority medicines and the FDA's Fast Track designation and accelerated approval pathway. We seek to take advantage of these opportunities in order to facilitate the development, review, and approval processes for our product candidates.

IXCHIQ, or VLA1553 in jurisdictions where it is subject to ongoing regulatory review, received PRIME designation from the EMA. The PRIME scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options, reviewed under the centralized procedure.

VLA15, our candidate against Lyme disease, and S4V2, the vaccine candidate against shigellosis that we are developing with LimmaTech Biologics, each received Fast Track designation from the FDA. Fast Track designation may be available

to help expedite the development or approval process for a drug that is intended for the treatment of a serious or life-threatening condition and that demonstrates the potential to address an unmet medical need for this condition.

PRIME or Fast Track designation does not change the standards for product approval or ensure that the product will receive marketing approval at all or within any particular timeframe. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. We may seek PRIME and/or Fast Track designation for other vaccine candidates in the future. If we do seek such designations for our other vaccine candidates, we may not receive such designations, and even if we receive designations, we may not experience a faster development process, review, or approval compared to conventional EMA or FDA procedures.

Although VLA15 and S4V2 have received Fast Track designation, this designation might not result in a faster or more successful development or review process or in ultimate approval of these product candidates by the FDA. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of any future products on this pathway.

Finally, the license for IXCHIQ in the United States (which we voluntarily withdrew in January 2026, as described elsewhere in this Annual Report) was granted under the FDA's accelerated approval pathway, and we may seek such approval for other vaccine candidates in the future. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials, such as the Phase 4 clinical trials that it required for IXCHIQ.

Even if we do receive accelerated approval for a future product candidate, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate approval.

***If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

The European Union provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial marketing authorization of the reference product in the European Union. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

We also believe that our product candidates in the EEA should benefit from this data and market exclusivity. As with the United States, however, if competitors obtain marketing authorization for their biosimilar products, our products may become subject to competition from these biosimilars, with the attendant competitive pressure and consequences.

***Even if we successfully commercialize any of our vaccine candidates, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement, and healthcare reform, all of which could adversely affect any commercial success of our vaccine candidates.***

Market acceptance and sales of any vaccine candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors. Therefore, our ability to collect revenue from the commercial sale of our vaccines may depend on our ability, and that of any current or potential future collaboration partners or customers, to obtain recommendations for us or adequate levels of approval, coverage, and reimbursement for such products from third-party payors such as:

- government health administration authorities, such as ACIP in the United States;
- private health insurers;
- managed care organizations;
- pharmacy benefit management companies; and
- other healthcare related organizations.

Third-party payors decide which therapies and vaccines they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, biological, and vaccine products, or formulary, generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of such product by patients and physicians. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Even patients for whom our products are recommended by the local health authority may be less likely to use our products if the level of coverage and reimbursement provided, if any, is not adequate relative to the level of potential risk of travelling while unvaccinated, as determined by the patient and their physician. In addition, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Third-party payors are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the applicable regulatory authorities, is not used in accordance with cost-effective treatment methods as determined by the third-party payor, or is experimental, unnecessary or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third parties is the biggest driver of the prices of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular product. We cannot be sure that coverage and reimbursement will be available for any vaccine that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any vaccine candidates that we develop.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced pharmaceutical pricing or reimbursement rates for medical products, which could adversely affect our business strategy, operations, and financial results.

For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug

Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business in the United States or elsewhere. In addition, we face uncertainties because there are ongoing federal legislative and administrative efforts to repeal, substantially modify, or invalidate some or all of the provisions of the ACA in the United States. We cannot predict the ultimate content, timing, or effect of any healthcare reform legislation or the impact of potential legislation on us. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement, the commercial success of our vaccine products may be greatly hindered, and our financial condition and results of operations may be materially and adversely affected.

Legislators, policymakers, and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

***Our relationships with customers, healthcare providers, and third-party payors are subject, directly or indirectly, to healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors subject us to various fraud and abuse laws and other healthcare laws.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Restrictions under applicable U.S. federal, state, and foreign healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses, and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf, and their subcontractors that use, disclose, or otherwise process individually identifiable health information;

- the Federal Food Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- similar healthcare laws and regulations in other jurisdictions, such as state anti-kickback and false claims laws, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts. Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These laws may include the French "Bertrand Law", French Ordinance n° 2017-49 of January 19, 2017 and Decree No. 2020-730 of June 15, 2020 relating to benefits offered by persons manufacturing or marketing health products or services, and the UK's Bribery Act 2010, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing, and/or transparency laws applicable to manufacturers or any company providing services related to their products that may be broader in scope than the federal requirements. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations is and will continue to be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, as well as damages, fines, disgorgement, imprisonment, exclusion from participating in U.S. government-funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, and the curtailment or restructuring of our operations.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares and ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing, or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal, or administrative sanctions, including exclusions from U.S. government-funded healthcare programs.

***Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations, and prospects.***

In the United States, the European Union and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States.

There have been amendments to and executive, judicial, and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and through subsequent legislation will remain in effect through 2032, unless additional Congressional action is taken.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, Centers for Medicare & Medicaid Services, or CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct- to -consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the Loper decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products, and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

In some countries, the proposed pricing for a biopharmaceutical product must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of biopharmaceutical products is subject to government control, and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, refuse to reimburse a product at the price set by the manufacturer, or adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Moreover, in the EEA some countries require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021, the HTA Regulation was adopted, and it entered into force on January 11, 2022. It will apply from 2025.

There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission, and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint

assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation and such changes were laid before parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization for the Company's product candidates on the basis of clinical trials conducted in the United Kingdom.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a number of changes to the regulatory framework governing medical products, including a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States or any other jurisdiction. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or if we or relevant third parties are not able to maintain regulatory compliance, we may not achieve or sustain profitability or our business may otherwise be materially impact.

***We are subject to various risks in connection with sustainability (environmental, social, and governance matters), including evolving and potentially conflicting regulatory regimes related to sustainability, which may impact our reputation, business, financial condition, and results of operations.***

As a publicly listed company in France and the United States, we are subject to regulations related to sustainability in both jurisdictions, including most notably the European Union's Corporate Sustainability Reporting Directive (CSRD), under which we are required to report extensive information about our environmental, social, and governance practices and associated impacts, risks, and opportunities. This information is included in our annual report for 2025 filed with the French Financial Markets Authority (*Authorité des marchés financiers*, or AMF). On February 26, 2025, the European Commission issued a proposal for significant changes to the CSRD and related regulations which, if implemented, would substantially reduce our future sustainability-related reporting obligations from a European perspective. We cannot guarantee that these proposed changes will be implemented, in whole or in part, and the timing of such implementation will determine numerous aspects of our sustainability-related activities, including the amount of resources allocated to support compliance with reporting on the scale required for the year ended December 31, 2025. Compliance with the CSRD and with the related EU Taxonomy Regulation requires significant time, attention, and resources. Similarly, we would be subject to the SEC's climate disclosure rules which were published in March 2024 and are currently suspended. We cannot predict if, when, or in what form such rules may apply to us in the future. Additionally, pushback against sustainability-related regulations and practices has gained momentum in the United States at the federal level and in certain states. Most notably, executive orders signed in January 2025 by President Trump addressing diversity, equity, and inclusion (DEI) could result in additional compliance obligations, scrutiny of our practices, and potential harm to our business, given that the U.S. Department of Defense is one of our key customers. Monitoring and adjusting to ongoing regulatory developments related to sustainability may impose unexpected costs or result in other interruptions to our operations that could have a material adverse effect on our business, financial condition, and results of operations.

Furthermore, expectations of stakeholders regarding sustainability also continue to evolve and may conflict with one another. Relevant stakeholders include investors, governments, customers, employees, third party business partners, and the communities in which we operate. While some stakeholders wish for companies to make commitments to sustainability, for example related to climate change, others may oppose such activities. In this context, we may not be able to meet stakeholder expectations, by failing to meet commitments, failing to make commitments or commitments of sufficient ambition, or by making commitments that may be perceived as misaligned with our strategy or corporate interests. Failing to meet stakeholder expectations related to sustainability could result in litigation or regulatory actions and impact our reputation, share price, recruitment and retention, financial condition, and results of operations. Our actions related to sustainability could also have a long-term and potentially negative impact on our operations and achievement of our strategic goals.

Additionally, our sustainability-related information published in compliance with the CSRD is subject to a different, more expansive standard of materiality than is understood in the context of U.S. federal securities laws and regulations. The double materiality standard requires the reporting entity to consider both financial materiality (i.e., sustainability matters which generate risks or opportunities that affect, or could reasonably be expected to affect, the Company's financial position, financial performance, cash flows, access to finance, or cost of capital over the short, medium, or long term) and impact materiality (i.e., the Company's material actual or potential, positive or negative impacts on people or the environment over the short-, medium-, and long-term). Impacts, risks, and opportunities are material if they satisfy one or both of these materiality tests. Such information should therefore not necessarily be interpreted as material in the U.S. context, even if the words "material" or "materiality" are used.

***We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations, and financial condition.***

We are subject to other laws and regulations governing our international operations, including regulations administered by the authorities in the United States, European Union, and United Kingdom, including applicable export control regulations, economic sanctions on countries and persons, and customs requirements and currency exchange regulations, collectively referred to as the trade control laws. Specifically, as a result of the Russian invasion of Ukraine in February 2022, the United States, the European Union, the United Kingdom, and other jurisdictions adopted a series of financial and trade sanctions in relation to Russia and Belarus and Russian and Belarussian listed citizens and entities.

Exports of our products and product candidates must be made in compliance with trade control laws. In some cases, certain licensing, authorization, or reporting requirements may need to be performed. In addition, these laws may restrict or prohibit altogether the supply of certain of our products, product candidates, or services to certain governments, persons, entities, countries, and territories. Changes in our products and product candidates or changes in applicable trade control laws may create delays in the introduction or provision of our products and product candidates in certain jurisdictions, prevent others from using our products and product candidates or, in some cases, prevent the export or import of our products and product candidates to certain countries, governments, or persons altogether. Any limitation on our ability to export or provide our products, product candidates, and services could adversely affect our business, financial condition, and results of operations.

We are also subject to anti-corruption laws in the countries where we operate, including the United States. The Foreign Corrupt Practices Act, or FCPA, prohibits companies and their employees, third-party intermediaries, and other associated persons from paying, offering, authorizing payment, or providing anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of a foreign entity in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. An executive order issued in February 2025 has created considerable uncertainty regarding whether and how the FCPA will continue to be enforced.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

French anti-corruption laws also prohibit acts of bribery and influence peddling:

- Article 433-1-1° of the French Criminal Code (bribery of domestic public officials);
- Article 433-1-2° of the French Criminal Code (influence peddling involving domestic public officials);
- Article 434-9 of the French Criminal Code (bribery of domestic judicial staff);
- Article 434-9-1 of the French Criminal Code (influence peddling involving domestic judicial staff);
- Articles 435-1 and 435-3 of the French Criminal Code (bribery of foreign or international public officials);
- Articles 435-7 and 435-9 of the French Criminal Code (bribery of foreign or international judicial staff);
- Articles 435-2, 435-4, 435-8 and 435-10 of the French Criminal Code (active and passive influence peddling involving foreign or international public officials and foreign or international judicial staff);
- Articles 445-1 and 445-2 of the French Criminal Code (bribery of private individuals); and
- French Law n°2016-1691 of December 9th, 2016 on Transparency, the Fight Against Corruption and the Modernization of the Economy (Sapin 2 Law), which provides for numerous new obligations for large companies such as the obligation to draw up and adopt a code of conduct defining and illustrating the different types of behavior to be proscribed as being likely to characterize acts of corruption or influence peddling, to set up an internal warning system designed to enable the collections of reports from employees relating to the existence of conduct or situations contrary to the company's code of conduct, to set up accounting control procedures, whether internal or external, designed to ensure that the books, registers and accounts are not used to conceal acts of corruption or influence peddling, to set up a disciplinary system for sanctioning company employees in the event

of a breach of the company's code of conduct or a system for monitoring and evaluating the measures implemented.

We are also subject to the UK Bribery Act 2010, which makes it a criminal offense to:

- Offer, promise, or give a financial or other advantage to a person to induce them to perform improperly or reward a person for improper performance (directly or via a third party). A bribe can be of any form, size, or value that would provide the intended recipient with some form of benefit or advantage. Bribes can include money, discounts, vouchers, loans, gifts, hospitality, accommodation, use of assets, preferential treatment, business advantage, and employment opportunities, among others;
- Request, agree to receive or accept a financial or other advantage with the intention of or as reward for improper performance (directly or via a third party);
- Attempt bribery of a foreign public official in order to obtain or retain business or an advantage in the conduct of business, either directly or via a third party;
- As a commercial organization, fail to prevent bribery, as a result of not having adequate procedures in place to prevent a person directly or associated with a company to commit any of the other offenses.

For the purposes of the UK Bribery Act 2010, "foreign public official" means an individual who:

- is an official or agent of a public international organization; or
- exercises a public function:
    - for or on behalf of a country or territory outside the Island (or any subdivision of such a country or territory); or
    - for any public agency or public enterprise of that country or territory (or subdivision).

We might not be effective in ensuring compliance by our employees, representatives, contractors, business partners, and agents with all applicable anti-corruption laws, including the FCPA, the French anti-corruption laws, or other applicable legal requirements, including trade control laws. If we are not in compliance with the FCPA, the French anti-corruption laws, and other anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. Likewise, any investigation of any potential violations of the FCPA, the French anti-corruption laws, other anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations, and financial condition.

***We (and the third parties with whom we work) receive, process, store, and use personal information and other data, which subjects us to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies, and other obligations related to data privacy and security. Our (and third parties with whom we work) actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, and otherwise adversely affect our business.***

We, and the third parties with whom we work, receive, process, store, and use personal information and other data about our clinical trial participants, employees, partners, and others. As a result, we, and the third parties with whom we work, are subject to numerous foreign and domestic laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations regarding data privacy and security. We strive to comply with all such applicable requirements and obligations; however, new laws, policies, codes of conduct, and other legal obligations may arise, continue to evolve, be interpreted and applied in a manner that is inconsistent from one jurisdiction to another, and conflict with one another. Any actual or perceived failure by us or third parties with whom we work to comply with applicable data privacy and security obligations may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims (to which we have been subject in the past), litigation, damage to our reputation, and loss of goodwill, any of which could have a material adverse effect on our business, operations, and financial performance.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., state surveillance and wiretapping laws such as California Invasion of Privacy Act). For example, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In addition, in the past few years, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt

some data processed in the context of clinical trials, but these developments further complicate compliance efforts and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers. Similar laws are being considered at the federal and local levels, and we expect more states to pass similar laws in the future. .

Our employees and personnel use generative, or AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR") and the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, apply to our operations and impose strict requirements for processing personal data.

For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to 20 million euros under the EU GDPR, 17.5 million pound sterling under the UK GDPR, or in each case, 4% of global annual revenue for the preceding financial year, whichever is higher, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws are generally believed to be inadequate. Other jurisdictions have adopted or may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanism that may be used to transfer personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal data from the EEA or United Kingdom. The inability to transfer personal data from the EEA, United Kingdom, or Switzerland may also restrict our clinical trials activities in such jurisdictions, limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to European data protection laws, and require us to increase our data processing capabilities in the EEA, United Kingdom, or Switzerland, likely at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

The EU GDPR provides that EEA countries may make their own further laws and regulations to introduce specific requirements related to the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes, and genetic information, as well as personal data related to criminal offences or convictions. In the United Kingdom, the United Kingdom Data Protection Act 2018 complements the UK GDPR in this regard. This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and/or United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use, and share data in the context of our EEA and/or United Kingdom establishments (regardless of where any processing in question occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

For example, in France, the conduct of clinical trials is subject to compliance with specific provisions. The French Law No.78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties, as amended, establishes a strict framework applicable to the processing of personal data in the health sector. This framework requires, among others, the filing of compliance undertakings with "reference methodologies" (such as the MR-001) adopted by the French Data Protection Authority, or CNIL, or, if not complying, obtaining an authorization from the CNIL. Failure to comply with the stringent provisions of the reference methodologies or failure to obtain the CNIL's authorization could expose us to adverse consequences, including the interruption of our clinical trials in France, increased exposure to regulatory actions, or the need to relocate part of or all of our data processing activities to other jurisdictions at significant expense.

It is possible that the EU and UK GDPR or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices, and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations, and we cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. Furthermore, other jurisdictions outside the EEA are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, and our efforts to comply with the evolving data protection rules may be unsuccessful. We cannot guarantee that we, our third-party collaborators, or our vendors are in compliance with all applicable data protection and privacy laws and regulations as they are enforced now or as they evolve. Further, for example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws. Our non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures, and systems. In addition, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts.

In addition to data privacy and security laws, we are subject to contractual obligations based on industry standards adopted by industry groups, such as best practices governing the conduct of clinical trials, and we are, or may become, subject to such obligations in the future. We are also subject to contractual obligations related to data privacy and security. Our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU and UK GDPR and CCPA, may require us to impose specific contractual restrictions on certain service providers that have access to personal data, such as clinical trial patient data or personal data of clinical trial site personnel. We publish privacy policies, marketing materials, and other statements regarding data privacy and security on our website. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, or unfair, or to misrepresent our practices, we may be subject to investigation, enforcement actions by regulators (such as the Federal Trade Commission), or other adverse consequences.

Our actual or perceived failure to adequately comply with applicable obligations relating to data privacy and security, could result in regulatory enforcement actions against us, including fines, penalties, orders that require a change in our practices, additional reporting requirements and/or oversight, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits, or reputational damage.

***We benefit from tax credits in Austria, France, and Scotland that could be reduced or eliminated.***

As a company with research and development activity, we benefit from certain tax advantages, including the Austrian Research and Development tax credit, the French Research Tax Credit (*Crédit Impôt Recherche*) and the Scottish Research and Development tax credit, which are tax credits aimed at stimulating research and development. Our Austrian Research and Development tax credits were €3.5 million, €3.6 million, and €5.7 million for the years ended December 31, 2025, 2024, and 2023, respectively. Our French Research Tax Credits were €1.1 million, €1.3 million, and €1.1 million for the years ended December 31, 2025, 2024, and 2023, respectively. Our Scottish Research and Development tax credit amounted to €0.4 million in the year ended December 31, 2025 (December 31, 2024: €5.2 million , December 31, 2023: zero). The Austrian Research and Development tax credit is calculated based on claimed amount of eligible research and development in Austria, while the French Research Tax credit is calculated based on our claimed amount of eligible research and development expenditures in France. The main differences between the Austrian and French research tax credits are the applicable percentage of and the basis for the tax credit. The tax credits are a source of financing to us that could be reduced or eliminated by the Austrian and French tax authorities or by changes in Austrian and French tax law or regulations.

The Austrian Research and Development tax credit is reimbursed to us. While the Austrian Research and Development tax credit is reviewed as a part of the issuance of a certificate by the local auditor and the research and development projects need an approval from the Austrian Research Promotion Agency (FFG), the Austrian tax authority may audit each research and development claim. The Austrian tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions in respect of our research and development activities (and therefore the amount of Research and Development Tax Credit claimed). Furthermore, the Austrian Parliament may decide to eliminate, or to reduce the scope or the rate of, the Research Tax Credit benefit, either of which it could decide to do at any time.

The French Research Tax Credit can be offset against French corporate income tax due with respect to the year during which the eligible research and development expenditures have been made. The portion of tax credit in excess which is not being offset, if any, represents a receivable against the French Treasury which can in principle be offset against the French corporate income tax due by the company with respect to the three following years. The remaining portion of tax credit not being offset upon expiry of such a period may then be refunded to the company. The French Research Tax credit is reimbursed within the expiry of a period of three years.

The French tax authorities, with the assistance of the Higher Education and Research Ministry, may audit each research and development program in respect of which a Research Tax Credit benefit has been claimed and assess whether such program qualifies in their view for the Research Tax Credit benefit. The French tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities (and therefore the amount of Research Tax Credit claimed). Furthermore, the French Parliament may decide to

eliminate, or to reduce the scope or the rate of, the Research Tax Credit benefit, either of which it could decide to do at any time.

The United-Kingdom Research and Development (R&D) tax relief supports companies that work on innovative projects in science and technology. To qualify for R&D relief, a project must seek an advance in a field of science or technology. Only companies chargeable to UK Corporation Tax can qualify for this relief. The British tax authority may audit each research and development claim. The British tax authorities may challenge our eligibility for, our calculation of, certain tax reductions in respect of our research and development activities (and therefore the amount of Research and Development Tax Credit claimed).

If we fail to receive future Research Tax Credit amounts or if our calculations are challenged, even if we comply with the current requirements in terms of documentation and eligibility of its expenditure, our business, prospects, financial condition, and results of operations could be adversely affected.

Our Research Tax Credits may periodically be subject to audits by local tax authorities. In January 2026, the Austrian tax authorities initiated a tax audit for the years 2021-2023 and covering Research Tax Credits as well as income tax and Value Added Tax. A tax audit could potentially in a reduction of previously reimbursed tax credits and related claw back or an increase in prior year income tax.

***We may be unable to carry forward existing tax losses.***

We have accumulated tax loss carry forwards of €899.6 million, €843.6 million, and €879.1 million for the years ended December 31, 2025, 2024, and 2023, respectively in several locations, including Austria. Applicable French law provides that, for fiscal years ending after December 31, 2012, the use of these tax losses is limited to €1.0 million, plus 50% of the portion of net earnings exceeding this amount. The unused balance of the tax losses in application of such rule can be carried forward to future fiscal years, under the same conditions and without time restriction. If we decide to change our corporate structure or substantially change our presence in a particular jurisdiction, this could have an effect on our ability to retain or use these tax loss carry forwards. In addition, future changes to applicable tax law and regulation could eliminate or alter these or other provisions in a manner unfavorable to us.

***Comprehensive tax reform legislation or other changes to tax laws could adversely affect our business and financial condition.***

Corporate tax reform, anti-base-erosion rules and tax transparency continue to be high priorities in many jurisdictions. As a result, policies regarding corporate income and other taxes in numerous jurisdictions are under heightened scrutiny and tax reform legislation has been, and will likely continue to be, proposed or enacted in a number of jurisdictions in which we operate.

Legislation referred to as the One Big Beautiful Bill Act enacted in 2025 (the "OBBBA"), the Inflation Reduction Act enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 made many significant changes to the U.S. Internal Revenue Code of 1986, as amended. The U.S. Department of Treasury has broad authority to issue regulations and interpretative guidance with respect to new or existing legislation, and certain aspects of existing legislation could be repealed or modified or sunset in future years, which may have a significant impact on our results of operations in the period issued, including our effective tax rate.

In addition, many countries are implementing legislation and other guidance to align their international tax rules with those of the Organization for Economic Co-operation and Development, or OECD, whose base erosion and profit shifting recommendations and action plan aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. The OECD is also continuing discussions surrounding fundamental changes in allocation of profits among tax jurisdictions in which companies do business, as well as the implementation of a global minimum tax (namely the "Pillar One" and "Pillar Two" proposals). As a result of this heightened scrutiny, prior decisions by tax authorities regarding treatments and positions of corporate income taxes could be subject to enforcement activities and legislative investigation and inquiry, which could also result in changes in tax policies or prior tax rulings. Any such changes may also result in the taxes we previously paid being subject to change.

## Risks Related to Ownership of Our Ordinary Shares and the ADSs

***We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ordinary shares and ADSs. In addition, French law may limit the amount of dividends we are able to distribute.***

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth.

Therefore, the holders of our ordinary shares and ADSs are not likely to receive any dividends for the foreseeable future and the success of an investment in our ordinary shares and ADSs will depend upon any future appreciation in value. Consequently, investors may need to sell all or part of their holdings of the ordinary shares or ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ordinary shares or ADSs will appreciate in value or even maintain the price at which our shareholders have purchased them.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with accounting standards applicable in France. Moreover, pursuant to French law, we must allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends, should we propose to declare any, may be paid for that year, until the amount in the legal reserve is equal to 10% of the aggregate nominal value of our issued and outstanding share capital. In addition, payment of dividends may subject us to additional taxes under French law. Therefore, we may be more restricted in our ability to declare dividends than companies that are not incorporated in France.

In addition, exchange rate fluctuations may affect the amount of euro that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euro, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

***Future sales of ordinary shares or ADSs by existing shareholders could depress the market price of the ordinary shares or ADSs.***

Future sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs and/or ordinary shares. Sales in the United States of our ADSs and ordinary shares held by our directors, officers, and affiliated shareholders or ADS holders are subject to restrictions. If these shareholders or ADS holders sell substantial amounts of ordinary shares or ADSs in the public market, or the market perceives that such sales may occur, the market price of our ADSs or ordinary shares and our future ability to raise capital through an issue of equity securities on favorable terms could be adversely affected.

***The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.***

Our ADSs are listed on the Nasdaq Global Select Market and our ordinary shares are listed on Euronext Paris. Trading of the ADSs or ordinary shares in these markets takes place in different currencies (U.S. dollars on Nasdaq and euro on Euronext Paris), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and France). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on Euronext Paris could cause a decrease in the trading price of the ADSs on Nasdaq. Investors could seek to sell or buy our ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange, and the ordinary shares available for trading on the other exchange. In addition, holders of ADSs will not be immediately able to surrender their ADSs and withdraw the underlying ordinary shares for trading on the other market without effecting necessary procedures with the depositary. This could result in time delays and additional cost for holders of ADSs. We cannot predict the effect of this continued dual listing on the value of our ordinary shares and the ADSs. However, the continued dual listing of our ordinary shares and ADSs may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States.

***The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.***

We are a European public company with limited liability (*Societas Europaea or SE*), with our registered office in France. Our corporate affairs are governed by our bylaws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our Board of Directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our Board of Directors is required by French law to consider the interests of our company, its shareholders, its employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder or holder of ADSs. Further, in accordance with French law, as long as a double voting right is attached to each ordinary share which is held in registered form in the name of the same shareholder for at least two years, ordinary shares deposited with the depositary will not be entitled to double voting rights. Therefore, holders of ADSs who wish to obtain double voting rights will need to surrender their ADSs, withdraw the deposited shares, and take the necessary steps to hold such ordinary shares in registered form in the holder's name for at least two years. See "Item 16G—Corporate Governance."

***U.S. investors may have difficulty enforcing civil liabilities against our company and members of the Executive Committee and the Board of Directors.***

Most of the members of our Executive Committee and Board of Directors and the experts named in this Annual Report are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these

civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters.

***Our bylaws and French corporate law contain provisions that may delay or discourage a takeover attempt.***

Provisions contained in our bylaws and French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of the share capital and voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the EEA Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, a non-resident of France as well as any French entity controlled by non-residents of France may have to file a declaration for statistical purposes with the Bank of France (Banque de France) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- under French law, certain investments in a French company relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France or controlled by entities not French or not resident in France, are subject to prior authorization of the Ministry of Economy;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our Board of Directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted our Board of Directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our ordinary shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our Board of Directors appoints the members of the Executive Committee, notably the Chief Executive Officer (*Directeur Général*);
- our Board of Directors has the right to appoint members of the Board to fill a vacancy created by the resignation or death of a member of the Board for the remaining duration of such member's term of office, and subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our Board;
- our Board of Directors can be convened by the Chair, Vice-Chair, or Lead Independent Member or, if there has been no Board meeting for more than two months, by Directors representing one-third of the Board;
- our Board of Directors meetings can take place in person, by way of videoconference or teleconference or by written consultation and for decisions of the Board of Directors to be valid, at least half of the Directors must be present or represented;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove members of the Board of Directors with or without cause;
- the crossing of certain ownership thresholds has to be disclosed and can impose certain obligations;

- advance notice is required for nominations to the Board of Directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a member of the Board can be proposed at any shareholders' meeting without notice;
- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Regulation 596/2014 of April 16, 2014; and
- pursuant to French law, our bylaws, including the sections relating to the number of members of the Board of Directors and Associate Managing Officers, and election and removal of members of the Board of Directors, the Chief Executive Officer, and Associate Managing Officers from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

***There is a material weakness in our internal controls over financial reporting, and if we are unable to maintain effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence, and depress the market price of our securities.***

There is a material weakness in our internal controls over financial reporting, and if we are unable to maintain effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence, and depress the market price of our securities.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting, and we are also required to have our independent registered public accounting firm issue an opinion on the effectiveness of our internal controls over financial reporting on an annual basis. To ensure compliance with Section 404, we will need to continue to dedicate internal resources to our remediation efforts.

We have identified a material weakness in our internal controls over financial reporting in connection with the preparation of the consolidated financial statements included with this Annual Report. In connection with the preparation of our consolidated financial statements as at and for the year ended December 31, 2025, we identified that we did not did not design and operate effective controls to ensure that all instances of complex, judgmental, and non-routine or unusual transactions were (i) timely identified, (ii) subjected to a level of technical accounting analysis and review commensurate with their complexity, and (iii) supported by sufficiently detailed documentation evidencing management's evaluation of applicable IFRS recognition and measurement criteria.

These deficiencies, which individually do not qualify as material weakness constitute a material weakness in the aggregate. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. This and other potential material weaknesses that we could identify in the future could result in a material misstatement in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. For further information about the material weaknesses identified, see Item 15 of this Annual Report.

We are in the process of designing and implementing remediation plans to address the material weakness, which we believe will address the underlying causes of each deficiency. We will continue to evaluate the effectiveness of these enhanced controls, including a structured process for ensuring that any identified deficiencies are remediated promptly. However, remediation will not occur until the plans are implemented and there has been appropriate time for us to conclude through testing that the controls operate effectively. See Item 15 of this Annual Report for further details about the planned remediation measures.

We cannot assure you that our remediation efforts will be effective, that we will be able to remedy this material weakness or that we will be able to prevent any future material weaknesses in our internal control over financial reporting.

The process to document and evaluate our internal control over financial reporting is both costly and challenging, and we need to continue to dedicate internal resources to this process. Besides the material weakness identified, the controls that we have judged to be effective for the year ended December 31, 2025 may not continue to be effective, and we might not be able to prevent any future material weaknesses in our internal control over financial reporting.

If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the United States, our business and reputation may be harmed, and the price of our ordinary shares and ADSs may decline. In addition, undetected material weaknesses in our internal control over financial reporting could lead to restatements of financial statements and require us to incur the expense of remediation. Any of these developments could result in investor perceptions of us being adversely affected, which could cause a decline in the market price of our securities.

***Existing and potential investors in our ordinary shares or ADSs may have to request the prior authorization from the French Ministry of Economy prior to acquiring a significant ownership position in our ordinary shares or ADSs.***

Under French law, investments of more than 10% by certain individuals or entities in a French-listed company deemed to be a strategic industry may be subject to prior authorization of the French Ministry of Economy pursuant to Articles L. 151-1 et seq. and R. 151-1 et seq. of the French Monetary and Financial code.

If an investment requiring the prior authorization of the French Minister of Economy is completed without such authorization having been granted, the French Minister of Economy might direct the relevant investor to nonetheless (i) submit a request for authorization, (ii) have the previous situation restored at its own expense or (iii) amend the investment. The relevant investor might also be found criminally liable and might be sanctioned with a fine which cannot exceed the greater of: (i) twice the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company and (iii) €5 million (for an entity) or €1 million (for an individual). Criminal penalties may also be imposed upon complaint by the French Minister of Economy in accordance with the French Customs Code.

Failure to comply with such measures could result in significant consequences on the applicable investor. Such measures could also delay or discourage a takeover attempt, and we cannot predict whether these measures will result in a lower or more volatile market price of our ADSs.

***Purchasers of ADSs are not directly holding our ordinary shares.***

A holder of ADSs is not treated as one of our shareholders and does not have direct shareholder rights, unless he or she withdraws the ordinary shares underlying his or her ADSs. French law governs our shareholder rights. The depositary, through the custodian or the custodian's nominee, is the holder of the ordinary shares underlying ADSs. Purchasers of ADSs have ADS holder rights. The deposit agreement among us, the depositary, and ADS holders sets out ADS holder rights, as well as the rights and obligations of us and the depositary. ADS holders are encouraged to read the deposit agreement, which is filed as an exhibit to this Annual Report.

***Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings.***

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, our ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

***You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.***

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (i) the notice of the meeting or solicitation of consent or proxy sent by us and (ii) a statement as to the manner in which instructions may be given by the holders.

You may instruct the depositary of your ADSs to vote the ordinary shares underlying your ADSs. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the ordinary shares underlying the ADSs you hold. However, you may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for your instructions, the depositary, upon timely notice from us, will notify you of the upcoming vote and arrange to deliver our voting materials to you. We cannot guarantee you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares or to withdraw your ordinary shares so that you can vote them yourself. If the depositary does not receive timely voting instructions from you, it may give a proxy to a person designated by us to vote the ordinary shares underlying your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote, and there may be nothing you can do if the ordinary shares underlying your ADSs are not voted as you requested.

***You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying ordinary shares.***

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer, or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government, or

governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting, or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes, and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

***ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.***

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders, including holders who acquire ADSs in the secondary market, waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action. Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

***As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.***

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents, or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. Members of our Board of Directors and Executive Committee are exempt from the reporting provisions of Section 16(a) of the Exchange Act, and they and our 10% or greater shareholders are still exempt from the "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Paris and expect to file financial reports on an annual and semi-annual basis, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. In addition, foreign private issuers are not required to file their Annual Report on Form 20-F until four months after the end of each fiscal year. Accordingly, there is less publicly available information concerning our company than there would be if we were not a foreign private issuer.

***As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards, and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.***

As a foreign private issuer listed on Nasdaq, we are subject to Nasdaq's corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of its home country. Some corporate governance practices in France may differ significantly from Nasdaq corporate governance listing standards. We intend to continue to rely on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq corporate governance standards, to the extent possible. For example, neither the corporate laws of France nor our bylaws require a majority of the members of our Board of Directors to be independent, and although the corporate governance code to which we currently refer (the Middlenext Code) recommends that at least two of the members of the

Board of Directors be independent (as construed under such code), this code only applies on a "comply-or-explain" basis, and we may in the future either decide not to apply this recommendation or change the corporate code to which we refer. Furthermore, we could include non-independent members of the Board of Directors as members of our Nomination, Governance and Compensation committee, and the independent members of our Board of Directors would not necessarily hold regularly scheduled meetings at which only independent members of the Board are present. In addition, we follow French law with respect to shareholder approval requirements in lieu of the various shareholder approval requirements of Nasdaq. Currently, we intend to continue to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

***We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.***

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made on June 30, 2026. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our Board of Directors or Executive Committee are residents or citizens of the United States, we could lose our foreign private issuer status. As of December 31, 2025, approximately 27% of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held by U.S. residents (assuming that all holders of ADSs as of such date are residents of the United States).

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer in the future, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices required of U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

***If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.***

Under the Code, a non-U.S. company will be considered a passive foreign investment company, or PFIC, for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the weighted-average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property, and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation or partnership is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation or partnership. If we are a PFIC for any taxable year during which a U.S. holder (as defined in Item 10D, "Taxation") holds our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds our ordinary shares or ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

We do not believe that we were characterized as a PFIC for the taxable year ending December 31, 2025. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance regarding if we currently are treated as a PFIC, or may be treated as a PFIC in the future. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current or future taxable year.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see Item 10D of this Annual Report.

***Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes, or non-realization of expected benefits.***

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

A tax authority may take the position that material income tax liabilities, interest, and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

## General Risk Factors

***The trading price of our equity securities has been and may continue to be volatile, and purchasers of our ordinary shares or ADSs could incur substantial losses.***

The price of our ordinary shares and ADSs has been, and likely will continue to be, significantly affected by events such as announcements regarding scientific and clinical results concerning product candidates currently being developed by us, our collaboration partners, or our main competitors, changes in market conditions related to our sector of activity, announcements of new contracts or amendments or terminations to existing contracts, technological innovations and collaborations by us or our main competitors, developments concerning intellectual property rights, the development, regulatory approval and commercialization of new products by us or our main competitors, and changes in our financial results.

Equity markets are subject to considerable price fluctuations, and often, these movements do not reflect the operational and financial performance of the listed companies concerned. In particular, biotechnology companies' share prices have been highly volatile and may continue to be highly volatile in the future. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry. Fluctuations in the stock market as well as the macro-economic environment could significantly affect the price of our ordinary shares. As a result of this volatility, investors may not be able to sell their ordinary shares or ADSs at or above the price originally paid for the security. The market price for our ordinary shares and ADSs may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results, including as a result of clinical trial results, particularly the Phase 3 results of our Lyme disease vaccine candidate, and other announcements related to our clinical pipeline;
- adverse results or delays in our or any of our competitors' pre-clinical studies or clinical trials or regulatory timelines;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates or suspension or withdrawal of regulatory approval for existing products;
- the termination or amendment of a strategic alliance, partnership, or collaboration or the inability to establish additional strategic alliances, partnerships, or collaborations;
- actual or expected regulatory or legal developments in the United States, European Union, and other jurisdictions, including those that may impact the pharmaceutical industry as a whole;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, divestitures, strategic partnerships, joint ventures, collaborations, or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- ordinary share and ADS price and volume fluctuations attributable to inconsistent trading volume levels of our ordinary shares and ADSs;
- price and volume fluctuations in trading of our ordinary shares on Euronext Paris;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent and other intellectual property protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions, including macroeconomic factors such as geopolitical instability, rising interest rates, the impact of trade policies, including the implementation of tariffs, and inflation.

These and other market and industry factors may cause the market price and demand for our ordinary shares and ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares or ADSs and may otherwise negatively affect the liquidity of the trading market for the ordinary shares and ADSs. In addition, in the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could be costly and time consuming and divert management's attention and resources. We are aware through publicly

available information that U.S.-based law firms specializing in shareholder lawsuits have announced the commencement of "investigations" of our company following a decline in ADS trading price allegedly in connection with announcements about IXCHIQ in 2025. As of the date of this Annual Report, we have not received notice of any actual claims, but we cannot exclude the possibility of a lawsuit relating to these investigations or any others that may be announced.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ordinary shares or ADSs and their trading volume could decline.***

The trading market for the ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. As a public company in France since 2013 and in the United States since May 2021, our equity securities are currently subject to coverage by a number of analysts. If fewer securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares could be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of our ordinary shares and ADSs would likely decline. Additionally, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our ordinary shares and ADSs could decrease, which could cause the price of our ordinary shares and ADSs or their trading volume to decline.

# Item 4. Information on the Company

## A. History and Development of the Company

Our legal name is "Valneva SE". We are a public company listed on the Nasdaq Global Select Market and Euronext Paris that was formed in 2013 through the merger of Intercell, an Austrian vaccine biotech company listed on the Vienna Stock Exchange, and Vivalis, a French biotech company listed on Euronext Paris. We were incorporated on March 24, 1999 as a limited liability company and converted into a European Company (Societas Europaea, or SE) on May 28, 2013. Our registered office is located at Îlot Saint Joseph Bureaux Convergence – 12T Quai Perrache – 69002 Lyon, France. We are registered at the Lyon Trade and Companies Registry under the number 422 497 560. Our telephone number at our principal executive offices is +33 2 28 07 37 10.

We have nine wholly owned subsidiaries—Valneva Austria GmbH, a limited liability company formed under the laws of Austria in 2013; Valneva Scotland Ltd., a private company limited by shares formed under the laws of Scotland in 2003; Valneva USA, Inc., a Delaware corporation formed in 1997; Vaccines Holdings Sweden AB, a private limited company formed under the laws of Sweden in 2014; Valneva Sweden AB, a private limited company formed under the laws of Sweden in 1992; Valneva Canada, Inc., a corporation formed under the laws of Canada in 2015; Valneva UK Ltd., a private company formed under the laws of England and Wales in 2015; Valneva France SAS, a *société par actions simplifiée* formed under the laws of France in 2019; and VBC 3 Errichtungs GmbH, a limited liability company formed under the laws of Austria that we acquired in 2023 in connection with the purchase of the office building we occupy in Vienna. Our agent for service of process in the United States is Valneva USA, Inc.

Our website address is www.valneva.com. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not incorporated by reference into this Annual Report and does not constitute a part of this Annual Report.

The SEC maintains an internet site at http://www.sec.gov that contains reports and other information that we file electronically with the SEC.

Our full capital expenditures in the years ended December 31, 2025, 2024, and 2023 totaled €2.7 million, €17.2 million, and €18.3 million respectively, primarily related to investments in our manufacturing facilities in Scotland and Sweden. We expect our capital expenditures in 2026 to be primarily financed from our existing cash and cash equivalents.

## B. Business Overview

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best-, or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early Research & Development (R&D) to approvals, and currently market three proprietary travel vaccines.

Revenues from our commercial business help fuel the continued advancement of our vaccine development pipeline. Our clinical portfolio is composed of highly differentiated vaccine candidates that are designed to provide preventative solutions for diseases with high unmet need. Our pipeline includes the only Lyme disease vaccine candidate (VLA15) in advanced clinical development, which we are developing in partnership with Pfizer, as well as the world's most clinically advanced tetravalent Shigella vaccine candidate, under development in collaboration with LimmaTech Biologics AG (LimmaTech), and proprietary vaccine candidates against other global public health threats.

**VLA15** is a Phase 3 vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease, under development in collaboration with Pfizer, and it is the only vaccine candidate against Lyme disease currently undergoing late-stage clinical trials. Pfizer and Valneva are currently executing the Phase 3 field efficacy trial for VLA15 called VALOR (Vaccine Against Lyme for Outdoor Recreationists). Vaccinations were completed in July 2025. Participants were monitored for the occurrence of Lyme disease cases until the end of 2025. VLA15 targets the six most prevalent serotypes of Borrelia in the

Northern Hemisphere. In the United States approximately 476,000 people are diagnosed with Lyme disease each year and in Europe at least a further 132,000 cases occur annually.

**VLA1553** is a single-dose, live-attenuated vaccine against chikungunya, currently marketed outside the United States under the brand name IXCHIQ. The product continues to be evaluated in ongoing Phase 3/4 clinical trials, including post-marketing studies. It is currently approved for use in individuals 12 years of age and older in the European Union and Canada and in individuals 18 years to 59 years of age in the United Kingdom (UK) and Brazil. IXCHIQ received approval in the United States in November 2023; however, in January 2026, we voluntarily withdrew both the Biologics License Application (BLA) and the Investigational New Drug (IND) application for IXCHIQ. For additional details about decisions of regulatory agencies and changes to the IXCHIQ label since its initial licensure, please see the section on IXCHIQ in our "Our Commercial Portfolio", further below in this Item 4B.

**Shigella4V2 (S4V2)** is a Phase 2 tetravalent bioconjugate vaccine candidate against shigellosis, a diarrheal infection caused by Shigella bacteria, under development in collaboration with LimmaTech. Shigellosis is the second leading cause of fatal diarrheal disease worldwide. It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to Shigella each year, particularly among children in Low and Middle Income Countries (LMICs). No approved Shigella vaccine is currently available outside of Russia or China, and the development of Shigella vaccines has been identified as a priority by the World Health Organization (WHO). In October 2024, the FDA granted Fast Track designation to S4V2, recognizing its potential to address a serious condition and fill an unmet medical need. Two clinical trials of S4V2 are ongoing: a Phase 2 infant safety and immunogenicity trial, and a Phase 2b Human Challenge Study (CHIM), sponsored by LimmaTech. Subject to positive results for both of these trials, we will assume responsibility for all further development of S4V2.

**VLA1601** is a Phase 1 vaccine candidate targeting the Zika virus (ZIKV), a mosquito-borne viral disease whose transmission has been reported in 92 countries and territories and persists in several countries in the Americas and other endemic regions. There are no preventive vaccines or effective treatments available. As such, Zika remains a public health threat and is included in the FDA's Tropical Disease Priority Review Voucher Program. VLA1601 was developed on the original manufacturing platform of our licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop our inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. We reported positive Phase 1 results in November 2025 and will only consider further potential development steps for VLA1601 if concrete private and public funding opportunities materialize.

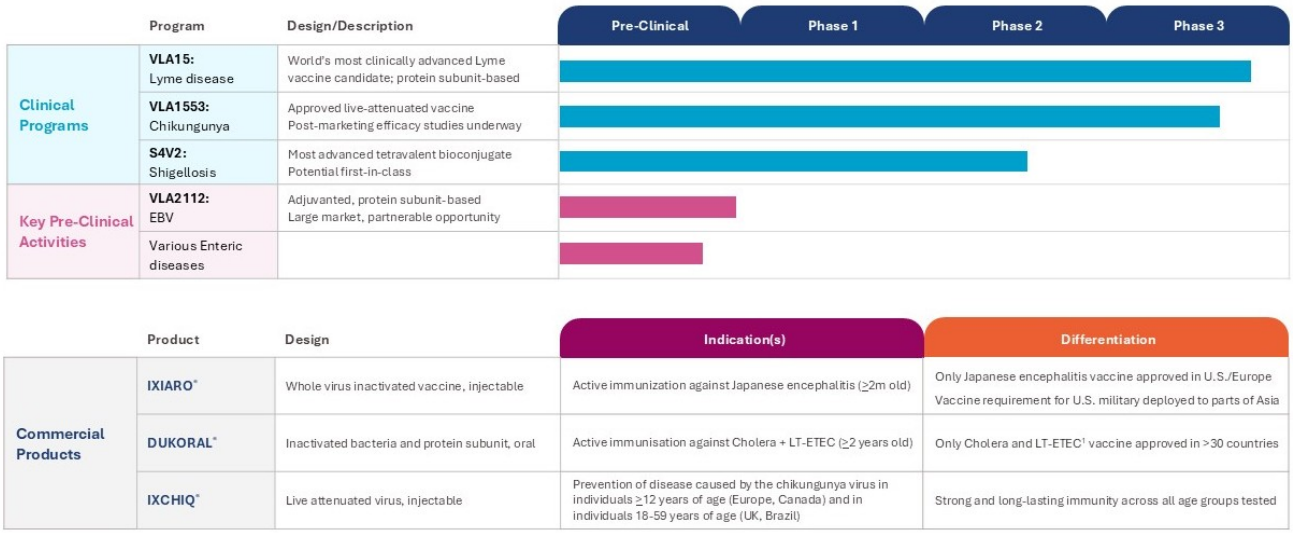
We commercialize a portfolio of proprietary and differentiated traveler vaccines, which is composed of IXIARO (also marketed as JESPECT in Australia and New Zealand), DUKORAL, and IXCHIQ. IXIARO is indicated for the prevention of Japanese encephalitis in travelers and military personnel. DUKORAL is indicated for the prevention of cholera and, in Canada, Switzerland, New Zealand, and Thailand, prevention of diarrhea caused by LT - Enterotoxigenic Escherichia coli, or LT- ETEC, the leading cause of travelers' diarrhea. IXCHIQ is indicated for active immunization for the prevention of disease caused by chikungunya virus (CHIKV) and marketed in Europe, Canada, Brazil, and the United Kingdom. This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody levels and is subject to confirmatory Phase 4 trials. IXCHIQ received approval in the United States in November 2023; however, in January 2026, we voluntarily withdrew both the BLA and the IND, as further detailed in "Our Commercial Products" below.

We have a highly developed, nimble and sophisticated manufacturing infrastructure with facilities across Europe to meet our clinical and commercial needs, including BioSafety Level 3 (BSL-3) manufacturing and R&D facilities. We have assembled a team of experts with deep scientific, clinical and business expertise in biotechnology and specifically in vaccine development, manufacturing and commercialization. Our senior leadership team has extensive experience and demonstrated ability to move vaccines through the clinic and into successful commercialization. Members of our team have previously worked at industry leaders such as Novartis, Chiron, GlaxoSmithKline, Janssen and Daiichi Sankyo.

## Our Pipeline

Our pipeline consists of assets at all stages of research & development. Our goal is to develop vaccine candidates that are first-, best-, or only-in-class and address unmet needs in infectious diseases. Our aim is to develop these assets for future commercialization either in-house or through and with partners.

Our advanced clinical pipeline and commercialized products are summarized below:




*1.Indications differ by country. ETEC stands for Enterotoxigenic Escherichia coli (E. Coli) bacterium. 2 Controlled human infection model.*

## Our Strategy

Our strategy supports our vision to live in a world in which no one dies or suffers from a vaccine-preventable disease. Our strategy is based on an integrated business model that has allowed us to build a portfolio of differentiated clinical and pre-clinical assets as well as an established commercial business. We are focused on utilizing our proven and validated product development capabilities to rapidly advance vaccine candidates addressing unmet needs in infectious diseases towards regulatory approval, with the goal of delivering first-, best-, or only-in-class preventative solutions. We have entered into strategic partnerships with other well-established pharmaceutical companies to leverage their clinical and commercial capabilities to optimize the potential value of select assets. As we advance our late-stage portfolio, we also remain focused on investing in our research and development pipeline in order to develop our earlier-stage assets as well as identify new targets and indications where we believe we can make a significant difference.

In order to execute upon this strategy as an independent, financially sustainable company, we are pursuing the following strategic goals:

- **Advance VLA15 for the prevention of Lyme disease in collaboration with Pfizer.** We are awaiting results from the pivotal, placebo-controlled efficacy clinical trial, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)" in the first half of 2026, conducted by our partner Pfizer. Pfizer aims to submit a BLA to the FDA and an MAA to the EMA in 2026, subject to positive data. If VLA15 is approved, Pfizer will have sole responsibility for the vaccine's manufacturing and commercialization, and we will be eligible to receive milestone and royalty payments.
- **Drive commercial growth.** We aim to maintain the trajectory of our established proprietary travel vaccines (IXIARO, DUKORAL) and unlock IXCHIQ's value in the markets where the vaccine is and may in the future be approved. We expect to further expand global reach with new partnerships with a focus on generating cash to invest in innovative R&D.
- **Progress our pipeline of clinical and pre-clinical programs and curate a rich portfolio of differentiated niche and large market opportunities.** To become a leader in the development of prophylactic vaccines, we intend to continue progressing our vaccine candidates to fulfill unmet medical needs and identify additional disease targets with the potential to be effectively prevented by vaccines. This includes further strategic augmentation of our clinical pipeline in order to generate long-term shareholder value.
- **Opportunistically pursue strategic collaborations to maximize full potential of our clinical and commercial portfolios.** We intend to continue to selectively evaluate collaborations to leverage the clinical and commercial expertise of large pharmaceutical companies.
- **Focus on stringent cost management.** We will continue focusing on stringent cost management for optimal alignment of capital allocation and shareholder value creation.

- **Maintain an attractive workplace by further strengthening our focus on sustainability agendas.** As a member of the United Nations Global Compact, we intend to further deliver on our three pillars of responsible business commitments: Protecting Lives, Reaching People, and Preserving the Planet.

## Background to Vaccine Development

Infectious diseases have widely affected, and continue to widely affect, humankind. Prevention of infectious diseases through vaccination, known as prophylactic vaccination, is considered one of the most beneficial and cost-effective health care interventions. Prophylactic vaccines often represent the preferred solution to debilitating and widespread infectious diseases given their capacity to bring about significant health benefits to both individuals and communities, while remaining highly cost effective. This is a result of the fact that vaccines provide health benefits not only to individuals who have actually received the vaccine, but also to the broader community as the vaccinated population brings the immunological benefits of protection to non-vaccinated populations through the "herd immunity" effect that helps to reduce the spread of the disease.

Despite the large and growing need for vaccines, many urgent medical needs remain unaddressed, including diseases for which we are developing vaccine candidates. Advancing vaccines for diseases that are theoretically preventable but still lack adequate immunization options remains a high priority for the research and development community.

There are a number of approaches to engineering vaccine candidates. Most vaccines in use today utilize one of the following technological principles:

- **Live attenuated vaccines.** Live attenuated vaccines use a weakened, or attenuated, form of the virus or bacteria that causes a disease. Live attenuated vaccines typically provoke more durable immunological responses. However, they may not be safe for use in immunocompromised individuals, and on rare occasions can mutate to a virulent form and cause disease. Live attenuated vaccines protect against diseases such as measles/mumps/rubella, rotavirus, smallpox, chickenpox and yellow fever. Our chikungunya virus vaccine IXCHIQ is an example of a live attenuated vaccine.
- **Inactivated vaccines.** Inactivated vaccines use a version of the disease-causing virus or bacteria that has been killed with chemicals, heat or radiation so it cannot cause disease but can still train the immune system to recognize and fight the real infection later. Inactivated vaccines have a long history of use and are among the safest types of vaccine, with possibilities for use in special target populations, such as patients with weakened immune systems. We believe that the extensive knowledge and experience with the existing viral inactivation procedures for vaccine manufacture will continue to serve as a foundation of vaccinology for novel inactivated vaccines. Today millions of people are, and will be, protected worldwide with inactivated viral vaccines. Inactivated vaccines protect against diseases such as hepatitis A, flu, polio, and rabies. Our Japanese encephalitis vaccine IXIARO is an example of an inactivated vaccine.
- **Subunit, recombinant, polysaccharide, and conjugate vaccines.** Subunit, recombinant, polysaccharide, and conjugate vaccines use specific pieces of the virus or bacteria, such as its protein, sugar, or casing, to generate an immune response. Rather than introducing an inactivated or attenuated microorganism to an immune system (which would constitute a "whole-agent" vaccine), a subunit vaccine uses a fragment of the microorganism to generate an immune response. Subunit vaccines can produce a long-lived immunity and are relatively safe since only parts of the virus are used and can be applicable to people with weakened immune systems. These vaccines protect against diseases such as Hib (Haemophilus influenza type b), hepatitis B, HPV (human papillomavirus), whooping cough (part of the DTaP combined vaccine), pneumococcal disease, meningococcal disease, and shingles. Our clinical development and manufacturing technology have allowed us to develop our VLA15 vaccine candidate, a multivalent, protein subunit vaccine for prevention of Lyme disease.
- **Messenger RNA (mRNA) vaccines.** mRNA vaccines are one of the newest areas in vaccine technology. As shown during the COVID-19 pandemic, they can be developed quickly using the pathogen's genetic code. When an mRNA vaccine is delivered, the RNA material teaches our body how to make a specific type of protein that is unique to the virus, but does not make the person sick. The protein triggers an immune response, which includes the generation of antibodies that recognize the protein. That way, if a person is ever exposed to that virus in the future, the body would likely have the tools (antibodies) to fight against it.

Our deep expertise and capabilities across many of these approaches gives us the flexibility to follow our strategy of first targeting diseases that lack a preventative solution and then developing an efficacious and safe vaccine candidate based on our determination of the most effective technological approach.

In addition to the vaccine's primary component, vaccines may contain adjuvants, which are used to improve the immune response to the vaccine, for example through producing more antibodies. Adjuvants used in human vaccines include alum (aluminium hydroxide) and others (e.g. CpG-1018, manufactured by Dynavax). Adjuvants have a proven safety record based on more than 60 years of use. Effective use of adjuvants requires expertise in vaccine formulation and development. We have utilized different adjuvants in a number of our vaccine candidates or licensed vaccines.

Vaccines are administered through various routes such as orally, subcutaneously, intramuscularly, intradermally and intranasally. These various methods of administration help to simplify the vaccination process, allowing more people to be vaccinated and promoting adherence to the recommendations, such as receiving a follow-up dosage.

The different approaches to vaccine development cannot be universally applied to infectious diseases and be effective; instead, each approach must be targeted against a disease according to a compelling biological rationale. As such, development of vaccines are intensive and complicated processes that require evaluation of multiple modalities, endpoints and clinically meaningful data points. The efficacy and safety of vaccines are measured using multiple methodologies and approaches, although research and regulatory bodies often focus on the following measures:

- Immunogenicity — the ability of a foreign substance, such as an antigen, to provoke an immune response
- Seroconversion rates (SCR) — the proportion of subjects in a trial for whom a specific antibody develops and becomes detectable in blood
- Seroconversion — an antibody response capable of preventing infection
- Titer — a laboratory test that measures the presence and amount of antibodies in the blood
- Viremia — the presence of a virus in the blood

**Our Clinical Pipeline**

Our current clinical programs are summarized in the below chart:


## VLA15— Our vaccine candidate targeting Lyme disease

We are developing VLA15 as an investigational vaccine against Borrelia, the bacterium that causes Lyme disease. VLA15 is a recombinant protein vaccine candidate that targets six serotypes of Borrelia representing the most common serotypes found in North America and Europe. We reported results of three Phase 2 clinical trials of VLA15 in over 900 healthy adults and children, and the results demonstrated the generation of high titers of antibodies against all six serotypes. In August 2022, together with Pfizer, we 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 North America and Europe. In December 2023, we and Pfizer announced that we completed recruitment for the study. 9,437 participants five years of age and older were enrolled to receive three doses of VLA15 or a saline placebo (1:1 ratio) within the first year, and one booster dose approximately one year after completion of the first three doses, as part of the primary immunization. In July 2024, we announced completion of the three-dose primary vaccination series and in July 2025, completion of booster vaccinations. Participants were monitored for the occurrence of Lyme disease cases until the end of 2025, and topline results are expected in the first half of 2026. Subject to positive data, Pfizer aims to submit a BLA to the FDA and a MAA to the EMA in 2026.

We announced our collaboration with Pfizer for late phase development and commercialization of VLA15 in April 2020 and received a $130 million upfront payment upon signing. We also received milestone payments of $10 million and $25 million from Pfizer following initiation of the Phase 2 and Phase 3 studies, respectively. In June 2022, the terms of this agreement were updated, and Pfizer invested €90.5 ($95) million in our company as part of an Equity Subscription Agreement. As per the updated terms, Pfizer will fund 60% of the remaining shared development costs. We will receive tiered royalties ranging from 14% to 22%, which will be complemented by up to $100 million in milestones payable to us based on cumulative sales. The remaining early commercialization milestones were unchanged, which total an aggregate of $143 million. See "Item 10.C—Material Contracts—Pfizer License Agreement" for more details.

***Overview of Lyme disease***

Lyme disease is a systemic infection caused by Borrelia bacteria transmitted to humans by infected *Ixodes* ticks. It is considered the most common vector-borne illness in the Northern Hemisphere. According to the U.S. Centers for Disease Control and Prevention, approximately 476,000 people in the United States are diagnosed with Lyme disease each year, and at least a further 132,000 cases occur in Europe. Research suggests that Lyme disease cases may nearly double by 2100 in the United States due to climate change. Although most patients recover from Lyme disease, 10-20% have persistent symptoms, which for some are chronic and disabling. Studies indicate that Lyme disease costs up to approximately $1.3 billion each year in direct medical costs in the United States alone. The global market for a Lyme disease vaccine is estimated to exceed $1 billion.

The transmission of Lyme disease infection is well understood and documented. Borrelia bacteria colonize in the salivary glands of ticks. When a tick attaches for feeding, it injects its saliva into the human or animal host, bringing along with it antihistamines, cytokine blockers, and anticoagulants and, in the case of an infected tick, Borrelia bacteria as well.

Early symptoms of Lyme disease can often be overlooked or misinterpreted as they are often associated with other, often less severe, illnesses. These symptoms include fever, chills, headache, fatigue, muscle and joint aches, as well as swollen lymph nodes. In 70-80% of cases, a gradually expanding rash called erythema migrans forms. As this rash enlarges, it appears as a target or bulls-eye, three to thirty days after infection. Left untreated, the disease can disseminate beyond this initial area into the circulation, the joints, the heart, the brain, and the rest of the central nervous system. Once the infection has progressed it can cause serious complications, including arthritis with severe joint paint, heart palpitations or irregular heartbeat, and inflammation of the brain and spinal cord.

When diagnosed sufficiently early, Lyme disease can be successfully treated with a two-week to four-week course of oral antibiotics. However, given that the disease is often misdiagnosed in its early stages, patients often miss this therapeutic window. Additionally, chronic symptoms can commonly persist despite antibiotic treatment, a set of conditions referred to as Post-Treatment Lyme Disease Syndrome, or PTLDS. There are no proven treatments for PTLDS, which often resolves over time but unfortunately may take many months. There is therefore a strong emphasis on prophylactic approaches to preventing the disease through behavior modification – avoiding areas where ticks are prevalent, wearing clothing which minimizes tick exposure, using insect repellants and physically removing ticks that have attached. However, even with education and behavior modification, Lyme disease remains a serious and prevalent disease in the regions where it is endemic.

***VLA15 Approach***

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. Third-party studies have shown that antibodies against OspA in the blood of an animal bitten by an infected tick are transmitted to the tick during feeding and kill the Borrelia in the tick's gut before it can migrate to the tick's salivary glands and be transmitted to the animal. VLA15 is a recombinant protein subunit vaccine that is designed to achieve this protective effect using a truncated form of the OspA protein to generate antibodies against the OspA protein through a process summarized in the table below.

| 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- to 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** |

There are multiple serotypes or variants of Borrelia that lead to Lyme disease. The difference among the serotypes includes the fact that they have variant genetic sequences in the code for the OspA protein, meaning that each serotype requires a specific antigen targeting its OspA protein. In the United States, Lyme disease is predominantly associated with B. *burgdorferi* infection, or serotype 1 (ST1), while in Europe, there are multiple serotypes with B. *afzelii*, or serotype 2 (ST2), accounting for slightly more than half of infections. We have developed VLA15 as a single vaccine candidate that includes the OspA antigens from the six most frequently observed serotypes of Borrelia in North America and Europe.

To simplify production of the antigenic proteins, we linked the antigenic regions of two OspA proteins from different serotypes into a fusion construct. This allows us to produce the antigens against the six primary serotypes of Borrelia with just three protein constructs.

***Phase 1 Clinical Trial and Results***

We evaluated VLA15 in a partially randomized, multi-center dose escalation Phase 1 clinical trial conducted in Belgium and the United States in 179 healthy adults below 40 years of age. The first 24 subjects were included in an open-label trial in which they participated in a staggered dose escalation design. The remaining 155 subjects were enrolled in one of six blinded treatment groups, receiving VLA15 at a dose of either 12 µg, 48 µg, or 90 µg, with or without alum as an adjuvant, by intramuscular injection on Days 0, 28, and 56. The trial was designed to investigate the safety and tolerability as well as immunogenicity of VLA15. The primary endpoint was safety and tolerability of VLA15 up to three months after enrollment (Day 84).

The final Phase 1 data supported the tolerability profile observed at all time-points, as reported in the interim analysis. The Phase 1 trial met its study endpoints in terms of safety and immunogenicity. The majority of adverse events were mild or moderate, and there were no vaccine-related serious adverse events, allergic reactions, or reactions potentially related to Lyme borreliosis observed. The most common local adverse events were injection site pain (67.0%) and tenderness (84.4%). Solicited systemic adverse events were reported by 58.1% (48 µg with alum group, 90 µg with alum group) to 76.7% (90 µg without alum group) of subjects. The most common solicited systemic adverse events were headache (44.7%), excessive fatigue (25.1%), and myalgia (25.1%). Adverse event rates following subsequent doses in the primary series declined compared to the first dose, indicating no enhanced reactogenicity risk with subsequent vaccinations.

In addition, the final Phase 1 immunogenicity results indicated that the alum-adjuvanted formulations elicited higher immune responses at all time-points, confirming interim data findings as compared to respective non-adjuvanted groups of the same dose level. As expected, based on the interim Phase 1 data, antibody titers declined post Day 84 across all groups, trending towards baseline at approximately one year after initial vaccination.

For some vaccines, immunity begins to decline after a certain period of time, at which point a "booster" dose is needed to raise immunity levels. To evaluate the benefit of a booster dose, 64 subjects across the two higher dose groups (48 µg and 90 µg, both with and without alum) from the Phase 1 trial received a booster in the period 12 to 15 months after their initial dose in the primary immunization. Safety and immunogenicity of VLA15 was evaluated up to month 19, with an interim analysis four weeks after the booster. This booster dose resulted in a significant anamnestic response, yielding OspA antibody titers at levels from 2.7-fold for ST2 and ST3 to 5.8-fold for ST1 over the initial titers observed at Day 84. This potent immunogenic response was observed against all six OspA variants. Additional data about a booster dose follow in the Phase 2 discussion below.

***Phase 2 Clinical Trials and Results***

We have evaluated the safety and immunogenicity of VLA15 at different dosage levels and schedules in three Phase 2 clinical trials in Europe and the United States. Together, these trials enrolled 1443 healthy participants of 5 to 65 years of age.

***VLA15-201 Clinical Trial and Results***

Our first Phase 2 clinical trial, VLA15-201, was a randomized, observer-blind, placebo-controlled, multi-center Phase 2 clinical trial conducted in Belgium, Germany, and the United States, consisting of a "run-in phase" and a "main study phase." In the run-in phase, a total of 120 participants aged 18-40 were randomized into one of four groups: a placebo group and three groups at different dosage levels of VLA15 with alum (90 µg, 135 µg, or 180 µg). The participants received intramuscular injections on Days 1, 29, and 57. Based on the elicited higher antibody responses across all serotypes observed from the run-in phase, we selected the two higher VLA15 dose levels to be evaluated in the main study phase. A total of 452 subjects aged 18-65 were randomized 2:2:1 to receive one of two VLA15 doses (135 µg or 180 µg) or placebo and received intramuscular injections on Days 1, 29, and 57. The primary endpoint for the trial was GMTs for IgG against each OspA serotype ST1 to ST6. Secondary endpoints examined SCR, geometric mean fold rise, or GMFR, and occurrence of adverse events.

In July 2020, we announced results from our Phase 2 clinical trial of VLA15-201 in which we observed VLA15 was immunogenic across all dose groups tested. Compared to results from the Phase 1 clinical trial, the higher doses used in our Phase 2 clinical trial elicited higher antibody responses across all serotypes than those observed after the primary series in the Phase 1 clinical trial. SCR in the highest dose ranged from 81.5% (ST1) to 95.8% (ST2) on Day 85. No statistically significant differences between 135 µg and 180 µg treatment groups were observed.

In the age group comparable to the age group investigated in the Phase 1 clinical trial (18-39 years), SCRs ranged from 85.6% to 97%. The immunological response in older adults (50-65 years), one of the main target groups for a Lyme vaccine, had SCRs ranging from 71.9% to 93%. Results indicated that prior exposure to *Borrelia burgdorferi sensu lato* (Bb sl), the bacteria that causes Lyme disease (baseline Bb sl sero-positivity) did not have an impact on immunogenicity or safety.

VLA15 was generally well tolerated across all dose and age groups tested. No serious adverse events related to VLA15 were observed in any treatment group. The most common solicited local adverse events were injection site pain (68.4%) and tenderness (76.6%), whereas the most common solicited systemic adverse events were headache (33.2%), fatigue (31.6%), and muscle pain (myalgia) (41.1%). The proportion of adverse events decreased with subsequent vaccinations and were transient. Overall, the tolerability profile including rates of fever appeared to be comparable to what has been observed in third-party trials of other lipidated recombinant vaccines or lipid-containing formulations.

***VLA15-202 Clinical Trial and Results***

Our second Phase 2 clinical trial, VLA15-202, was a randomized, observer-blind, placebo-controlled multi-center Phase 2 clinical trial conducted in the United States with 246 healthy volunteers aged 18-65. The subjects were randomized 2:2:1 to receive either VLA15 with alum (either 135 µg or 180 µg) or placebo, administered through intramuscular injection at month zero, two, and six. The primary endpoint of the trial was GMTs for IgG against each OspA serotype, measured at month 7 to highlight the importance of further increases in OspA-specific IgG titers after the primary immunization series, which are likely necessary to achieve a successful vaccine candidate. Secondary endpoints evaluated SCRs, GMFRs, and the occurrence of adverse events.

On October 20, 2020, we reported interim results from VLA15-202. Compared to VLA15-201, immunogenicity was further enhanced using an immunization schedule of vaccinating at zero, two, and six months. SCRs, after completion of the primary vaccination series, showed similar responses and ranged from 93.8% (ST1) to 98.8% (ST2, ST4).

Antibody responses were comparable in the two dose groups tested as of Day 208. The immunological response in older adults, one of the main target groups for a Lyme vaccine, was consistent with our observations in VLA15-201. Furthermore, results did not indicate that prior exposure to *Borrelia burgdorferi sensu lato* (Bb sl), the bacteria that causes Lyme disease (baseline Bb sl sero-positivity) has an impact on immunogenicity or safety, also consistent with our observations in VLA15-201.

Unlike our previous trials, we also performed a Serum Bactericidal Assay, or SBA, assessing the functional immune response against Lyme disease after vaccination with VLA15. Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses. Over the course of our trial, the SBAs demonstrated functionality of antibodies against all OspA serotypes.

VLA15 was generally well tolerated across all doses and age groups tested in VLA15-202. The tolerability profile including fever rates was comparable to what has been observed in trials of other lipidated recombinant vaccines or lipid containing formulations. Overall, 232 of 246 participants (94.3%) reported any adverse event, solicited or unsolicited, up to Day 208. Rates of participants who experienced adverse events were similar in the VLA15 treatment groups: 96.9% (135 µg group) and 99.0% (180 µg group), compared with 80.4% in the placebo group. Most adverse events were mild or moderate in severity and no related serious adverse events were reported. A total of 6.1% of participants experienced severe related adverse events; 5.7% of participants experienced at least one severe solicited Grade 3 reactogenicity event, and as such, were considered to be related, including 6.2% in the 135 µg group, 7.1% in the 180 µg group, and 2.0% in the placebo group. One participant in the 135 µg group experienced a severe unsolicited adverse event of ventricular extrasystoles 13 days after the second vaccination, which was assessed as possibly related to the study vaccine by the investigator. The participant had a history of benign premature ventricular contractions, was treated with propranolol and recovered after 39 days. Six unrelated serious adverse events were reported: 3.1% in the 135 µg group (invasive ductal breast carcinoma, prostate cancer, and vertigo) and 2.0% in the 180 µg group (intervertebral disc protrusion, osteoarthritis). One case of Lyme disease (135 µg group) was reported as an adverse event of significant interest: erythematous rash, developed approximately two weeks after the first vaccination.

On September 28, 2021, we announced further positive results from VLA15-202. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all dose groups, remaining above baseline and confirming the need for a booster strategy. Participants who received a complete primary vaccination series with the 180 µg dose of VLA15 were invited to continue the trial in a booster extension phase and were randomized 2:1 to receive an additional 180 µg dose of VLA15 or placebo at Month 18. VLA15's acceptable safety profile was confirmed through one-month post-booster. No related serious adverse events were observed in any treatment group. Administration of the booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (GMT) in anti-OspA IgG antibody titers compared with titers observed after primary immunization. All participants seroconverted to anti-OspA IgG after the booster dose, meaning SCRs were 100% for all OspA serotypes. SCR was defined as the rate of participants that changed from seronegative at baseline to seropositive. Additionally, participants who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by SBA, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The trial is continuing to monitor persistence of antibody responses.

The results of the VLA15-201 and VLA15-202 trials were published in the peer-reviewed medical journal, *The Lancet Infectious Diseases*, in June 2024. The article, titled "Optimization of Dose Level and Vaccination Schedule for the VLA15 Lyme Borreliosis Vaccine Candidate Among Healthy Adults: Two Randomized, Phase 2 Studies" provides a detailed analysis of the clinical results for the two trials.

***VLA15-221 Clinical Trial***

On December 2, 2020, we announced the acceleration of the pediatric development of VLA15. The Phase 2 clinical trial VLA15-221, which commenced in March 2021, is the first clinical trial of VLA15 that includes a pediatric test population between 5 and 17 years old. We announced completion of recruitment for VLA15-221 in July 2021 and reported positive topline and booster data in February 2022 and September 2023, respectively. The dosing of the first subject in this trial triggered a milestone payment from Pfizer of $10 million.

VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 clinical trial. A total of 625 participants, 5 to 65 years of age and in groups with age ranges of 5-11, 12-17 and 18-65, were randomized to receive VLA15 at Month 0-2-6 or Month 0-6 (approximately 200 volunteers each) or placebo at Month 0-2-6 (approximately 200 volunteers). The trial was conducted at sites in the US which are located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with *Borrelia burgdorferia* as well as *Borrelia burgdorferi*-naïve volunteers. Participants received VLA15 at a dose of 180µg, which was selected based on data generated in the two previous Phase 2 clinical trials.

The main safety and immunogenicity readout was performed approximately one month after completion of the primary vaccination schedule (i.e. at Month 7), when peak antibody titers were anticipated. A subset of participants received a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed for three additional years to monitor antibody persistence. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3 clinical development.

In the sub-analysis of participants 18-65 years old who received VLA15 in either the two-dose schedule (N=90) or the three-dose schedule (N=97), performed one month after the last vaccination, VLA15 was found to be immunogenic with both vaccination schedules tested. These data are consistent with the strong immunogenicity profile observed for this age group in previous Phase 2 studies. However, the induction of anti-OspA IgG (anti-outer surface protein A immunoglobulin G) antibody titers was higher in participants who received the three-dose primary series compared to those who received the two-dose primary series. Based on these results, we and Pfizer proceeded with a three-dose primary series vaccination schedule in the Phase 3 clinical trial discussed below. The analysis was also consistent with the acceptable safety and tolerability profile observed in previous studies of VLA15. No vaccine-related serious adverse events were observed.

In April 2022, together with Pfizer, we reported positive pediatric data for the VLA15-221 trial. In pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was

found to be more immunogenic than in adults with both vaccination schedules tested. The safety and tolerability profile observed in the 5- to 17-year age group was similar to the previously reported profile in adult participants. No vaccine-related serious adverse events (SAEs) were observed. Like in adults, the immunogenicity and safety data supported a three-dose primary vaccination schedule in pediatric participants in the Phase 3 trial.

Additionally, in September 2023, we reported positive booster results for this trial. The results showed a strong anamnestic antibody response for all serotypes in pediatric, adolescent, and adult participants one month after administration of a booster dose (month 19). Depending on the primary schedule they received (month 0-2-6 or month 0-6), participants seroconverted after the booster dose, yielding seroconversion rates of 95.3% and 94.6% for all OspA serotypes in all age groups, respectively. Additionally, OspA antibody titers were significantly higher one month after the booster dose compared to one month after the primary schedule with 3.3- to 3.7-fold increases (GMT) in adults, 2.0- to 2.7- fold increases in adolescents and 2.3- to 2.5-fold increases in children for all serotypes. The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies as the vaccine candidate was well-tolerated in all age groups regardless of the primary vaccination schedule. No vaccine-related serious adverse events and no safety concerns were observed by an independent Data Safety Monitoring Board.

In September 2024, we and Pfizer reported further booster results following vaccination with a second booster dose given one year after receiving the first booster dose. The immune response and safety profile of VLA15 one month after receiving the second booster dose were similar to those reported after receiving the first booster dose, showing compatibility with the anticipated benefit of a booster vaccination prior to each Lyme season. These latest booster results again demonstrated a significant anamnestic antibody response across all six serotypes covered by the vaccine candidate in pediatric (5 to 11 years of age) and adolescent (12 to 17 years of age) participants, as well as in adults (18 to 65 years of age), measured one month after administration of this second booster dose (month 31). A high proportion of participants seroconverted after the second booster dose, yielding seroconversion rates* (SCRs) above 90% for all outer surface protein A (OspA) serotypes in all age groups, in-line with SCRs after the first booster. Geometric Mean Titers at one month post first and second booster (i.e. month 19 vs. month 31) were comparably high. The safety and tolerability profile of VLA15 after a second booster dose was comparable to the profile observed after the first booster.

In November 2025, we announced positive final immunogenicity and safety data from the VLA15-221 Phase 2 study. The results showed strong anamnestic immune response and favorable safety profile six months after a third booster dose (month 48) in all age groups. No safety concerns were observed by the independent Data Monitoring Committee (DMC) in any vaccination or age group during the trial. These results further validate the use of the three-dose vaccination schedule and a yearly booster dose, already included in the Phase 3 protocols.

***Phase 3 Trial***

In August 2022, together with Pfizer, we announced the initiation of a Phase 3 clinical trial, Vaccine Against Lyme for Outdoor Recreationists (VALOR), to investigate the efficacy, safety, and immunogenicity of VLA15.

The randomized, placebo-controlled, Phase 3 VALOR trial enrolled participants five years of age and older and was conducted in areas where Lyme disease is highly endemic, including Finland, Germany, the Netherlands, Poland, Sweden, Canada, and the United States.

As per the terms of our collaboration, we received a $25 million milestone payment from Pfizer following initiation of the Phase 3 trial. In February 2023, Pfizer, as the study sponsor, decided to discontinue a significant percentage of enrolled U.S. study participants following violations of Good Clinical Practice at certain clinical trial sites run by a third-party clinical trial site operator. The discontinuation of these participants was not due to any safety concerns with the investigational vaccine and was not prompted by a participant-reported adverse event. The trial continued with other sites not operated by the third party and new sites in North America and Canada. In December 2023, we and Pfizer announced that we completed recruitment for the trial. 9,437 participants (five years of age and older) were enrolled to receive, as part of the full primary series, three doses of VLA15 180 µg or a saline placebo (1:1 ratio) within the first year of vaccination, and one booster dose of VLA15 or saline placebo approximately one year after vaccination with the first three doses. In July 2024, we announced completion of the three-doses primary vaccination series and in July 2025, completion of the booster vaccinations to all trial participants. Participants were monitored for the occurrence of Lyme disease cases until the end of 2025. Results from the VALOR trial are expected in the first half of 2026, and Pfizer aims to submit a BLA to the FDA and an MAA to the EMA in 2026, subject to positive data.

## VLA1553 / IXCHIQ—Our vaccine targeting the chikungunya virus

VLA1553 is a single-dose, live-attenuated vaccine candidate against CHIKV, marketed under the brand name IXCHIQ. It is approved for use in individuals 12 years of age and older in the European Union and Canada and in individuals 18 to 59 years of age in the UK and Brazil. IXCHIQ received approval in the United States in November 2023; however, in January 2026, we voluntarily withdrew both the BLA and IND application for IXCHIQ. For additional details about decisions of regulatory agencies and changes to the IXCHIQ label since its initial licensure, please see the section on IXCHIQ in our "Our Commercial Portfolio", further below in this Item 4B.

There are currently no clinical studies involving IXCHIQ that are actively vaccinating participants, and we intend to move forward with our planned post-marketing clinical activities, subject to further discussions with relevant regulatory authorities.

We are continuing to monitor antibody persistence in a dedicated trial, VLA1553-303. We reported positive twelve, twenty-four, thirty-six, and forty-eight month antibody persistence data in December 2022, 2023, 2024, and September

2025, respectively, demonstrating a very high level of seroconversion, with 99%, 97%, 96%, and 95% of participants, respectively, highlighting the durability of protective CHIKV neutralizing antibodies following a single vaccination. We will continue to evaluate persistence in the VLA1553-303 trial for a period of ten years.

***Overview of the chikungunya virus***

Chikungunya is a mosquito-borne virus posing a serious public health problem in tropical and sub-tropical regions. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating and can cause a significant economic impact. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas. The true incidence of chikungunya is likely to be much higher due to the level of under-reporting, with available studies suggesting an under-reporting factor of five times due to difficulty in diagnosing the symptoms, which can be similar to those of dengue and Zika, and due to lack of access to good medical care in certain areas where outbreaks are prevalent. It is estimated that the global market for a chikungunya vaccine, including travel and endemic markets, will exceed $500 million annually by 2032.

Chikungunya infection is characterized by an acute onset of fever, rash, myalgia, and sometimes debilitating arthritic pain in multiple joints. Chikungunya causes symptomatic infection in 72-92% of infected humans around four to seven days after infection. Mortality of chikungunya is low (<1%) but the chronicity of its joint pain (arthralgia) and inflammatory symptoms represent a significant burden of disease with potential long-term debilitating impact. For example, following a significant outbreak in 2005, 94% of symptomatic travelers infected in La Reunion, an island in the Indian Ocean, complained of joint or bone pain six months after the epidemic peak, and this pain was constant in 41% of the cases. The effect of chronic symptoms on the quality of life was defined as totally disabling or important in almost half of the patients. Even at 32 months post-infection, 83% of people continued to report joint pain.

In addition to having significant impact on patients who become infected, chikungunya is highly transmissible, and prior outbreaks have led to significant spread of the virus. For example, in 2004, a chikungunya epidemic in Kenya triggered the spread of this virus to nearly all regions of the world with cases reported in Africa, Asia, Europe, the Americas, the Indian Ocean, the Pacific Ocean, and the Caribbean islands. Cases in Europe and the United States are typically tied to recent travel to endemic areas. However, one of the vector mosquitos, the tiger mosquito, is established in southern regions of Europe and the United States, and travel-related cases have generated local outbreaks as reported from Italy and France.

Without vaccination, we believe the spread of chikungunya will continue to increase rapidly, driven by a number of key factors:

- The recent development that chikungunya can be spread by a second species of mosquitos, one that has a broader worldwide distribution, is tolerant to colder temperatures, and is highly abundant in large parts of the world;
- The current lack of herd immunity in large portions of the human population;
- The ease of chikungunya's spread by travel, which can occur if an uninfected mosquito feeds on an infected person who has returned home from an endemic area; and
- An increase in the geographic distribution and size of the population at risk due to climate change.

Reports of chikungunya infection grew rapidly and globally in 2025, with seven countries (Bangladesh, Cuba, China, Kenya, Madagascar, Somalia, and Sri Lanka) experiencing CHIKV outbreaks as well as locally-acquired cases of chikungunya reported for the first time as far as Paris, New York, and China. So far, Brazil has reported the highest number of chikungunya cases worldwide, with over one million cases between January 2019 and July 2024, followed by India with 370,000 cases during the same period.

The current standard of care to treat individuals who have become infected with chikungunya is the application of non-steroidal anti-inflammatory drugs to relieve symptoms. Apart from the availability of CHIKV vaccines such as IXCHIQ in certain countries, preventive measures in other territories rely on avoiding mosquito bites. Effective mosquito control has proven challenging, even in higher income countries.

***VLA1553 / IXCHIQ Approach***

IXCHIQ is a live-attenuated chikungunya vaccine based on the East, Central, and Southern African, or ECSA, strain which has spread across the Indian Ocean. It is cross-reactive with other strains, meaning that it is designed to protect against those as well, including the strain of Asian lineage which is rapidly spreading across the Americas as observed in pre-clinical studies. Additionally, given that we have engineered IXCHIQ as a live-attenuated vaccine, we believe it may confer life-long immunity.

IXCHIQ is engineered using a strain of chikungunya, where specific segments of the virus have been deleted, thereby weakening, or attenuating, the virus. This approach enables IXCHIQ to catalyze the patient's immune system into generating the antibodies necessary to provide protection against the virus while the weakened strain does not cause the patient to develop significant symptoms. In our pre-clinical studies, growth of this strain on Vero cells resulted in a viral titer 35 times lower than observed with the original unattenuated strain, demonstrating the attenuation of our chikungunya strain. The deleted segment also remained absent following replication of the virus in the Vero cells, suggesting that the weakness of the virus is sustained.

***Phase 1 Clinical Trial and Results***

We conducted a single blind, randomized dose-escalation Phase 1 clinical trial of VLA1553 in 120 adults, at multiple centers in the United States, the results of which were published in the Lancet Infectious Diseases in 2020. Chikungunya virus neutralizing antibodies were observed in 100% of patients for 12 months at all three of the doses evaluated. A single vaccination was sufficient to induce sustaining high-titer neutralizing antibodies at 12 months post-vaccination.

We found that 100% of participants had seroconverted by day 14 at all three of the doses tested and this seroconversion persisted for one year across all dose groups. When re-evaluated with the assay that was used to define the seroresponse threshold for Phase 3, we confirmed that 100% of participants had seroresponded by day 14.

Individuals that received a single high dose of VLA1553 did not exhibit an increase in antibody titers following subsequent re-vaccination at month six. No viremia was detected in any participant after any re-vaccination, suggesting that a single dose provides sufficient protection.

The majority of adverse events across the dose groups were assessed as mild or moderate and were reported after the single vaccination. No adverse event of special interest, meaning adverse events resembling a chikungunya-like infection, and no vaccine-related serious adverse events were reported. Injection site reactogenicity was low, with less than 7% of individuals in the high-dose group reporting any local adverse event, all of which were mild in severity. Systemic adverse events were predominantly headache (32.5%), fever (26.7%) and fatigue (24.2%), followed by muscle pain (20.0%) and joint pain (13.3%), all of which were transient and are typical reactions after immunization and similar to those reported after vaccination with other vaccines in the general population. Severe fever (a temperature of 102.1°F or higher) was reported by seven participants. Adverse events decreased on re-vaccination at month six.

***Phase 3 Clinical Trials***

***VLA1553-301 Clinical Trial***

In September 2020, we initiated our pivotal Phase 3 clinical trial, VLA1553-301, in the United States. In this double-blind, multi-center, randomized Phase 3 clinical trial, 4,115 participants aged 18 years and above were randomized 3:1 into two groups to receive either VLA1553 0.5mL or placebo. Immunogenicity was determined with a µPRNT50 assay.

The primary endpoint was safety and immunogenicity 28 days after a single vaccination with VLA1553. The trial met its primary endpoint, inducing protective CHIKV neutralizing antibody titers in 98.9% of participants 28 days after receiving a single shot. The seroconversion rate result of 98.9%, and specifically the lower bound of the 95% CI of 96.7%, exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The excellent immunogenicity profile was maintained over time, with 96.3% of participants showing protective CHIKV neutralizing antibody titers six months after receiving a single vaccination. VLA1553 was highly immunogenic, with a GMT of approximately 3,362, confirming the immunogenicity profile seen in the Phase 1 clinical trial.

VLA1553 was generally well tolerated across all age groups among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. The final data safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within three days. 2.0% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of trial participants experienced solicited systemic adverse events, most commonly headache, fatigue, and myalgia. The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

Additionally, VLA1553 was highly immunogenic in elderly study participants (65 years of age or older), who achieved equally high seroconversion rates and neutralizing antibody titers over time as younger adults.

The final pivotal Phase 3 data were published in *The Lancet* in June 2023.

***VLA1553-302 Clinical Trial***

We also initiated a lot-to-lot consistency Phase 3 trial, VLA1553-302, in February 2021 to show manufacturing consistency of VLA1553, which is a requirement for licensure. We announced completion of recruitment for this trial in June 2021 and positive topline and final data from this trial in December 2021 and May 2022, respectively.

The VLA1553-302 trial met its primary endpoint, demonstrating that three consecutively manufactured vaccine lots elicited equivalent immune responses measured by neutralizing antibody titer GMT ratios on Day 29 after vaccination. The trial included 408 participants aged 18 to 45 and confirmed the excellent immunogenicity profile observed in the pivotal Phase 3 trial, VLA1553-301. All three lots were equally well tolerated, and the safety profile was consistent with results in VLA1553-301. The trial therefore confirmed clinical equivalence as well as manufacturing consistency of the three lots.

The lot-to-lot data were part of our submission to the FDA which we completed in December 2022.

***VLA1553-303 Clinical Trial***

In April 2021, we initiated an antibody persistence trial that will follow annually up to 375 subjects in the immunogenicity subset of the VLA1553-301 trial for a period of ten years after a single immunization with IXCHIQ. We reported positive twelve, twenty-four, thirty-six, and forty-eight month antibody persistence data in December 2022, 2023, 2024, and September 2025, respectively, with 99%, 97%, 96%, and 95% of participants, respectively, retaining neutralizing antibody titers above the seroresponse threshold of 150 after receiving a single vaccination. The antibody persistence was similar in older adults aged ≥65 years, who retained neutralizing antibody titers comparable to younger adults throughout the follow-

up. No safety concerns were identified for the duration of the follow-up study, confirming the safety profile observed in previous studies.

***VLA1553-321 Clinical Trial***

In January 2022, we announced the initiation of a Phase 3 trial of VLA1553 in 754 adolescents 12 to 17 years of age. Conducted in Brazil by Institution Butantan and funded by CEPI, the VLA1553-321 trial is intended to support the label extension in this age group following the initial regulatory approval in adults from the FDA.

In November 2023, we reported positive Phase 3 immunogenicity and safety data showing that a single-dose vaccination with VLA1553 induced a robust immune response in adolescents, thereby confirming the excellent immunogenicity previously observed in adults. VLA1553 induced levels of protective antibody titers in 98.8% of participants 28 days after a single vaccination significantly exceeding the FDA's requirement for study success of the lower bound of the 95% CI for seroresponse rate >70%. Additionally, VLA1553 was generally well tolerated in adolescents, irrespective of previous CHIKV infection, and showed a similar safety profile as reported in adults. In May 2024, we reported six-month data which confirmed the positive immunogenicity and safety data reported previously. A single-dose vaccination with VLA1553 induced a high, sustained immune response with a seroresponse rate of 99.1% (232 out of 234 participants) at Day 180 in an immunogenicity subset of individuals who were CHIKV negative at baseline. Additionally, the six-month data confirmed that a single dose of the vaccine was generally safe and well tolerated in adolescents receiving VLA1553, irrespective of previous infection with the chikungunya virus. Throughout the trial, an independent DSMB consistently assessed safety data and found no safety issues. The majority of solicited adverse events observed following VLA1553 administration were mild or moderate and resolved within three days post vaccination. In January 2025, we reported positive twelve-month Phase 3 data which showed a sustained seroresponse rate in 98.3% of adolescents one-year after single vaccination. These results support and strengthen the pivotal data previously reported for adolescents (12 to 17 years old) which supported filing for potential label extension to this age group. In December 2025, the twelve-month adolescent Phase 3 data were published in the peer-reviewed medical journal, *The Lancet Infectious Diseases*, in an article titled: "Safety and immunogenicity of a live-attenuated chikungunya virus vaccine in adolescents: final results from a 12-month, double-blind, randomised, placebo-controlled, phase 3 trial in endemic areas of Brazil*"*.

***VLA1553-221 Clinical Trial***

In January 2024, we initiated a Phase 2 pediatric trial in children one to eleven years of age to evaluate the safety and immunogenicity of two different dose levels of IXCHIQ. The multicenter, prospective, randomized, observer-blinded Phase 2 clinical trial enrolled 304 healthy children at three trial sites in the Dominican Republic and Honduras. Following a safety run-in phase, participants were randomized to receive either a full dose formulation of the vaccine (120 participants), a half dose formulation (120 participants), or a control vaccine (60 participants). In January 2025, we announced positive results for VLA1553-221. The trial met its primary endpoint demonstrating that the vaccine was well tolerated by children one to eleven years of age regardless of the dose (half dose or full dose) or previous chikungunya infection (CHIKV), and, to a similar extent, to an active control MenACYW vaccine (Nimenrix). Overall, the safety profile was consistent with the profile observed in our pivotal Phase 3 trials in adults and adolescents. Our vaccine was highly immunogenic in both dose groups. A full dose of the vaccine exhibited a more robust immune response compared to a half dose by providing protective antibody titers already at Day 15 and Day 29 post-vaccination, confirming the excellent immunogenicity previously observed in adults and adolescents. The six-month and final twelve-month data, announced in June and December 2025, respectively, confirmed the previously-announced data. An independent DSMB rigorously monitored safety data throughout the trial and confirmed the absence of any safety concerns. The Phase 2 pediatric data support full dose selection for a future pivotal Phase 3 trial in children, which we are planning to initiate after gathering additional real-world experience in the adolescent population, in alignment with the regulatory authorities.

***Pilot Vaccination Campaign in Brazil***

In February 2026, we and Instituto Butantan announced the initiation of a Pilot Vaccination Strategy (PVS) in Brazil using our single-shot chikungunya vaccine, IXCHIQ. The vaccination campaign will serve as the basis for post-marketing commitment studies evaluating the effectiveness and safety of IXCHIQ in a real-world setting and generating real-world evidence in a large population.

The PVS, agreed between the Brazilian Ministry of Health (MoH) and Instituto Butantan, will be implemented in ten Brazilian municipalities strategically selected based on epidemiological and operational criteria in support of the PVS. In line with the current IXCHIQ label in Brazil, adults aged 18 to 59 will be invited to participate, with the objective of achieving 20% to 40% vaccine coverage within the target population. We, through our partner Instituto Butantan, donated up to 500,000 doses of IXCHIQ to the Brazilian MoH, for use in the program.

## S4V2— The most advanced tetravalent Shigellosis vaccine candidate

In August 2024, we entered into a collaboration with LimmaTech Biologics AG for the development of S4V2, a tetravalent bioconjugate vaccine candidate against shigellosis, a diarrheal infection caused by Shigella bacteria.

Shigellosis is the second leading cause of fatal diarrheal disease worldwide. It is estimated that up to 165 million cases of disease and an estimated 600,000 deaths are attributed to Shigella each year, particularly among children in LMICs. No approved Shigella vaccine is currently available outside of Russia or China, where two vaccines exist for limited use. The development of Shigella vaccines has been identified as a priority by the WHO. In October 2024, the U.S. FDA granted Fast Track designation to S4V2, recognizing its potential to address a serious condition and fill an unmet medical need.

At the time the collaboration was established, LimmaTech had already generated initial safety and immunogenicity data with its S4V2 candidate in adults and infants. Two Phase 2 clinical studies of S4V2, sponsored by LimmaTech Biologics AG, are ongoing. In November 2024, together with LimmaTech, we announced the launch of a parallel-group, randomized, double-blind, multicenter, placebo-controlled Phase 2b controlled human infection model (CHIM) study to assess the safety, immunogenicity, and preliminary efficacy in approximately 120 healthy Shigella-naïve participants aged 18 to 50 at three sites in the United States. Additionally, in April 2025, we announced the initiation of a Phase 2 infant safety and immunogenicity study in approximately 110 nine-month-old infants with the goal of identifying the best dose to be tested in a Phase 3 trial. First Phase 2 data are expected mid 2026, with a decision on subsequent development steps in the second half of 2026.

Subject to positive results and completion of both studies, we will become the IND holder and assume responsibility for all further product development, including CMC (chemistry, manufacturing, and controls) and regulatory activities, and be responsible for S4V2's commercialization worldwide, if approved.

## Our other clinical programs

***VLA1601—Our Zika virus vaccine candidate currently on hold***

Zika is a mosquito-borne viral disease caused by the Zika virus (ZIKV). It is the first and only flaviviral disease that was declared a public health emergency because of devastating birth defects following maternal infection. According to the WHO, there is scientific consensus that Zika virus is a cause of microcephaly and Guillain-Barré syndrome. The incidence of Zika significantly declined after its peak in 2016 due to high population level immunity in affected countries. However, Zika virus transmission persists in several countries in the Americas and in other endemic regions. According to the WHO, a total of 89 countries and territories have reported evidence of mosquito transmitted Zika virus infection to date; however, surveillance remains limited globally. There are no preventive vaccines or effective treatments available and, as such, Zika remains a public health threat and is included in the FDA's Tropical Disease Priority Review Voucher Program.

VLA1601 is a highly purified inactivated, adjuvanted vaccine candidate against the Zika virus. It has been developed on the original manufacturing platform of our licensed Japanese encephalitis vaccine IXIARO, which was further optimized to develop our inactivated, adjuvanted COVID-19 vaccine VLA2001, the first one to receive a standard marketing authorization in the European Union. We had reported Phase 1 results from our first-generation Zika vaccine candidate in 2019, showing a favorable safety profile in all doses and schedules tested and immunogenicity in all treatment groups.

In March 2024, we initiated a Phase 1 clinical trial in the United States to investigate the safety and immunogenicity of our optimized vaccine candidate in approximately 150 participants aged 18 to 49. In November 2025, we reported positive Phase 1 results, showing that VLA1601 was generally safe, well tolerated, and immunogenic across all five treatment arms.

Despite the medical need, regulatory pathways and market opportunities for potential Zika vaccines remain uncertain. We will therefore only consider further potential development steps for VLA1601 if concrete private and public funding opportunities materialize.

***VLA84—Our Clostridium difficile vaccine candidate put on hold - now out licensed***

We developed VLA84, a vaccine candidate targeting the prevention of primary symptomatic *Clostridium difficile* infection, or CDI, a leading cause of life-threatening, healthcare-associated infections worldwide. VLA84 is designed to produce an immune response to neutralize the effects of *C. difficile* toxins A and B, considered to be largely responsible for CDI. We completed Phase 2 development of VLA84 in 2015, and all key objectives of the Phase 2 trial were met. Valneva was unable to secure a partnership for the asset at that time due to significant clinical setbacks and failures in other late-stage *C. difficile* development programs.

In March 2026, we entered into an exclusive license agreement for VLA84 with Elaris, an Austrian company founded by two former Valneva employees that is developing a next-generation vaccine for *Clostridium difficile* infection. The agreement includes two development-related milestone payments and several milestone payments in connection with regulatory approval and commercialization.

## Our Pre-clinical Portfolio

In addition to our clinical-stage assets, our portfolio includes several pre-clinical assets against disease targets that reflect our strategy of providing prophylactic solutions to significant diseases that lack a preventative and effective therapeutic treatment option.

Our pre-clinical work involves exploratory study of a given disease, including extensive review of existing literature and early data that will inform our view of whether and how we could develop a vaccine for that disease.

Our two most advanced pre-clinical assets against EBV and Enterotoxigenic Escherichia coli (ETEC) are presented below. Additionally, we have initiated pre-clinical work on vaccine candidates against different enteric diseases.

***VLA2112 - Our vaccine candidate targeting Epstein-Barr Virus (EBV)***

Epstein-Barr virus (EBV), also known as human herpesvirus 4, is a member of the herpes virus family. It is found all over the world and is one of the most common human viruses. Most people get infected with EBV by early adulthood. EBV

spreads most commonly through bodily fluids, primarily saliva. EBV can cause infectious mononucleosis, also called mono, and is strongly associated with different cancers and multiple sclerosis.

Our EBV vaccine candidate, VLA2112, is based on adjuvanted, subunit viral glycoproteins to elicit high titers of EBV-neutralizing antibodies.

The selection of antigens that best neutralize infection of both epithelial cells and B cells was completed in 2023, and confirmatory preclinical research is ongoing.

***Our vaccine candidate targeting Enterotoxigenic Escherichia Coli (ETEC)***

We have started research work on a vaccine candidate against ETEC. Antigen selection is ongoing for the candidate, which we expect to be highly differentiated compared to other existing ETEC vaccine candidates.

ETEC is the most common cause of traveler's diarrhea and a major cause of diarrhea in children in LMICs. There is currently no specific treatment or vaccine available against ETEC.

## Our Commercial Portfolio

Our proprietary commercial portfolio is composed of three vaccines, our travel vaccines IXIARO/JESPECT, DUKORAL, and IXCHIQ. Our travel vaccines serve a wide range of potential travelers to countries where the diseases they prevent are endemic, from business and leisure travelers to government and military personnel traveling on behalf of their government. We also distribute certain third-party vaccines in countries where we operate our own marketing and sales infrastructure. Our commercial activities have generated meaningful revenues, which we have largely reinvested into our research and development capabilities in order to advance our clinical assets and drive future growth.

**IXIARO—Our Japanese encephalitis vaccine**

***Japanese encephalitis background***

Japanese encephalitis (JE) is a considerable public health problem for many Asian countries. Recent estimates for JE point to close to three billion people living in regions at risk for this mosquito-borne viral disease, with 67,900 being diagnosed annually. JE is transmitted to humans by mosquitos that have bitten an infected animal, and less than 1% of infected individuals develop the disease. Those that do develop the disease face a 20-30% mortality rate, and up to 50% of survivors have significant permanent neurological damage. Many individuals infected by JE develop symptoms within five to 15 days, usually starting as a flu-like illness with fever, chills, tiredness, headache, nausea, and vomiting. Confusion and agitation also occur in the early stage of JE. Later symptoms may include swelling around the brain and coma, which can result in death.

In 2023, over 32 million people traveled from Europe and North America to the countries where JE is endemic. Vaccination remains the single most important control measure against JE worldwide.

***IXIARO Overview***

IXIARO (or JESPECT in Australia and New Zealand), is an inactivated Vero cell culture-derived JE vaccine and is the only JE vaccine currently approved for use in the U.S., Canada, and the European Union. It is indicated for active immunization against Japanese encephalitis in adults, adolescents, children, and infants aged two months and older, and is a required vaccine for U.S. military personnel who are deployed to areas of risk for JE. The pediatric indication of IXIARO was granted orphan drug designation by the FDA.

IXIARO is administered intramuscularly in two parts, between seven and 28 days apart depending on the age of the recipient, and with the second dose completed at least a week prior to potential exposure to JEV. A booster shot may be given at least 11 months after completion of the primary immunization series if ongoing exposure or re-exposure to JEV is expected. IXIARO's shelf life is currently 36 months.

In a randomized clinical trial, high titers of neutralizing antibodies were detected in 96.4% of adults 28 days after the last dose. The immune response to IXIARO was durable, with high levels of neutralizing antibodies in 84.9% of participants three years after initial immunization. A separate trial administration of a booster dose at 14 months after completion of the initial two doses resulted in 100% of participants having neutralizing antibodies.

***Sales of IXIARO***

IXIARO was first approved by the FDA and European Commission in 2009. Sales of IXIARO / JESPECT in 2025 were €98.4 million, of which 76.4% was generated directly through our own sales force. In January 2025, we announced the signing of a $32.80 million contract with the U.S. Department of Defense (DoD).

**DUKORAL—Our vaccine against cholera and LT-ETEC**

***Cholera disease background***

Cholera is an acute diarrheal disease caused by ingestion of food or water contaminated with the bacterium *V. cholerae*. Cholera remains a global threat to public health and an indicator of inequity and lack of social development. Researchers have estimated that every year, there are roughly 1.3 to 4.0 million cases, and 21,000 to 143,000 deaths worldwide due to

cholera. Cholera is an extremely virulent disease that can cause severe acute watery diarrhea. It takes between 12 hours and five days for a person to show symptoms after ingesting contaminated food or water. Cholera affects both children and adults and can kill within hours if untreated.

Most people infected with *V. cholerae* do not develop any symptoms, although the bacteria are present in their feces for up to 10 days after infection and are shed back into the environment, potentially infecting other people. Among people who develop symptoms, the majority have mild or moderate symptoms, while a minority develop acute watery diarrhea with severe dehydration. This can lead to death if left untreated.

***LT-ETEC disease background***

Heat-labile toxin-producing enterotoxigenic E. coli (LT-ETEC) is the leading cause of travelers' diarrhea and a major cause of diarrheal disease in lower-income countries. There are approximately 5-18 million reported cases of ETEC per year worldwide. ETEC is transmitted by food or water contaminated with animal or human feces. Infection by ETEC can cause profuse watery diarrhea and abdominal cramping. Illness develops one to three days after exposure and usually lasts three to four days. Most patients recover without any specific treatment other than rehydration.

***DUKORAL Overview***

DUKORAL is an oral vaccine containing four inactivated strains of the bacterium Vibrio cholerae serotype O1, and part of a toxin from one of these strains as active substances. 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 LT-ETEC. Originally licensed in Sweden by SBL Vaccines in 1991, and subsequently in the European Union in 2004 through a centralized procedure, followed by other international markets, the vaccine was acquired by us in 2015 from Janssen Pharmaceuticals as part of our strategic vision to extend our proprietary travel vaccine portfolio.

DUKORAL is intended for active immunization against cholera (and LT-ETEC diarrhea in certain jurisdictions) in adults and children from two years of age who will be visiting endemic/epidemic areas.

DUKORAL is administered orally after dissolving the product in a glass of water. Vaccination requires two doses given one to six weeks apart. In an efficacy trial done in Bangladesh in 89,596 adults and children aged two years and older, the efficacy of DUKORAL against cholera was 85% in the six months after the third dose and 57% in the second year after immunization. Protective efficacy declined over the three-year trial period. DUKORAL conferred 67% protection against episodes of diarrhea caused by LT-ETEC during the initial three months of follow-up but demonstrated no protection thereafter.

***Sales of DUKORAL***

DUKORAL was granted marketing authorization throughout the European Union in 2004, having previously been licensed in Sweden and Norway in 1991 through national licensure processes. DUKORAL was approved in Canada in 2003. Sales of DUKORAL in 2025 were €31.9 million of which 88.0% were generated directly through our own sales force.

**IXCHIQ—Our Chikungunya Vaccine**

***Chikungunya disease background***

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus, a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in up to 97% of humans after four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash, and chronic arthralgia.

Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. Before IXCHIQ, there were no preventive vaccines or effective treatments available and, as such, the WHO has highlighted chikungunya as a major public health threat.

***IXCHIQ Overview***

IXCHIQ is a single-dose, live-attenuated vaccine licensed in the European Union, Canada, the UK, and Brazil.

IXCHIQ was the first licensed chikungunya vaccine available to address this unmet medical need in adults and the third vaccine we brought from early R&D to approval. It is indicated for the prevention of disease caused by chikungunya virus. We received marketing approval for IXCHIQ in the U.S., Canada, the European Union, the UK, and Brazil in November 2023, June 2024, July 2024, February 2025 and April 2025, respectively. IXCHIQ was granted label extensions in adolescents aged 12 to 17 in the European Union and Canada in April and August 2025, respectively. IXCHIQ is currently approved for use in individuals 12 years of age and older in the European Union and Canada and in individuals 18 years to 59 years of age in the United Kingdom (UK) and Brazil.

In the second quarter of 2025, we reported on changes to recommendations for use of IXCHIQ in the U.S., France, and the European Union based on reports of serious adverse events (SAEs), mainly in elderly people with several underlying

medical conditions, during an outbreak vaccination campaign on the French island of La Reunion. In June 2025, the UK MHRA implemented a temporary suspension on the use of IXCHIQ in elderly adults and in February 2026 updated its recommendation for the use of IXCHIQ in the UK by including a restriction for individuals 60 years of age and older, for people with specified health conditions as well as timing of vaccination prior to travel. The MHRA confirmed that the benefit–risk profile of IXCHIQ remains favorable for individuals aged 18 to 59 years who are at risk of chikungunya infection and do not have the contraindicated underlying medical conditions. In August 2025, the FDA suspended the license for IXCHIQ in connection with additional SAEs, and in January 2026, we decided to voluntarily withdraw the BLA and IND application for IXCHIQ in the U.S. We had been awaiting further information with respect to our formal response to the vaccine license suspension and were informed in January 2026 of the FDA's decision to place the IND on clinical hold pending an investigation of a newly reported SAE in a patient who had received three concomitant vaccines, including IXCHIQ. For further information on our interactions with regulatory agencies concerning IXCHIQ, see Item 3D of this Annual Report.

Valneva is committed to upholding the highest safety standards, and we continue to engage proactively with health authorities in all territories where IXCHIQ is licensed, including the European Union, Canada, the UK, and Brazil. While we have focused on marketing IXCHIQ for travelers to regions where the virus is endemic, such as tropical and subtropical areas in Asia, Africa, and the Americas, and persons for whom vaccination is medically justified based on risk in accordance with the approved label and vaccination guidance, we continue to believe that IXCHIQ's benefit-risk profile also remains favorable for people living in the endemic and outbreak settings, where IXCHIQ may be uniquely positioned as a highly durable single-shot vaccine. A pilot vaccination campaign with IXCHIQ, agreed between the Brazilian MoH and Instituto Butantan, is currently being implemented in ten Brazilian municipalities with the objective of achieving 20% to 40% vaccine coverage within the target population (adults aged 18 to 59). This pilot vaccination program will serve as the basis for post-marketing commitment studies evaluating the effectiveness and safety of IXCHIQ in a real-world setting.

***Sales of IXCHIQ***

Our commercial teams launched the vaccine in the U.S., Canada, and France in March, October and November 2024, respectively. Considering IXCHIQ was the first vaccine worldwide against this unmet need, we focused in 2024 on raising awareness on the disease, shaping the market, and booking first sales. IXCHIQ sales were €3.7 million in 2024 and increased to €8.4 million in 2025. In 2025, IXCHIQ sales benefited from the launch of the vaccine in several European countries, including the supply of vaccine doses to combat a major chikungunya outbreak on the French island of La Réunion. This growth was partly offset by the temporary restrictions and U.S. license suspension.

***Third-party Vaccines***

In the past, we have distributed select third-party vaccines in countries where we operate our own marketing and sales infrastructure. In June 2020, we entered into a distribution agreement with Bavarian Nordic to commercialize their rabies and tick-borne encephalitis vaccines, leveraging our commercial infrastructure in Canada, the United Kingdom, France, and Austria during the COVID-19 pandemic. Our agreements to distribute Bavarian Nordic's rabies vaccine in Canada and the United Kingdom terminated on December 31, 2024, and the remaining distribution agreements concluded on December 31, 2025.

In September 2022, we also announced a partnership with VBI Vaccines for the marketing and distribution of their Hepatitis B vaccine, PreHevbri, in select European markets. This contract ended in 2024 following VBI's voluntary withdrawal of PreHevbri from the market amid insolvency proceedings.

We will continue to distribute Kamada Pharmaceuticals rabies vaccine (KamRAB) in Canada in 2026, which is now our only remaining third-party distribution contract. In 2025, our third-party sales were €19.2 million compared to €33.2 million in 2024. As previously announced, we do not expect to enter into new significant third-party sales contracts and anticipate that third-party sales will continue to wind down in 2026.

For additional information about our commercial agreements, see "Item 10.C—Material Contracts" of this Annual Report.

## Competition

We compete in an industry characterized by rapidly advancing technologies, significant competition and a complex intellectual property landscape. We face substantial competition from large pharmaceutical, specialty pharmaceutical, and biotechnology companies. Academic research institutions and governmental agencies can and will continue to compete with support from public and private research institutions. Many of our competitors, either alone or through their collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, commercialize, and market products before or more successfully than we do. Below is a description of competition surrounding each of our disease targets and other technologies in development in the vaccines field.

***IXIARO/JESPECT Competition***

Our commercial vaccine against Japanese encephalitis, IXIARO (marketed as JESPECT in Australia and New Zealand), is the only approved and marketed vaccine for travelers to Japanese encephalitis endemic areas who originate in the U.S., Canada, and European countries.

Given the large population in the Japanese encephalitis endemic region, consisting of over 3 billion people, and the inclusion of the Japanese encephalitis vaccine in many national immunization programs, the competitive landscape in the endemic region is more crowded. Many of the first generation, locally manufactured mouse-brain derived vaccines have been phased out over the past 5-10 years, making way for the introduction of second-generation technologies. This includes companies such as Biken and Kaketsuken (Japan), both with inactivated vero-cell based vaccines, Chengdu (China and GAVI/UNICEF markets) with a live-attenuated vaccine, and Sanofi's live-attenuated chimeric vaccine, IMOJEV (Australia/some Asian territories). None of these vaccines are currently approved for sale in the European Union, Canada or the United States. Therefore, there is currently no direct competitor to IXIARO in those markets, which represented over 83% of total IXIARO revenues in 2024.

The only country where our Japanese encephalitis vaccine currently faces direct competition is Australia, where it splits market share with the IMOJEV vaccine, originally manufactured by Sanofi and now owned by Substipharm, a French company. This acquisition may result in future competition for IXIARO in travel markets.

***DUKORAL Competition***

DUKORAL has historically been the only vaccine licensed and marketed to travelers within the European Union, Canada, and Australia against cholera and, in certain countries including Canada, Switzerland, and New Zealand, ETEC. Canada, the Nordic countries, and Australia accounted for approximately 82% of DUKORAL sales in 2025, with Canada alone representing over 58%. DUKORAL is also registered in several endemic countries, and is on the WHO's list of prequalified vaccines, meaning it has been assessed as safe and effective.

While DUKORAL is relevant for both traveler and endemic segments, our commercial strategy focuses on the traveler market, which included approximately 453 million travelers to Asia, South America, and Africa in 2019.

Endemic market sales currently represent less than 3% of DUKORAL sales. This segment is supplied directly and through UNICEF procurement programs by an Indian vaccine, Shancol, and a Korean vaccine, Euvichol.

Product sales for DUKORAL are driven by typical factors associated with travelers' vaccines, including the number of travelers in endemic regions, national recommendations, awareness about the illness, and the perception of risk by health practitioners and tourists.

An indication for LT-ETEC diarrhea in Canada, in conjunction with educational and promotional efforts, has resulted in higher penetration rates of DUKORAL in this market.

Another cholera vaccine, Vaxchora, received FDA approval in the United States in 2016. The clinical trial attempting to demonstrate the vaccine's protection against ETEC was not successful in the Phase 1 clinical trial. Vaxchora was approved by the European Commission in April 2020 for protection against cholera only.

***IXCHIQ Competition***

Vimkunya, a virus-like particle based chikungunya vaccine was licensed both in the U.S. and Europe in February 2025. Given the regulatory actions involving IXCHIQ and a generally unfavorable perception on vaccination against chikungunya, we have seen a continuous loss of market share in travelers markets where we distribute IXCHIQ. In endemic countries, such as Brazil, where IXCHIQ obtained marketing approval in April 2025, we see a commercial opportunity given IXCHIQ's single dose profile and long-lasting protection. There are additional vaccines in development which could enter certain markets in the coming years.

**Competition related to our product pipeline**

***Lyme disease***

We are aware of companies developing mRNA vaccines such as Moderna, therapeutic antibiotic drug candidates such as Ixodes, or antibody-mediated treatment such as Takeda Pharmaceuticals, Tonix Pharmaceuticals, Inovio Pharmaceuticals, Tarsus, and Euroimmun. However, their programs are in pre-clinical and/or Phase 1/2 clinical stage. Other companies such as GlaxoSmithKline, Sanofi, and Baxter had clinical programs against Lyme disease. LYMErix, from GSK, achieved approval in the U.S. and was later taken out of the market due to lack of market access and potential safety concerns, although it was later proven to be safe by a FDA advisory committee. Sanofi and Baxter were not successful and stopped their programs before requesting a marketing authorization.

***Shigellosis***

No approved Shigella vaccine is currently available outside of Russia or China, where two vaccines exist for limited (primarily military) use, neither of which are tetravalent. Through our exclusive partnership with LimmaTech Biologics AG, we are currently developing the world's most clinically advanced tetravalent Shigella vaccine candidate (Phase 2). Our candidate includes the four most prevalent Shigella species/serotypes which we believe is a strong advantage compared to competition. We are aware of a Phase 3 Shigella vaccine candidate developed by Beijing Zhifei Lvzhu but it is bivalent. Two other trivalent vaccine candidates developed by Institut Pasteur and GVGH are also in Phase 2. An additional five shigella vaccine candidates, including four oral ones, are in Phase 1.

## Sales and Marketing

We have a specialist commercial capability comprising approximately 60 employees for the distribution of our travel vaccines, IXCHIQ, IXIARO, and DUKORAL, and third-party vaccines.

We have established our own commercial operations in certain travel vaccine markets including the United States, Canada, the United Kingdom, Sweden, France, Austria, Norway, Denmark, Finland, Belgium, and the Netherlands. We commercialize our own and third-party vaccine brands to both private and government customers, including the U.S. military. In other markets, we have entered into marketing and distribution agreements with companies that specialize in the promotion of travel brands and/or for which there is a strategic fit with their product portfolio. Examples of such distribution partnerships include Germany (CSL Seqirus), Eastern Europe (IMED), Israel (Kamada), and Australia and New Zealand (CSL Seqirus).

## Commercial Operations in Key Markets

We manage nearly all of our global product sales revenues through our own commercial operations. Local operations include expertise in Sales, Marketing, Medical Affairs, business support functions, and General Management.

Our commercial teams work continuously to improve service and performance, including embracing digital technology, which allows us to better connect with travelers, physicians, and other health care professionals. We put the customer at the heart of our activities and focus on their needs for improved awareness, a deeper understanding of the travel health landscape, and tailor-made services to achieve their objectives.

We have leveraged our commercial organization to distribute third-party products. We entered into a partnership with Seqirus in 2016 to commercialize two differentiated flu vaccines in Austria. We also entered into a marketing and distribution partnership with Kamada in 2018 to commercialize their Rabies immunoglobulin in Canada and with Bavarian Nordic in 2020 to commercialize their Rabipur and Encepur brands in Austria, the UK, France, Belgium, the Netherlands, and Canada. In September 2022, we announced a marketing and distribution agreement with VBI Vaccines Inc. to commercialize their Hepatitis B vaccine PreHevbri in the United Kingdom, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands which ended in 2024. Our distribution agreements with VBI Vaccines and Seqirus ended in 2024 while our distribution agreement with Bavarian Nordic ended at the end of 2025; for further information, please see Item 10C.

## Manufacturing

Manufacturing of vaccines is considered one of the most complex pharmaceutical manufacturing operations. It can take between six to 36 months to produce, package, and deliver high quality vaccines to those who need them. The process includes testing each batch of vaccine at every step of its journey, and repeat quality control of batches by different authorities around the world.

Our manufacturing base provides a long-term and sustainable industrial network to supply clinical trial material and commercial products based on objectives for delivery schedule, costs, flexibility, and quality.

We operate three manufacturing sites augmented by contract manufacturing partners. Our manufacturing network has been operating and producing licensed vaccines for more than ten years. We have a highly experienced management team and workforce operating our production network. We have the expertise and capability to produce most types of viral or bacterial vaccines.

***Livingston (Edinburgh), Scotland, UK***

We own two adjacent manufacturing facilities at our site in Livingston, Scotland, both operating under a Manufacturer's License issued by the MHRA. The first facility (Manson) comprises 3,547 square meters, and the second facility (Almeida), added in August 2020, covers approximately 6,500 square meters. The site supports multi-product manufacturing and serves as our viral vaccine center of excellence, employing approximately 140 staff. The Livingston site operates different, dedicated production units which we have used for IXIARO, IXCHIQ and various other viral vaccine clinical trial material manufacturing.

The site expansion and construction of Almeida was part of our COVID-19 vaccine program in 2020. Following the decline in order volumes from EU Member States, we ceased manufacturing our COVID-19 vaccine and subsequently decided to consolidate all manufacturing over time into Almeida. The transfer of IXIARO and IXCHIQ production from Manson to Almeida, along with the associated regulatory approval processes, is currently underway.

***Solna (Stockholm), Sweden***

Our Solna facility can operate on a multi-product basis and comprises approximately 11,000 square meters. The site is qualified to meet required standards of several regulatory bodies including the competent Swedish authorities, Health Canada, and TGA. Our Solna site has a heritage and history from more than 100 years in vaccines operations. It is currently our center of excellence for fill-finish operations. As part of our COVID-19 activities, we expanded our fill-finish capacity by fitting out a nearby site for formulation, filling, and packaging and have now transferred our manufacturing

activities to this new site. With around 130 current employees, the site operates as a dedicated and integrated production unit for DUKORAL. In 2023, as part of a review of our global R&D strategy, we took the decision to divest our Clinical Trial Manufacturing (CTM) unit to NorthX Biologics. Our Solna site is operated on a long-term lease under a Manufacturers License from MPA.

***Vienna, Austria***

Our facility in Vienna includes a dedicated Quality unit for Quality control (in vitro and in vivo) and Quality Assurance. This unit covers both proprietary and third party products. As such, this facility is registered with the FDA and operates under respective licenses from the Austrian Agency for Health and Food Safety. In Vienna, where we have centralized our product development capabilities we also have a GMP technical development unit that establishes our new vaccines prior to the final industrialization stage. The management of all contract manufacturing partners is managed by a dedicated external manufacturing unit based in Vienna.

## Intellectual Property

Our commercial success depends in part on obtaining and maintaining patent, trade secret, and other intellectual property and proprietary protection of our technology, current and future products, and product candidates and methods used to develop and manufacture them. We cannot be sure that patents will be granted with respect to any of the pending patent applications or to any patent applications that we file in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be sufficient to protect our technology or will not be challenged, invalidated. or circumvented. Our success also depends on our ability to operate our business without infringing, misappropriating, or otherwise violating any patents and other intellectual property or proprietary rights of third parties.

We manage our intellectual property by:

- seeking protection for our products, technologies, and processes by actively using the patent, trademark, copyright, and trade secrets systems in Europe, the United States, Canada, Brazil, India, and other jurisdictions where we might have business interests;
- defending, and if needed, enforcing our property rights in selected jurisdictions; and
- identifying, reviewing and monitoring third party patent rights and challenging, invalidating and/or in-licensing such rights where applicable, in order to establish and ensure the unrestricted use and operation of our products, product candidates, and technologies, in those jurisdictions where we have business interests.

***Patents and patent applications***

We consider protecting technologies and products through patents and patent applications essential to the success of our businesses.

As of December 31, 2025, we had a portfolio of 495 issued patents, including 86 granted with effect in Germany, France, the United Kingdom, Spain, and Italy, 47 issued in the United States, and 104 pending patent applications, including 16 pending in Europe and 3 pending international (or PCT) patent applications.

In countries where we seek legal protection through patents, the duration of legal protection for a particular product, method or use, is generally 20 years from the filing date. This protection may be extended in some countries, particularly in the European Union, China, Japan, South Korea, Australia, Canada and the United States. The protection, which may also vary by country, depends on the type of patent and its scope. In most industrialized countries, any new active substance, formulation, indication, use or manufacturing process may be legally protected. We conduct ongoing checks to protect our inventions and to act against any infringement of our patents.

***IXIARO***

In regards to our Japanese encephalitis marketed vaccine, IXIARO, as of December 31, 2025, we own a patent family that includes 5 issued U.S. patents (9,884,115, 9,895,437, 9,913,898, 10,668,146, and 11,110,170) with claims covering the aqueous composition of IXIARO and methods for preparing IXIARO, and 1 pending U.S. patent application. This patent family also includes 3 granted European patents directed to compositions comprising IXIARO and/or methods for preparing IXIARO, and one pending European patent application. One of the granted European patents EP3’269’386 directed to a method for preparing an aqueous composition comprising aluminium, a reactive compound and a protein, was opposed at the EPO in June 2023 and upheld with amended claims as confirmed in an interlocutory decision of December 19, 2025. This decision is open to appeal. A second of the granted European patents EP3’785’730 directed to an aqueous composition comprising aluminium, a reactive compound, and a protein, was opposed at the EPO in January 2025. This patent was limited to bacterial proteins in the opposition proceeding and thus does not cover IXIARO anymore. Patent applications, if issued, and patents in this family are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a pending U.S. and European patent application with claims covering the manufacturing processes of IXIARO and potentially other vaccines. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We further own a pending U.S., Canadian, and a European patent application with claims covering a particular use of the IXIARO formulation and potentially other vaccines. Patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

***DUKORAL***

In regards to our DUKORAL product, as of December 31, 2025, we own a pending U.S., Canadian, and European patent application with claims directed to stable pharmaceutical compositions covering a currently non-commercialized formulation of DUKORAL and methods of use thereof, and patent applications or applications relating to these applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. Patents covering the composition of matter of DUKORAL are expired.

***IXCHIQ***

In regards to our chikungunya vaccine IXCHIQ and the VLA1553 vaccine candidate, as of December 31, 2025, we own 2 patent families that include 4 granted U.S. patents and 2 granted European patents with claims covering methods of preparing and methods of purifying VLA1553, and 1 pending European patent application. Patent applications, if issued, and patents in this family are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to pharmaceutical compositions of VLA1553 that includes 3 U.S. patents, 1 Brazilian, 1 Chinese, 2 Japanese, 1 Korean, Mexican, 2 Malay, 2 New Zealander, 1 Taiwanese, 1 Singaporean, and 1 Vietnamese patents and over 10 pending patent applications in such jurisdictions as the U.S., Europe, Australia, Brazil, Canada, China, India, Japan, Colombia, Argentina, Thailand, Panama, Indonesia, and Mexico. Patent applications, if issued, in this family are expected to expire in 2038, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of December 31, 2025, we also own two patent families with claims covering formulations, secondary uses, and manufacturing processes of VLA1553. Each of these families were nationalized in 17 jurisdictions, and all are still pending except in South Africa and Israel. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own four patent families with claims directed to the administration of VLA1553 in immunocompromised subjects, and three patent families directed to particular formulations and combination uses. As of December 31, 2025, these patent families of different uses and combinations are either in the priority year or recently filed as an international patent application or nationalized in Canada, Europe, and the U.S. Patent applications if issued, are expected to expire in 2044 or 2045 or 2046, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

***Lyme disease vaccine candidate***

In regards to our Borrelia vaccine candidate VLA15 which is currently licensed to Pfizer, as of December 31, 2025, we own a patent family which includes 8 issued U.S. patents, 1 pending U.S. patent application, and 2 European patents that are validated, one in 38 of the European Patent Convention member states and the other in 12 of those member states and one pending European patent application, as well as 33 foreign patents and 1 patent application with claims covering the composition of matter of VLA15. We further own a second patent family which includes 3 issued U.S. patents and 2 granted European patents that are validated, one in 38 of the European Patent Convention member states and the other in 28 of those member states as well as 24 foreign patents and 2 patent applications with claims covering the composition of matter of VLA15. Patent applications, if issued, and patents in these families are expected to expire in 2033 and 2035, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We also own a patent family with claims directed to immunogenic polypeptides with C-terminus domains of OspA to induce a protective immune response that includes 2 U.S. and 1 European patent validated as a Unitary patent, 1 UK patent, 1 Spanish patent, 1 Hong Kong patent, and one patent application pending in the Canada. Patent applications, if issued, in this family are expected to expire in 2038, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of December 31, 2025, we also own two patent families with claims directed to compositions comprising OspA fusion proteins including uses thereof and to improved methods for producing a vaccine. Both families were nationalized in Europe, the U.S., and Canada in 2022. Patent applications claiming priority to these patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We further co-own with a third party a patent family which includes pending patent applications in Europe, the U.S., and 13 further foreign jurisdictions of which one foreign patent is granted. Patent applications claiming priority to these patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and

patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We further own four U.S. patents and a European patent directed to an aqueous composition comprising aluminium, a reactive compound, and a protein and methods of production thereto. The European patent was opposed at the EPO in January 2025. Patent applications, if issued, and patents in this family are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

***Shigella vaccine candidate***

In regards to our Shigella vaccine VLA2401, as of December 31, 2025, our in-licensed 12 patent families of which most are related to a bioconjugation technology using mutated PglB oligosaccharyltransferases and its uses to produce vaccine candidates including vaccine candidate VLA2401. The latest of these patents, which relates to an immunogenic composition of VLA2401, if maintained, is expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

***Zika vaccine candidate***

In regards to our Zika vaccine candidate VLA1601, as of December 31, 2025, we own a patent family that includes 5 issued U.S. patents with claims covering the aqueous composition of VLA1601 and methods for preparing VLA1601, and one pending U.S. patent application. This patent family also includes 3 granted European patents with claims directed to compositions comprising VLA1601 and/or methods for preparing VLA1601, and 1 pending European patent application. One of the granted European patents EP3'269'386, directed to a method for preparing an aqueous composition comprising aluminium, a reactive compound, and a protein, was opposed at the EPO in June 2023 and upheld with amended claims as confirmed in interlocutory decision of December 19, 2025. This decision is open to appeal. A second of the granted European patents EP3'785'730 directed to an aqueous composition comprising aluminium, a reactive compound, and a protein, was opposed at the EPO on January 2025. This patent was limited to bacterial proteins in the opposition proceeding and thus does not cover IXIARO anymore. Patent applications, if issued, and patents in this family are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Furthermore, we own a patent family with 5 granted U.S. patents with claims covering the formulation of VLA1601, 1 pending U.S. patent application, 1 granted European patent validated in 30 countries, 1 pending European patent application, 7 further foreign patents, and 10 further pending foreign patent applications. The granted European patent directed to a Zika virus vaccine was opposed at the EPO in November 2023 and upheld with amended claims as confirmed in interlocutory decision of November 14, 2025. This decision is open to appeal. Patent applications, if issued, and patents in this family are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. A third party has filed an Inter Partes Review Proceeding against one of the U.S. patents, for which the U.S. Patent Trial and Appeal Board has now issued a decision denying Institution after we withdrew some of the claims. We have filed an Inter Partes Review Proceeding against one of the U.S. patents of said third party, for which the third party has limited the claims. The U.S. Patent Trial and Appeal Board has issued a decision to institute inter partes review on all claims not already statutorily disclaimed whereupon the parties have filed a joint motion to terminate without a settlement agreement. The U.S. Patent Trial and Appeal Board has therefore issued a decision to terminate the proceeding.

We also own two patent families that include 4 granted U.S. patents with claims covering methods of preparing and methods of purifying VLA1601, and 2 granted Europeans. Patents in these families are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a pending U.S. and a European patent application with claims covering the manufacturing processes of VLA1601 and potentially other vaccines. Patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also own a patent family with claims directed to a second generation Zika vaccine including VLA1601. As of December 31, 2025, this patent family is still in the international patent application phase. Patent applications if issued, are expected to expire in 2044, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

***Clostridium difficile candidate***

In regards to our *C. difficile* candidate VLA84, as of December 31, 2025, we own a patent family with 6 granted U.S. patents with claims covering the composition of matter of VLA84 and methods of use thereof, 1 pending U.S. patent application, and 20 granted foreign patents in such jurisdictions as Australia, China, Brazil, Canada, Hong Kong, India, Korea, Mexico, South Africa, and Japan. This patent family also includes two granted European patents of which one was validated in 38 member states and that has been opposed and is now maintained by the European patent in amended form, which still covers VLA84. The second European patent has not been opposed and is validated in 9 member states, and a third European patent application is pending. Patent applications, if issued, and patents in this family are expected to expire

in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We also filed an opposition against two European patents owned by a third party that has claims that might cover VLA84. The European Patent Office revoked both of these patents in opposition proceedings and after the patentee withdrew both appeals, the proceedings were canceled without substantive decisions.

We filed also a further opposition against a European patent that has claims that might cover VLA84 in July of 2024. The European patent office has revoked the patent in the meantime.

***EB66 cell platform***

We obtained several patents covering (i) the establishment of embryonic derived cell lines, (ii) their use for the production of biologicals including their use in virus replication and virus production, and (iii) in some jurisdictions the cell line per se. The latest of these patents and patent applications, if issued, and patents in these families are expected to expire in 2036, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

***Other protection mechanisms***

Our core technologies, products, and many of our projects for the development of products candidates depend upon the knowledge, experience, and skills of our scientific and technical personnel. In order to protect our trade secrets, proprietary know-how, and technologies, we generally require all employees, contractors, advisors, and collaborators to enter into confidentiality agreements. These agreements prohibit the disclosure of our confidential information. Agreements with employees and consultants also require disclosure and assignment to us of any ideas, developments, discoveries, and inventions. Furthermore, we have a number of identified trade secrets in our manufacturing processes which are particularly marked and handled by us, our subcontractors, and our sublicensees.

The expiration of a patent for a product may result in significant competition, due to the emergence of biosimilar or similar products, and in a substantial reduction of product sales which benefited from patent protection. However, the vaccine field is largely protected from direct substitutions, as regulatory and manufacturing complexity has for now blocked the pathway in developed markets for vaccine biosimilars. However, this is not the case regarding similar products relying on a full or abbreviated regulatory approval process and this situation may also change in the future, thus opening a pathway to biosimilars. Nevertheless, in many cases, we may still continue to reap commercial benefits from our product manufacturing secrets, even when the patents for such product have expired.

***Trademarks***

The trademark rights we hold are national, international, and European-wide in scope. The rights are generally granted for a period of ten years and are indefinitely renewable, although in some cases, their validity is contingent on the trademark's continued use in the particular jurisdiction. We hold the title to the names of the products used and those associated therewith.

Our trademarks benefit primarily from protection for pharmaceutical products included in Class 5 and for services in Class 42 of the International Classification of Products and Services.

Our company name, key products, technologies and product candidates, namely VALNEVA, IXIARO, JESPECT, DUKORAL, IXCHIQ, and EB66, and the number of trademarks related to these products and our company held by us on December 31, 2025 are shown in the table below.

**TRADEMARKS – NUMBER OF REGISTRATIONS**

| Trademarks | Number of registrations or applications |
|---|---|
| Valneva, Valneva logos | 87 |
| IXIARO, IXIARO logo | 136 |
| JESPECT | 19 |
| DUKORAL | 60 |
| IXCHIQ | 63 |
| EB66 | 11 |
| CHIK-A-WHAT | 3 |

We also hold registrations for our different entities' names, as well as the slogan and logo which constitute our graphic charter. We defend our trademark rights by filing a notice of opposition against applications for identical or similar trademarks, and initiates, if such is the case, legal actions to have its rights recognized.

***VALNEVA trademark***

Valneva SE and the company KRKA, tovarna zdravil, d.d., Novo Mesto (KRKA) signed a co-existence agreement on January 20, 2014, with respect to KRKA's earlier trademark DALNEVA covering goods of Class 5. We agreed on restricting the specification of goods for the trademark Valneva, by adding the limitation "none of the afore-mentioned goods for the treatment of cardiovascular diseases" to the European Union Trademark (EUTM) application No. 011441268, and to any future applications.

Moreover, we also filed a notice of opposition before the European Union Intellectual Property Office (EUIPO) against the trademark application VALNECOR (application No. 13.519889) of the Company Vetpharma Animal Health SL, for Class 5, invoking Articles 8(1)b and 8(4) of the Regulation (EC) No. 207/2009 on the Community trademark (EUTMR – as amended). On February 19, 2016, the Opposition Division of the EUIPO decided in our favor and upheld the opposition (No. B 2508755) for all the contested goods in Class 5.

A letter of undertakings effective as of July 25, 2016 has been signed by VALNÉVA, a French Simplified Joint Stock company (SASU), and Valneva SE, in order to:

- acknowledge our prior rights; and
- record VALNÉVA's undertaking never to contest or challenge the Company name and the trademarks Valneva – registered or filed – for any goods and services.

VALNÉVA SASU further agreed not to use the name VALNÉVA for scientific R&D in the fields of medicine, antibodies and vaccines.

We and Boehringer Ingelheim International GmbH also signed a prior rights agreement on July 28, 2016. Pursuant to this agreement, we undertake not to use the trademark Valneva as a product name or part of a product name for the identification of specific products, but only to identify the manufacturer of the product ("house mark" or "manufacturers brand"). We also undertake to limit the registration of the mark "Valneva" in Class 5 to the "Pharmaceutical products for human and veterinary use, namely vaccines and antibodies and fragments thereof, blood serum, adjuvants for medical or veterinary use", only if so specifically requested by Boehringer Ingelheim.

We filed a notice of opposition before EUIPO against the trademark application VALNOBI No.17579525 made in Class 5 in the name of Bayer AG. On February 4, 2019, the Opposition Division of the EUIPO decided in our favor and upheld the opposition (No. B 3047941) for all the contested goods in Class 5.

We filed notices of opposition against the EU trademark application VALNEVA No. 017895207 and the Austrian trademark application VALNEVA No. 295810. The Austrian trademark application was withdrawn and the EU trademark application was rejected to a large part of the contested goods and services, and in particular to all of the goods in Class 5.

***IXIARO trademark***

On October 30, 2015, Valneva Austria GmbH acquired from GSK (GlaxoSmithKline Biologics SA, GlaxoSmithKline GmbH and CO.KG) the trademark IXIARO and the related trademarks and domain names, for all jurisdictions. No co-existence or prior rights agreements exist for the trademark IXIARO.

***OxARO vs. IXIARO***

We filed an Opposition in 2021 and signed a prior rights agreement with the result that SafeRx withdrew the application OxARO in the U.S. The Settlement Agreement was signed on January 26, 2022. According to the Settlement Agreement SafeRx undertakes to refrain from asserting rights deriving from U.S. Application Serial No. 90/233,007 or use of the trademark OXARO for pharmaceutical preparations and agrees to expressly abandon U.S. Application Serial No. 90/233,007. SafeRx agrees never to use OXARO by itself on a product distributed in the marketplace and will instead use "OxARO ER" and "OxARO IR". SafeRx may use OXARO solely for fundraising for product development and FDA review, but once through FDA review, SafeRx agrees never to use the mark OXARO by itself, but instead will use the marks "OxARO ER" and "OxARO IR".

***DUKORAL trademark***

Various prior rights agreements related to the trademark DUKORAL were executed in the years 1996 to 2002. A further prior rights and delimitation agreement between Crucell Sweden AB, now Valneva Sweden AB, and Berlin-Chemie AG was signed on June 29, 2012. For mutual settlement of the opposition filed by then Crucell Sweden AB, Berlin Chemie AG undertakes not to derive any rights from the registration and use of their German trademark DUCORA against the Community Trademark registration of DUKORAL, and to tolerate new applications and modifications of the prior DUKORAL trademark, provided that Crucell Sweden AB shall not apply for the trademark DUCORA. Berlin-Chemie AG restricted the goods and services of their German registration of DUCORA. Crucell agreed to the registration or use of German trademark DUCORA under the conditions specified and to withdraw the opposition. Since this agreement is effective worldwide, the party who possesses prior rights in any country agrees to consent to the registration or use of the other party's respective mark under the same conditions as mentioned in this agreement.

***Domain names***

On December 31, 2025, we held 218 domain names (reserved or in the process of being reserved).

## Government Regulation

Government authorities in the United States at the federal, state, and local level and in other countries and jurisdictions including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of biological products, such as our products, product candidates, and any future product candidates we develop. We, along with our third-party contractors, will be required to navigate the various pre-clinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies, seek approval or licensure of our product candidates, and distribute and market our products, if approved. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

***Regulatory Approval in the United States***

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and other federal, state, local, and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with the FDA's Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each clinical trial may be commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity, and potency of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application, or BLA, after completion of all clinical trials;
- payment of any user fees for FDA review of the BLA;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with current Good Manufacturing Practice, or cGMP requirements to assure that the facilities, methods, and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data; and
- FDA review and approval of the BLA, to permit commercial marketing of the product for particular indications for use in the United States.

***Pre-clinical Studies***

Before testing any biological product candidates in humans, the product candidate must undergo rigorous pre-clinical testing. Pre-clinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/ toxicology studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term pre-clinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

***Clinical Trials***

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product candidate, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Disclosure of the results of these clinical trials can be delayed in certain circumstances.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA submission and approval, clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2, and Phase 3, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, absorption, metabolism, and distribution of the product candidate in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness.
- Phase 2 clinical trials generally involve studies conducted in a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide statistically significant evidence of clinical efficacy of the product for its intended use, further evaluate its safety, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

Phase 1, Phase 2, Phase 3, and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic does not undergo unacceptable deterioration over its shelf life.

***FDA Review Processes***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

The FDA reviews a submitted BLA to determine if it is substantially complete before the FDA accepts it for filing and may request additional information from the sponsor. The FDA will make a decision on accepting a BLA for filing within 60 days of receipt, and may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the BLA must be resubmitted with any additional information requested in order to be reviewed by FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and whether the facility in which it is

manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets 10 months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

The cost of preparing and submitting a BLA is substantial. Under PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether such facilities comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety, purity, and potency of the product candidate. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally considers such recommendations carefully when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product is produced, it will issue either an approval letter or a Complete Response Letter, or CRL. A CRL or deferred action on the application may also occur where FDA is unable to complete required pre-approval inspections due to travel restrictions. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies, or manufacturing in order for FDA to reconsider the application. If a CRL is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months from receipt, depending on the type of information included. Even if data and information are submitted in response to the deficiencies identified in a CRL, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may require a REMS to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use, or ETASU. An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan

exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

***Expedited Development and Review Programs***

The FDA offers a number of expedited development and review programs for qualifying product candidates intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. For example, Fast Track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and where pre-clinical or clinical data demonstrate the potential to address unmet medical needs for the disease condition. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. The sponsor of a biological product candidate can request the FDA to designate the candidate for a specific indication for Fast Track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner. The designation also includes all of the Fast Track program features, including eligibility for rolling review of BLA submissions if the relevant criteria are met.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify the product's clinical benefit in relationship to the surrogate endpoint. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast

Track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

***Additional Controls for Biologics***

To help reduce the increased risk of the unintentional introduction of other microorganisms, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA generally does not apply to any biological product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any exclusivity—patent or non-patent—for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, completing, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as applications, with all of the benefits that designation confers.

***Post-Approval Requirements***

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Once a BLA is approved, a product will be subject to certain additional post-approval requirements.

The FDA also may require post-marketing testing, known as Phase 4 testing, impose a REMS and/or post-market surveillance to monitor the effects of an approved product, or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Manufacturers are subject to periodic unannounced inspections by the FDA, including those focused on manufacturing facilities to assess compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warnings, or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;

- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity, and potency that are consistent with the provisions of the FDA-approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, issuance of warning or untitled letters, requirements to issue corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict the manufacturer's communications on the subject of off-label use of their products, as well as actions taken on behalf of the manufacturer, such as sponsored scientific and educational activities conducted by a third party.

***Biosimilars and Reference Product Exclusivity***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

Under the BPCIA an application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period.

***Regulatory Approval in the EU***

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies, and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in EU Member States for a marketing authorization application, or MAA, and granting of a marketing authorization, or MA, by competent authorities in EU Member States or the European Commission before the product can be marketed and sold in the EU.

***Clinical Trial Approval***

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20, or CTD.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials, and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the

application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State concerned. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

***Orphan Drug Designation and Exclusivity***

Regulation (EC) No. 141/2000 as implemented by Regulation (EC) No. 847/2000 provides that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating, or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the ten-year period if: (i) the MA holder of the authorized product consents to a second original orphan medicinal product application, (ii) the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) the second applicant can establish that its product, although similar, is safer, more effective, or otherwise clinically superior to the authorized orphan medicinal product. A company may voluntarily remove a product from the register of orphan products. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication.

***Pediatric Development***

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

***Marketing Authorization***

To obtain a marketing authorization for a product in the EU, an applicant must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions, and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients authorization through, the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has an initial validity of five years in principle. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety, and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention, or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a

traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations, and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. MA holders and/or manufacturing and import authorization, or MIA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

***Data and Market Exclusivity***

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

***Regulatory Requirements after Marketing Authorization***

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion, and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

***Advertising Regulation***

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

***Regulatory Approval in the United Kingdom***

On January 31, 2020, the United Kingdom, or UK, left the EU (commonly referred to as "Brexit") and accordingly is no longer an EU Member State. As the UK is no longer an EU Member State, the UK's participation in the European Medicines Regulatory Network has ceased and the UK Medicines and Healthcare products Regulatory Agency, or MHRA, has assumed the functions that were previously undertaken by the EU institutions for human medicines on the UK market.

While the UK's regulatory framework for clinical trials was historically based on the Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the former EU Clinical Trials Directive, this has been significantly reformed by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024. The new legislation, which was adopted in April 2025, modernizes the UK's approach to make it a more attractive location for research, and includes key features such as: (i) a risk-proportionate approach, including a notification scheme for lower-risk trials; (ii) a combined review process integrating ethics committee and regulatory approvals into a single, streamlined pathway; (iii) enhanced transparency requirements mandating registration of clinical trials in a public registry and publication of trial results within 12 months of trial completion (with scope for deferrals in certain circumstances); (iv) greater flexibility to support innovation in clinical trial design; and (v) measures to promote patient and public involvement. The amendments will become applicable on April 28, 2026 following a one-year transition period.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK.

All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products until January 1, 2025. On January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. Pursuant to the Windsor Framework holders of Great Britain marketing authorizations converted into UK marketing authorizations on January 1, 2025 unless the entities holding such marketing authorizations also held a Northern Ireland marketing authorization that they failed to cancel before December 31, 2024. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. Companies must follow one of the United Kingdom's national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the United Kingdom.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, and rolling review procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures, are considered to be authorizations for the purposes of the IRP. The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applications should be decided within a maximum of 60 days if: (i) there are no major objections identified that cannot be resolved within such 60 day period and (ii) the approval from the trusted regulatory partner selected has been granted within the previous 2 years. Where major objections are identified or such approval has not been granted within the previous 2 years, the decision timeline extends to 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the United Kingdom, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the United Kingdom.

***International Regulation***

In addition to regulations in the United States and the EU, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA, European Commission, or EU Member State competent authority approval.

## Other Healthcare Laws and Regulations and Legislative Reform in the United States and the EU

***U.S. Healthcare Laws and Regulations***

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, third-party payors, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would market, sell, and distribute our products. Our current and future operations are subject to regulation by various federal, state, and local authorities in addition to the FDA, including but not limited to the Centers for Medicare & Medicaid Services, or CMS, the Department of Health and Human Services, or HHS, (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Services Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- Federal civil and criminal false claims laws, such as the False Claims Act, which can be enforced by private citizens through civil *qui tam* actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious, or fraudulent claims for payment of federal funds, and knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Drug manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- The Health Insurance Portability and Accountability Act, or HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses, and certain healthcare providers, known as covered entities, and their respective business associates and their covered subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- Federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to

report annually to CMS information related to payments and other transfers of value provided to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Similar healthcare laws and regulations in other jurisdictions, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers, and state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts; and
- State laws that require the reporting of marketing expenditures or drug pricing, including information pertaining to and justifying price increases; state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; state laws that require the posting of information relating to clinical trials and their outcomes.

If our operations are found to be in violation of any of these laws or any other current or future healthcare laws that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

***U.S. Legislative Reform***

We operate in a highly regulated industry, and new laws, regulations, and judicial decisions, or new interpretations of existing laws, regulations, and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition, and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, which included changes to the coverage and reimbursement of drug products under government healthcare programs.

There have been executive, judicial, and congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Additional health reform measures may continue and affect our business in unknown ways. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across

government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional U.S. healthcare reform measures will be adopted in the future.

***Coverage and Reimbursement***

Market acceptance and sales of any vaccine candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations, and other private health insurers.

Third-party payors decide which therapies they will pay for and establish reimbursement levels. Travel vaccines are rarely reimbursed in Europe and, while no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, biological, and vaccine products, or formulary, generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of such product by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. In addition, because our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Further, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Third-party payors are increasingly challenging the prices charged for medical products and may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the EMA, FDA, or other government regulators; is not used in accordance with cost-effective treatment methods as determined by the third-party payor; or is experimental, unnecessary, or inappropriate. Prices could also be driven down by managed care organizations that control or significantly influence utilization of healthcare products. Outside the United States, pricing of competitive products by third-parties is the biggest driver of the prices of our products.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell vaccines and could adversely affect the prices that we receive for our vaccine candidates, if approved. Some of these proposed and implemented reforms could result in reduced pharmaceutical pricing or reimbursement rates for medical products.

In the EU, pharmaceutical companies, products and distributors are also generally subject to extensive governmental price controls and other market regulations. In many EU Member States, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits.

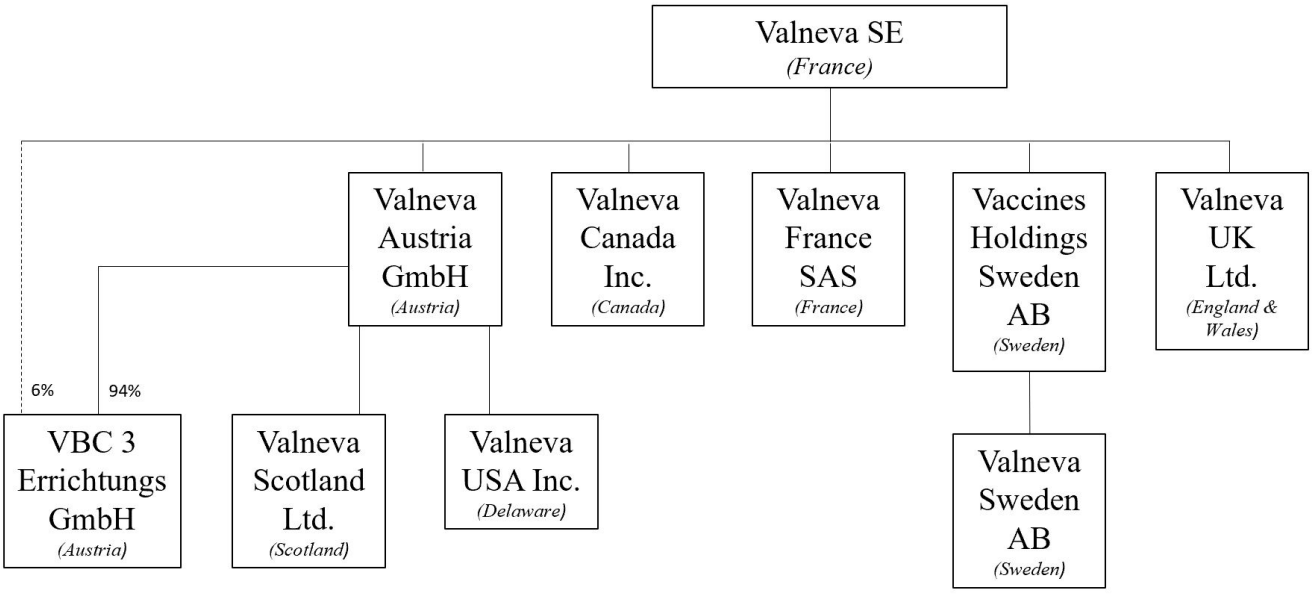
In various EU Member States, continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper products as an alternative apply. Health Technology Assessment, or

HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including countries representing major markets. The HTA process, which is currently governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

On January 12, 2025, the Health Technology Regulation, or HTA Regulation, entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and Healthcare Products Regulation Agency is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of March 31, 2025, relaunching the Innovative Licensing and Access Pathway with more predictable timelines and closer involvement of the National Health Service.

## C. Organizational Structure

The chart below presents our significant subsidiaries as of December 31, 2025. Each subsidiary shown is 100% owned by the relevant parent company unless otherwise noted.




## D. Property, Plants and Equipment

Our registered office is located at Îlot Saint-Joseph, Bureaux Convergence, Bât. A, 12 ter Quai Perrache, 69002 Lyon (France). We also have key manufacturing facilities located in Scotland and Sweden. We believe that our existing facilities are adequate for our near-term needs, and we believe that suitable additional or alternative manufacturing and office space will be available as required in the future on commercially reasonable terms.

In the following table you can find the overview of our facilities:

| Entity | Own/ Lease | Location | Country | Usage | Square meter |
|---|---|---|---|---|---|
| **Valneva SE** | own | Saint-Herblain | France | laboratories and offices | 3,178 |
| **Valneva Scotland Ltd.** | own | Livingston | Scotland | manufacturing, warehouse and offices | 3,547 |
| **Valneva Scotland Ltd.** | own | Livingston | Scotland | manufacturing, warehouse and offices | 6,500 |
| **VBC3 Errichtungs GmbH** | own | Vienna | Austria | laboratories and offices | 10,725 |
| **Valneva France SAS** | Lease | Lyon | France | sales and marketing activities | 451 |
| **Valneva Sweden AB** | Lease | Solna | Sweden | manufacturing, laboratories and offices | 10,739 |
| **Valneva Sweden AB** | Lease | Solna | Sweden | manufacturing, warehouse and offices | 4,000 |
| **Valneva UK Ltd.** | Lease | Fleet | England | offices | 72 |
| **Valneva Canada** | Lease | Kirkland | Quebec | offices | 136 |
| **Valneva USA, Inc.** | Lease | Bethesda | Maryland | offices | 470 |

Currently, a total of 2,128 square meters of the larger facility in Solna are subleased to NorthX Biologics Matfors AB. Within the Group, 152 square meters of the facility in Lyon are subleased to Valneva SE.

In November 2025, we announced our plans to close our site in Nantes and consolidate our French operations in Lyon. As a result, we are in the process of identifying possible purchasers of the facility we own in Saint-Herblain.

# Item 4A. Unresolved Staff Comments.

Not applicable.

# Item 5. Operating and Financial Review and Prospects

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related Notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in "Item 3.D—Risk Factors" of this Annual Report, our actual results could differ materially from the results described in or implied by these forward-looking statements.*

*Our audited consolidated financial statements as of and for the years ended December 31, 2025 and 2024 and the three years ended December 31, 2025 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.*

*For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.*

## Overview

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best-, or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early Research & Development (R&D) to approvals, and currently market three proprietary travel vaccines.

For more details about our business, see "Item 4.B—Business Overview" of this Annual Report.

Our operations have focused on organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, establishing our commercial infrastructure, growing our commercial portfolio, establishing and advancing our manufacturing capabilities, and conducting pre-clinical studies and clinical trials. As of December 31, 2025, we had €109.7 million in cash and cash equivalents. Our operating loss was €82.1 million for the year ended December 31, 2025, operating profit was €13.3 million for the year ended December 31, 2024 and operating loss was €82.1 million for the year ended December 31 2023. Our net losses were €115.2 million, €12.2 million, and €101.4 million for the years ended December 31, 2025, 2024, and 2023, respectively. We expect to continue to incur significant operating expenses and net losses for the foreseeable future.

## Factors Affecting Our Results

We believe that our financial performance has been and for the foreseeable future will continue to be primarily driven by the factors discussed below. While many of these factors present opportunities for our business, they also pose challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in "Item 3.D —Risk Factors".

***Revenues***

We principally derive our revenues from the sale of our commercialized travel vaccines in their respective markets, as well as from sales of third-party products. In the years covered by this Annual Report, revenues from our products derived from the sale of IXIARO, DUKORAL, and IXCHIQ. We also derive revenues from royalties, partnerships related to our vaccine candidates, as well as from collaborations, services, and licensing agreements and by offering our technologies and services to third parties.

***Product Sales of IXIARO, DUKORAL, IXCHIQ and Third-party Products***

Product sales of IXIARO and DUKORAL represented in aggregate 82.5%, 77.4%, and 71.4% of our revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Our primary markets for these products are the United States and Germany for IXIARO and Canada for DUKORAL.

We generated our first revenue from the sale of IXCHIQ in 2024, following initial regulatory approvals. For the year ended December 31, 2025, product sales of IXCHIQ represented 5.3% (December 31, 2024: 2.3%) of our revenues.

In addition, we generate revenues by leveraging our existing sales and marketing infrastructure to sell third-party products. Revenues from sales of third-party products represented 12.1%, 20.3%, and 24.7% of our revenues for the years ended December 31, 2025, 2024, and 2023, respectively.

Sales trends in travel vaccines are primarily driven by travel volume to endemic regions, national travel advisories, awareness about illness, and the perception of risk by health practitioners and tourists.

While COVID-19 impacted sales of our travel vaccines to the general public, sales of our Japanese encephalitis vaccine IXIARO to the Defense Logistics Agency, part of the U.S. Department of Defense (DoD), which purchases the vaccine for military personnel being deployed to endemic regions, have remained significant over the periods presented herein. Sales

of IXIARO to the DoD in 2025, 2024, and 2023 derived from contracts signed in prior years. The agreement signed in September 2023 was for one year and had a minimum value of approximately $32.3 million for approximately 200,000 doses, covering the needs for the end of 2023 and the full year 2024. In January 2025, we signed a new $32.8 million IXIARO supply contract with the DoD.

For the years ended December 31, 2025, 2024, and 2023, 28.4%, 30.9%, and 25.5%, respectively, of our total product sales of IXIARO were from sales to the DoD.

***Other revenues***

***Revenues from Collaboration***

We derive revenues from collaboration and partnership agreements. One source of collaboration revenues is through our research collaboration and license agreement with Pfizer. For further information on the accounting treatment on Collaboration and License Agreement see Note 5.5.2 Other revenues, Note 5.5.3 Disaggregated revenue information and Note 5.29 Refund liabilities.

As of December 31, 2025 revenues from the Lyme-Pfizer collaboration and license agreement amounted to €10.0 million. In the years ended December 31, 2023 and December 31, 2024, no revenues were recognized as Valneva determined that entitlement to the consideration was not yet highly probable, due to the possibility of increased payments to customers while R&D activities (including the Phase 3 study) are progressing ahead of possible BLA licensure submission to the FDA.

***Revenues from Technologies and Services***

We also derive revenues from sales of our technologies and services. Revenues from our technologies consist of revenues from our EB66 cell line, which is derived from duck embryonic stem cells and provides an alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines, and our IC31 vaccine adjuvant, which is a synthetic adjuvant targeting antigens to improve immune response and has been licensed to several pharmaceutical companies. Service revenues consist of research and development services we provide to third parties, including process and assay development.

***Key Cost Drivers***

***Cost of Goods and Services***

Historically, manufacturing costs have experienced limited cost increases. Manufacturing costs comprise site infrastructure, employees to operate the manufacturing, and the bill of materials. Incremental cost increase is driven by the variable cost in the bill of materials. We are manufacturing our IXIARO and IXCHIQ vaccines at our facilities in Livingston, Scotland. We are manufacturing our DUKORAL vaccine at our facility in Solna, Sweden. We also utilize external manufacturing partners to cover the fill/finish of our products.

Cost of goods and services were €107.1 million in the year ended December 31, 2025 (2024: €98.5 million, 2023: €100.9 million). The variation of COGS is affected by various factors. COGS related to IXCHIQ included €8.5 million of revaluation losses and batch write-offs from reduced demand. Suspension of the license by the U.S. FDA and the termination of the license agreement with Serum Institute of India were main drivers for the IXCHIQ write-offs. The transfer to the new manufacturing site Almeida in Scotland contributed to higher COGS impacting the gross margin of IXIARO and increased idle costs. The reduction of third party product sales contributed to a reduction of COGS of €9.8 million.. The slight decrease between 2024 and 2023 mainly resulted from a reduction in failed manufacturing batches of IXIARO.

***Research and Development***

We generate a significant amount of research and development expenses due to the nature of our business. Research and development expenses were €85.3 million, €74.1 million, and €59.9 million for the years ended December 31, 2025, 2024, and 2023, respectively. Research and development expenses generally track development of our underlying product candidate portfolio. Investment in research and development is required to support advancing programs through increasingly expensive stages of clinical development.

Our research and development costs in 2025 mainly comprised expenses relating to the Phase 3 and Phase 4 clinical trial for our chikungunya vaccine IXCHIQ, our Phase 2 study of the Shigella vaccine candidate S4V2 (in partnership with LimmaTech), the development of our Zika vaccine candidate, and work on pre-clinical projects. We expect R&D expenses to increase in the medium- to long-term as we advance other candidates in our pipeline. In 2024, the increase compared to 2023 was mainly due to incremental expenses incurred in relation to the development collaboration and licensing agreement signed for the S4V2 vaccine candidate. In addition, we have seen increased expenses associated with transferring manufacturing of our commercial products to our new Almeida manufacturing site in Scotland.

***Marketing and Distribution***

We have developed an established commercial infrastructure, dedicated to promoting and selling our products and educating physicians and travelers about our products and the diseases they target. We are continually investing in our

commercial infrastructure and have identified markets where we can increase our sales and marketing efforts and market penetration. We have also been able to leverage our commercial infrastructure for third-party product distribution.

Marketing and distribution expenses were €37.4 million for the year ended December 31, 2025, compared to €52.4 million in 2024 and €48.8 million in 2023. In 2025, advertising and promotional spend decreased significantly due to the adjustment of spending on IXCHIQ following the prior year's launch activities. We expect that marketing and distribution expenses will remain stable in the next year.

***General and Administrative Expenses***

General and administrative expenses decreased by €5.4 million, or 13%, to €37.3 million for the year ended December 31, 2025 from €42.8 million for the year ended December 31, 2024.

In 2025, Valneva benefited from an efficiency improvement program, which delivered process optimizations and costs savings versus the prior year. In 2024, we additionally benefited from lower directors and officers' insurance costs and lower fees for professional services and personnel costs included in this line item, all of which led to a decrease in general and administrative expenses. In 2023, Valneva put in place some new processes as we became a more complex organization requiring additional corporate support and therefore incurred initialization expenses in connection with these processes.

***Gain from sale of Priority Review Voucher, net***

We sold the Priority Review Voucher received from the FDA for $103 million (€95 million) on February 2, 2024. The Company was awarded a tropical disease PRV in November 2023 following the FDA's approval of IXCHIQ, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus. The net gain from the sale of the PRV amounted to €90.8 million, after deducting expenses in the amount of €4.2 million, which included transaction fees as well as expenses in connection with contractual payment obligations related to the PRV sale.

***Grants***

We seek grants from governmental agencies and non-governmental organizations to partially offset our increasing research and development costs. Grant income also includes research and development tax credits. Grants, which are recorded in other income, decreased to €10.9 million for the year ended December 31, 2025 from €20.2 million for the year ended December 31, 2024 primarily due to lower grant income and lower research and development tax credit. For more information as to the grants please see Note 5.8.1 Grants as well as Note 5.8.2 Research and development tax credits.

We plan to continue evaluating and pursuing grant opportunities.

***International Operations and Foreign Currency Exchange Risks***

We operate on a global basis with facilities, sales, and activities throughout the world, and our global operations subject our financial results to fluctuations in foreign currency exchange rates. Because we generate a substantial part of sales in the United States for IXIARO, with production costs in the British Pound, or GBP, and in Canada for DUKORAL, with production costs in Swedish Krona, or SEK, we are exposed to foreign exchange risks, principally with respect to the U.S. Dollar, or USD, GBP, SEK and the Canadian dollar, or CAD. Our results of operations continue to be impacted by exchange rate fluctuations.

## Financial Operations Overview

***Revenue***

Our product revenue is primarily derived from the sale of our commercialized products IXIARO, DUKORAL, and IXCHIQ in their approved markets and sales of third-party products pursuant to distribution partnerships. We generated our first revenue from the sale of IXCHIQ in 2024, following initial regulatory approvals. We distribute products both directly and through the use of third-party distributors. We primarily sell IXIARO in the United States (in the private market as well as to the U.S. Department of Defense for military personnel being deployed to endemic areas), Canada, Germany, the United Kingdom, and France. Our sales of DUKORAL are concentrated in Canada and the Nordics. IXCHIQ is primarily sold in Europe and in Canada. We derived product revenues from the sale of our COVID-19 vaccine to the Kingdom of Bahrain in 2023.

Our other revenue (from collaboration, licensing, and services) consists of milestone payments, upfront licensing payments, and reimbursement of services. Certain of these payments are initially recorded on our statement of financial position and subsequently recognized as revenue in accordance with our accounting policy as described further under "E Critical Accounting Estimates" and Note 5.2 "Summary of significant accounting policies" to our consolidated financial statements as of and for the years ended December 31, 2025 and 2024, included elsewhere in this Annual Report. We generate revenues from licensing and service agreements for our product candidates and proprietary technologies. We contract with third parties to provide a variety of services such as manufacturing services, lease arrangements, research licenses, commercial licenses, and research and development services. The terms of such licenses include license fees payable as initial fees, annual license maintenance fees, and fees to be paid upon achievement of milestones, as well as license option fees and fees for the performance of research services. In addition, our licensing arrangements generally provide for royalties payable on the licensee's future sales of products developed within the scope of the license agreement.

In the years ended December 31, 2024 and 2023, our other revenues still included certain amounts from the agreements relating to our COVID-19 vaccine: a) the UK Supply Agreement executed in September 2020, b) the Advance Purchase Agreement with the European Commission executed in October 2021 and c) the Advance Purchase Agreement with the Kingdom of Bahrain executed in December 2021.

For more detailed information, see Note 5.5 Revenues to the financial statements included elsewhere in this Annual Report.

***Operating Expenses***

***Cost of Goods and Services***

Cost of goods and services consist primarily of personnel costs, costs for materials, royalties, and costs for third-party services, as well as building and energy costs, depreciation and amortization, impairment charges of tangible assets, and other direct and allocated costs incurred in connection with the production of our products. Costs of goods and services also include costs of product sales from inventory produced in the prior year, idle production costs, and costs related to expired and faulty products which have been written off. Cost of goods and services also include costs relating to our revenue-generating collaboration, services, and licensing agreements.

***Research and Development Expenses***

The nature of our business and the primary focus of our activities generate a significant amount of research and development expenses. Research and development expenses include the costs associated with research and development conducted by us or for us by outside contractors, research partners, or clinical study partners, and expenses associated with research and development carried out by us in connection with strategic collaboration and licensing agreements. Our research and development expenses are primarily incurred as a result of the following activities:

- discovery efforts leading to product candidates,
- development efforts for our clinical programs, and
- development of our manufacturing technology and infrastructure.

The costs of the above activities driving research and development expenses comprise the following categories:

- expenses related to our research and development personnel, including salaries, social security expense, share-based compensation expense, and other related expenses,
- expenses incurred under agreements with third parties, such as consultants, investigative sites, and contract research organizations, or CROs, that conduct our pre-clinical studies and clinical trials, and under in-licensing arrangements,
- costs of acquiring, developing, and manufacturing materials for pre-clinical studies and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs,
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process, and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

The substantial majority of our direct expenses incurred for the years ended December 31, 2025, 2024, and 2023, including for CROs, other contracted research and development activities, and raw materials, related to our chikungunya vaccine, our Shigella vaccine candidate (S4V2), and our Lyme disease vaccine candidate. We also incur indirect research and development expenses primarily related to facilities, energy, and office costs as well as the cost of research and development personnel.

Research and development expenses are generally recognized in the period in which they are incurred.

Research and development expenses incurred in connection with product candidates are capitalized and recorded as intangible assets when the following criteria are met:

- the technical feasibility of completing the asset has been achieved so that it will be available for use or sale;
- we have the intention to complete the asset and use or sell it;
- we have the ability to use or sell the asset;
- we believe the asset will generate probable future economic benefits and can demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;
- we are confident of the availability of adequate technical, financial, and other resources to complete development of the asset and to use or sell it; and
- we have the ability to reliably measure the expenditure attributable to the intangible asset.

In the years ended December 31, 2025, 2024, and 2023, no capitalization of research and development expenses were recorded as intangible assets. As we had previously capitalized research and development costs recorded as intangible assets, as of December 31, 2025 and 2024, the net book value is amounting to €1.0 million and €1.1 million, respectively.

Research and development activities are a key component of our business model. The successful development and commercialization of a product candidate involves significant costs, which may vary from year to year depending upon factors such as the progress of clinical trials and other research and development activities, the timing of regulatory approvals, the duration of the regulatory approvals process and the possibility of, and potential expenses related to, filing, prosecuting, defending, or enforcing any patent claims or other intellectual property or proprietary rights. The most expensive stages in the regulatory approval process in the United States and the European Union are late-stage clinical trials, which are the longest and largest trials conducted during the approval process. The significant cost factors in our clinical trials include manufacturing compounds for product candidates, organizing clinical trials, including participant enrollment, production and testing of product candidates involved in clinical trials, and laboratory testing and analysis of clinical parameters. By contrast, pre-clinical research and development expenses primarily depend on the number of scientific staff employed. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate and progress clinical trials for our vaccine candidates.

***Marketing and Distribution Expenses***

Marketing and distribution expenses consist primarily of expenses relating to marketing and distribution personnel, including salaries, social security contributions, share-based compensation expense, and other employee-related expenses, advertising, media, and public relations expenses, warehousing and distribution costs, costs related to third-party services and other direct and allocated expenses incurred in connection with our own commercial sales infrastructure, business development, and other marketing and distribution activities. We incurred incremental costs for preparation of market access and launch activities of IXCHIQ following the first licensure of the vaccine in November 2023.

***General and Administrative Expenses***

General and administrative expenses consist primarily of non-research and development personnel-related costs, including salaries, social security contributions, share-based compensation expense, and other employee-related expenses for general management, finance, legal, human resources, investor relations, internal audit, and other administrative and operational functions, fees for professional services, such as consulting, legal, and financial services, information technology, and facility-related costs. These costs relate to the operation of our business and are unrelated to our research and development function or any individual product candidate program.

We anticipate that our general and administrative expenses in the near term will remain comparable to the costs incurred in the year ended December 31, 2025. We also anticipate continued material expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with U.S. exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs.

***Other Income (Expenses)***

Our other income results principally from grants and research tax credits. We expect to continue to be eligible for these tax credits and subsidies for so long as we incur eligible expenses.

***Grants***

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and that we will comply with all conditions.

For more details see Note 5.8.1 Grants.

***Research Tax Credits***

We benefit from Austrian research tax credit, British tax credit, and French tax credit (known as Crédit d'Impôt Recherche, or CIR). The qualifications for the tax credits are similar, as the Austrian, British, and French tax authorities encourage companies to conduct technical and scientific research. To be eligible, companies need to demonstrate that they have expenses that meet certain required criteria. The main differences between the three jurisdictions' tax credits are the applicable percentage of and the basis for the tax credit.

We have concluded that research tax credits in the three countries meet the definition of a government grant, as defined in IAS 20, Accounting for Government Grants and Disclosure of Government Assistance, and, as a result, it has been classified as other income within operating income in our statement of operations.

For more details see Note 5.8.2 Research and development tax credits.

***Finance Income (Expenses)***

Finance income relates primarily to interest income received from cash and cash equivalents deposits, as well as gains from investment in money market instruments. Our cash and cash equivalents are deposited primarily into cash accounts and term deposit accounts with short maturities and therefore generate only a modest amount of interest income. Investments in money market funds meet the definition of cash equivalents, being highly liquid, convertible to a known amount of cash, and subject to insignificant risk of value change.

Finance expenses relate primarily to interest expense paid to banks, lenders, and government agencies as well as to interest expense on lease liabilities and refund liabilities.

We also incur foreign exchange gains and losses related to our international operations, primarily with respect to the U.S. Dollar, the British Pound, the Swedish Krona, and the Canadian Dollar, which amounts are recorded as finance income or expenses.

***Income Tax***

Income tax income or expense reflects our current income tax, as well as our deferred tax income or expense.

***Adjusted EBITDA***

To provide investors with additional information regarding our financial results, we have provided within this Annual Report Adjusted EBITDA, a non-IFRS financial measure, which is defined as earnings (loss) from the period before income taxes, finance income/expense, foreign currency gain/(loss) – net, result from investments in associates, amortization, depreciation, and impairment. Adjusted EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management uses Adjusted EBITDA as a supplemental measure for assessing operating performance in conjunction with related GAAP amounts. It also uses Adjusted EBITDA in connection with matters such as strategic planning, annual budgeting, operating decision making, evaluating company performance, and comparing operating results with historical periods and with industry peer companies.

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 our current performance, performance trends, and financial condition.

We have provided reconciliations in "Item 5A—Operating Results—Results of Operations" to income/loss for the period, which is the most directly comparable IFRS measure, for the years ended December 31, 2025, 2024, and 2023. Our use of Adjusted EBITDA has limitations as an analytical tool, and you should not consider it in isolation or as a substitute for analysis of our results as reported under IFRS. For example:

- Although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and Adjusted EBITDA does not reflect cash capital expenditure requirements for such replacements or for new capital expenditure requirements.
- Adjusted EBITDA does not reflect changes in, or cash requirements for, our working capital needs.
- Adjusted EBITDA does not reflect interest expense or income tax payments that may represent a reduction in cash available to us.

***Presentation of Net Product Sales***

In the discussion below, we present our consolidated net product sales. We analyze our net product sales by commercial product and by geography. In addition to reported net product sales, we analyze non-IFRS financial measures designed to isolate the impact of foreign exchange rates on our net product sales. When we refer to changes in our net product sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

Following the termination of most third-party product distribution agreements by December 31, 2025, we present net product sales excluding third-party products and excluding foreign currency exchange results, in order to provide investors additional information concerning the sales performance of our proprietary products.

## Item 5A. Operating Results

## Results of Operations

***Overview***

***Results of Operations—Consolidated***

Our results of operations for the years ended December 31, 2025, 2024, and 2023 are summarized in the table below.

| | Year ended December 31, | | |
|---|---|---|---|
| **in € thousand** | **2025** | **2024** | **2023** |
| Product sales | 157,908 | 163,253 | 144,624 |
| Other revenues | 16,750 | 6,325 | 9,088 |
| **REVENUES** | **174,659** | **169,579** | **153,713** |
| Cost of goods and services | (107,139) | (98,538) | (100,875) |
| Research and development expenses | (85,303) | (74,143) | (59,894) |
| Marketing and distribution expenses | (37,356) | (52,356) | (48,752) |
| General and administrative expenses | (37,322) | (42,750) | (47,799) |
| Gain from sale of Priority Review Voucher, net | — | 90,833 | — |
| Other income and expense, net | 10,400 | 20,706 | 21,520 |
| **OPERATING PROFIT/(LOSS)** | **(82,060)** | **13,330** | **(82,087)** |
| Finance income | 2,644 | 2,362 | 1,210 |
| Finance expenses | (41,898) | (23,984) | (23,325) |
| Foreign exchange gain/(loss), net | 7,196 | (3,193) | 5,574 |
| **PROFIT/(LOSS) BEFORE INCOME TAX** | **(114,119)** | **(11,486)** | **(98,629)** |
| Income tax income/(expense) | (1,073) | (761) | (2,800) |
| **PROFIT/(LOSS) FOR THE PERIOD** | **(115,192)** | **(12,247)** | **(101,429)** |

***Results of Operations***

Our Executive Committee, as our chief operating decision maker ("CDM"), considers our operating business in its entirety to allocate resources and assess performance. The CDM evaluates all vaccine candidates and vaccine products together as a single operating segment, "development and commercialization of prophylactic vaccines". Therefore, the split used to allocate resources and assess performance is based on a functional view, thus correlating to the income statement format.

***Comparisons for the Years Ended December 31, 2025 and 2024***

***Revenue***

***Consolidated Revenue***

Revenue increased by €5.1 million, or 3%, to €174.7 million for the year ended December 31, 2025. The increase from 2024 to 2025 is mainly related to higher IXCHIQ and IXIARO product sales as well as revenue recognition related to R&D services performed for Pfizer in connection with VLA15, which had been deferred in previous years. This was partly offset by lower third party product sales following termination of distribution agreements for Bavarian Nordic's products in Canada and the UK as well as the termination of the distribution agreement with Seqirus for FLUAD in Austria. Our strategy is to progressively reduce our third-party product portfolio due to the comparatively lower margins associated with these products.

For more information as to the Consolidated Revenue, see Note 5.5.3 Disaggregated revenue information.

***Product sales***

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2025** | **2024** |
| IXIARO | 98,419 | 94,069 |
| DUKORAL | 31,909 | 32,303 |
| Third party products | 19,159 | 33,185 |
| IXCHIQ | 8,421 | 3,696 |
| **PRODUCT SALES** | **157,908** | **163,253** |

For more information as to the product sales, see Note 5.5.3 Disaggregated revenue information .

References to changes in net sales at constant exchange rates (CER) indicate that the impact of currency fluctuations has been removed. This is done by recalculating net sales for the period in question using the exchange rates applied in the prior period. Unless indicated differently, the amounts are expressed at actual exchange rates (AER).

In the year ended December 31, 2025, at constant exchange rates (CER) and excluding third-party product sales, product sales increased by 9% compared to 2024. This indicates that the decline in product sales is primarily attributable to adverse foreign exchange effects and a reduction in third-party product sales, while sales of own products continued to grow, as illustrated below using the actual exchange rate (AER).

| | Year ended December 31, | | |
|---|---|---|---|
| **in € thousand** | **2025** | **2024** | **Year-over-year growth %** |
| Product sales | 157,908 | 163,253 | -3.3 % |
| Third-party product sales | 19,159 | 33,185 | -42.3 % |
| Product sales excluding third-party sales | 138,749 | 130,068 | 6.7 % |
| Effect of exchange rates (excluding third-party sales) | 3,072 | | |
| **Product sales (excluding third-party sales) at constant exchange rates (CER)** | **141,821** | | **9.0%** |

***Revenues—By Geography***

We also monitor product sales generated in the countries and regions where we operate. The revenues by geography is presented in the table referenced in Note 5.5.3 Disaggregated revenue information and is based on the final location where our distribution partner sells the product or where the customer or partner is located.

Total product sales in the United States decreased by €5.0 million, or 10%, to €43.5 million in the year ended December 31, 2025, compared to €48.4 million in the year ended December 31, 2024. This decrease is primarily a result of the suspension of IXCHIQ sales in the U.S. in August 2025 and the unfavorable development of the USD against the EUR amounting to €2.0 million.

Product sales in Canada decreased by €2.2 million, or 7%, from €32.3 million in the year ended 2024 to €30.1 million in 2025 as a result of the termination of the distribution agreement for Bavarian Nordic products.

Sales in Germany decreased by €0.9 million, or 5%, to €17.3 million in the year ended December 31, 2025 due to effects of the transition from Bavarian Nordic to Seqirus as a new distribution partner for Germany.

***Other revenues from contracts with customers***

The table in Note 5.5.3 Disaggregated revenue information presents our other revenues (from collaboration, licensing, and services) for the years ended December 31, 2025 and 2024. As of December 31, 2025, revenues from the Collaboration and License Agreement with Pfizer amounted to €10.0 million. In the years ended December 31, 2023 and December 31, 2024, no revenues were recognized as Valneva determined that entitlement to the consideration was not yet highly probable, due to the possibility of increased payments to customers while R&D activities (including the Phase 3 study) are progressing ahead of possible BLA licensure submission to the FDA.

***Operating Income and Expenses***

***Cost of Goods and Services***

Cost of goods and services (COGS) increased by €8.6 million, or 8.7%, to €107.1 million for the year ended December 31, 2025. The variation of COGS is affected by various factors. COGS related to IXCHIQ included €8.5 million of revaluation losses and batch write-offs from reduced demand. Suspension of the license by the U.S. FDA and the termination of the license agreement with Serum Institute of India were main drivers for the IXCHIQ write-offs. The transfer to the new manufacturing site Almeida in Scotland contributed to higher COGS impacting the gross margin of IXIARO and increased idle costs. The reduction of third party product sales contributed to a reduction of COGS of €9.8 million.

The gross margin on commercial product sales amounted to 50.8% in the year ended December 31, 2025 compared to 50.6% in the year ended December 31, 2024. COGS of €39.7 million related to IXIARO product sales, yielding a product gross margin of 59.6% compared to 61.0% for the year ended December 31, 2024. COGS of €21.3 million related to DUKORAL product sales, yielding a product gross margin of 33.3% compared to 38.7% for the year ended December 31, 2024. Of the remaining COGS in 2025, €12.5 million related to the third-party products distribution business, €16.0 million to IXCHIQ, €7.2 million to cost of services, and €10.6 million to idle capacity costs and costs not allocated to products. In 2024, overall COGS were €98.5 million, of which €90.0 million related to cost of goods and €8.5 million related to cost of services.

***Research and Development Expenses***

Research and development expenses increased by €11.2 million, or 15.1%, to €85.3 million for the year ended December 31, 2025 from €74.1 million in the year ended December 31, 2024. Research and development expenses were 32% of our total operating expenses for the year ended December 31, 2025 (December 31, 2024: 28%). The increase in research and development expenses is primarily attributable to the Shigella vaccine candidate, as well as ongoing Phase 4 activities for IXCHIQ partly offset by the decrease of expenses related to the Zika vaccine candidate. Research and development expenses related to commercial product were lower in 2025 compared to 2024, as the prior year included costs related to the IXIARO tech transfer between two sites from Livingston in Scotland.

For the year ended December 31, 2025, research and development expenses consisted primarily of i) €27.5 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €39.5 million of external research and development services, including costs for clinical studies and external manufacturing, and iii) €3.2 million of material consumption.

For the year ended December 31, 2024, research and development expenses consisted primarily of i) €25.5 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €25.5 million of external research and development services, including costs for clinical studies and external manufacturing, and iii) €8.5 million of material consumption.

We track our research and development expenses by product or development program. The following table sets forth our research and development expenses by product or development program for the periods indicated:

| | Year ended December 31 | |
|---|---|---|
| **in € thousand** | **2025** | **2024** |
| IXCHIQ | 38,681 | 31,237 |
| Shigella vaccine candidate | 17,447 | 6,121 |
| Zika vaccine candidate (VLA1601) | 7,509 | 11,307 |
| EBV | 4,291 | 4,065 |
| Yellow Fever | 3,885 | — |
| IXIARO | 1,732 | 14,358 |
| DUKORAL | 969 | 838 |
| Lyme borreliosis vaccine candidate (VLA15) | 297 | 239 |
| Other research projects (*) | 10,492 | 5,978 |
| **TOTAL RESEARCH AND DEVELOPMENT EXPENSES** | **85,303** | **74,143** |

* In 2025 and 2024, other research projects included €3.5 million and €2.5 million of expenses related to IFRS 2 (share-based and cash-based compensation) programs, which have not been allocated to the projects.

**IXCHIQ.** Our research and development expenses related to our chikungunya vaccine IXCHIQ increased by €7.4 million, or 23.8%, to €38.7 million in the year ended December 31, 2025 from €31.2 million in the year ended December 31, 2024. The majority of our research and development activities have shifted towards Phase 4 obligations after the initial approval of the vaccine in November 2023 and ongoing Phase 3 adolescents and pediatrics studies.

**Shigella vaccine candidate:** Our research and development expenses related to our vaccine candidate against Shigella increased by €11.3 million, or 185.0%, to €17.4 million in the year ended December 31, 2025 from €6.1 million in the year ended December 31, 2024. The year-over-year increase results from the initiation of the program in the second half of 2024, combined with expenditures related to two Phase 2 clinical trials currently in progress during 2025.

**Zika vaccine candidate (VLA1601).** Our research and development expenses related to our Zika vaccine candidate program decreased in the year ended December 31, 2025 by €3.8 million, or 33.6%, to €7.5 million from €11.3 million in the year ended December 31, 2024. This reflects the substantial technical development expenses incurred in 2024 and the significantly lower cost base in 2025, attributable to the completion of the Phase 1 clinical trial. In addition, the program will be discontinued unless concrete external funding is identified.

**EBV and Yellow Fever:** The increase in our research and development expenses related to our EBV and Yellow Fever programs reflect their progression from preclinical to a future potential clinical stage.

**IXIARO.** Our research and development expenses related to IXIARO decreased to €1.7 million for the year ended December 31, 2025 from €14.4 million for the year ended December 31, 2024. This decrease is primarily attributable to the technology transfer activities carried out in Scotland during 2024, which resulted in significantly higher costs in the prior year.

**VLA15.** Our research and development expenses remained relatively unchanged. In 2025, Lyme disease clinical studies for Phase 3 of €5.0 million were included in COGS, since these studies were related to the Pfizer partnership accounted under IFRS15.

***Marketing and Distribution Expenses***

Marketing and distribution expenses for the year ended December 31, 2025 amounted to €37.4 million. In 2025, advertising and promotional spend decreased significantly due to the reassessment of IXCHIQ spending and the resulting lower expenses in 2025, linked to the efficiency improvement plan and restructuring of global marketing function. Marketing and distribution expenses for the year ended December 31, 2024 amounted to €52.4 million impacted mainly by the IXCHIQ launching in US and higher staff costs to support product sales growth across the direct markets. Marketing and distribution expenses comprised 14% of our total operating expenses for the year ended December 31, 2025, compared to 20% of our total operating expenses for the year ended December 31, 2024.

For the year ended December 31, 2025, marketing and distribution expenses consisted primarily of €14.9 million of employee-related expenses, including salaries, social security contributions, share-based compensation income/expense, and other employee-related expenses, €9.0 million of advertising expenses, including media and public relations expenses, €4.6 million of warehousing and distribution costs, and €3.5 million of expenses related to third-party services.

For the year ended December 31, 2024, marketing and distribution expenses consisted primarily of €17.3 million of employee-related expenses, including salaries, social security contributions, share-based compensation expense and other employee-related expenses, €16.8 million of advertising expenses, including media and public relations expenses, €5.8 million of warehousing and distribution costs, and €6.0 million of costs related to third-party services.

***General and Administrative Expenses***

General and administrative expenses decreased by €5.4 million, or 13%, to €37.3 million for the year ended December 31, 2025 from €42.8 million for the year ended December 31, 2024. General and administrative expenses comprised 14% of our total operating expenses for the year ended December 31, 2025 compared to 16% of our total operating expenses for the year ended December 31, 2024. The reductions were primarily related to lower spend for recruiting, lower insurance charges and savings in the advisory and professional services. All these reductions were mostly initiated through the efficiency improvement plan implemented in 2025.

For the year ended December 31, 2025, general and administrative expenses consisted primarily of €22.9 million of employee-related expenses (salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees), as well as of €10.4 million in costs and fees for professional services, such as consulting, legal and financial services. For the year ended December 31, 2024, general and administrative expenses consisted primarily of €20.5 million of employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense, and other employee-related expenses paid to employees in general and administrative functions, as well as of €16.7 million in costs and fees for professional services, such as consulting, legal, and financial services.

***Expenses by Nature***

The table in Note 5.6 Expenses by nature summarizes our cost of goods and services, research and development expenses, marketing and distribution expenses, and general and administrative expenses by nature of cost.

***Gain from sale of Priority Review Voucher, net***

The Company sold the PRV received from the FDA for $103 million (€95 million) on February 2, 2024.

The Company was awarded a tropical disease PRV in November 2023 following the FDA's approval of IXCHIQ, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus.

The net gain from the sale of the PRV amounted to €90.8 million, after deducting expenses in the amount of €4.2 million, which included transaction fees as well as expenses in connection with contractual payment obligations related to the PRV sale.

***Other Income (Expenses), net***

The table in Note 5.8 Other income/(expenses), net summarizes the other operating income (expenses), net for the years ended December 31, 2025 and 2024.

Other operating income and expenses decreased by €10.3 million, or 50%, to €10.4 million for the year ended December 31, 2025, from €20.7 million for the year ended December 31, 2024, primarily due to lower grant income and lower research and development tax credit.

***Financial Income (Expense)***

Finance expenses, net increased significantly compared to the prior year, which is primarily driven by the repayment of the loan from Deerfield and OrbiMed (D&O), resulting in contractual additional fees. The table in Note 5.9 Finance income/ (expenses), net summarizes our financial income (expense) for the years ended December 31, 2025 and 2024.

***Income Tax***

We recorded €1.1 million of income tax expenses for the year ended December 31, 2025 compared to €0.8 million of income tax expenses for the year ended December 31, 2024. This variation in tax was driven by impairment of inventory in 2025.

***Profit/(Loss) for the Period***

Our loss for the period ended December 31, 2025 was €115.2 million, increased from a loss of €12.2 million for the period ended December 31, 2024. The lower loss in 2024 was mainly caused by the one-off effect of the sale of the Priority Review Voucher for IXCHIQ in 2024. This development is partly offset in 2025 by higher Revenues, lower Marketing and Distribution expenses and lower General and Administrative expenses.

***Adjusted EBITDA***

Our Adjusted EBITDA loss was €59.4 million for the year ended December 31, 2025 compared to a profit of €32.9 million, benefiting from the PRV sale, for the year ended December 31, 2024. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure, is set forth below:

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2025** | **2024** |
| **PROFIT/(LOSS) FOR THE PERIOD** | **(115,192)** | **(12,247)** |
| Add: | | |
| Income tax (benefits)/expense | 1,073 | 761 |
| Financing income | (2,644) | (2,362) |
| Financing expenses | 41,898 | 23,984 |
| Foreign currency (gain)/loss – net | (7,196) | 3,193 |
| Amortization | 4,823 | 4,881 |
| Depreciation | 16,927 | 14,705 |
| Impairment | 895 | — |
| **ADJUSTED EBITDA** | **(59,416)** | **32,916** |

***Comparisons for the Years Ended December 31, 2024 and 2023***

***Revenue***

***Consolidated Revenue***

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2024** | **2023** |
| Product sales | 163,253 | 144,624 |
| Other revenues from contracts with customers | 5,622 | 8,075 |
| Other non-IFRS 15 revenue | 704 | 1,014 |
| **REVENUES** | **169,579** | **153,713** |

Revenue increased by €15.9 million, or 10%, to €169.6 million for the year ended December 31, 2024. The increase from 2023 to 2024 is mainly related to higher product sales.

For more detailed information on revenues, see Note 5.5.3 Disaggregated revenue information.

***Product sales***

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2024** | **2023** |
| IXIARO | 94,069 | 73,483 |
| DUKORAL | 32,303 | 29,775 |
| Third party products | 33,185 | 35,675 |
| IXCHIQ | 3,696 | — |
| VLA2001 | — | 5,691 |
| **PRODUCT SALES** | **163,253** | **144,624** |

For more detailed information on product sales, see Note 5.5.3 Disaggregated revenue information.

***Revenues—By Geography***

We also monitor product sales generated in the countries and regions where we operate. The table in Note 5.5.3 Disaggregated revenue information presents revenues by geography and is based on the final location where our distribution partner sells the product or where the customer or partner is located.

Total product sales in the United States increased by €15.8 million, or 49%, to €48.4 million in the year ended December 31, 2024, compared to €32.6 million in the year ended December 31, 2023. The increase was primarily a result of higher sales to the U.S. Department of Defense (DoD), higher demand in private markets, and first sales of IXCHIQ.

Product sales in Canada increased by €4.1 million, or 15%, from €28.2 million in the year ended 2023, to €32.3 million in 2024 as a result of the significant recovery in the private travel markets.

Sales in Germany increased by €4.9 million, or 37%, to €18.2 million in the year ended December 31, 2024 due to continued resumption of travel positively impacting sales of our travel vaccines.

***Other revenues from contacts with customers***

The table in Note 5.1 Disaggregated revenue information table presents our other revenues (from collaboration, licensing, and services), for the years ended December 31, 2024 and 2023.

***Operating Income and Expenses***

***Cost of Goods and Services***

Cost of goods and services (COGS) decreased by €2.3 million, or 2.3%, to €98.5 million for the year ended December 31, 2024. The slight reduction in cost of goods and services was primarily due to lower batch write-offs for failed batches in manufacturing, reductions in IXIARO related royalty payments and lower cost of services related to the Pfizer VLA-15 collaboration with Pfizer.

The gross margin on commercial product sales amounted to 50.6% in the year ended December 31, 2024 compared to 46.0% in the year ended December 31, 2023. COGS of €36.7 million related to IXIARO product sales, yielding a product gross margin of 61.0%. COGS of €19.8 million related to DUKORAL product sales, yielding a product gross margin of 38.7%. Of the remaining COGS in 2024, €22.3 million related to the third-party products distribution business, €7.2 million to IXCHIQ and €8.5 million to cost of services. In 2023, overall COGS were €100.9 million, of which €90.7 million related to cost of goods and €10.2 million related to cost of services. In 2023, COGS of the COVID-19 vaccine program amounted to €5.3 million.

***Research and Development Expenses***

Research and development expenses decreased by €14.2 million, or 23.8%, to €74.1 million for the year ended December 31, 2024 from €59.9 million in the year ended December 31, 2023. Research and development expenses were 28% of our total operating expenses for the year ended December 31, 2024. This increase was mainly resulting from Tech transfer activities performed in relation to IXIARO between the two manufacturing sites in Scotland. Reductions due to the discontinuation of the COVID-19 vaccine, VLA2001, partly offset the overall increase in research and development expenses.

For the year ended December 31, 2024, research and development expenses consisted primarily of i) €25.5 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €25.5 million external research and development services, including costs for clinical studies and external manufacturing, and iii) €8.5 million of material consumption.

For the year ended December 31, 2023, research and development expenses consisted primarily of i) €20.2 million of employee-related expenses, consisting of wages, salaries, social security and pension costs, and share-based compensation paid to employees in research and development functions, ii) €30.1 million of external research and development services, including costs for clinical studies and external manufacturing, and iii) €3.5 million of material consumption.

We track our research and development expenses by product or development program. The following table sets forth our research and development expenses by product or development program for the periods indicated:

| | Year ended December 31 | |
|---|---|---|
| **in € thousand** | **2024** | **2023** |
| IXCHIQ | 31,237 | 31,953 |
| IXIARO | 14,358 | 1,175 |
| Zika vaccine candidate (VLA1601) | 11,307 | 12,828 |
| Shigella vaccine candidate | 6,121 | — |
| EBV | 4,065 | 2,565 |
| DUKORAL | 838 | 875 |
| Lyme borreliosis vaccine candidate (VLA15) | 239 | 277 |
| Human metapneumovirus vaccine candidate (VLA1554) | 170 | 739 |
| COVID-19 Vaccine (VLA2001) | 78 | 5,796 |
| Other research projects (*) | 5,729 | 3,685 |
| **TOTAL RESEARCH AND DEVELOPMENT EXPENSES** | **74,143** | **59,894** |

—

* In 2024 and 2023, other research projects included €2.5 million and €1.4 million of expenses respectively, related to IFRS 2 (share-based and cash-based compensation) programs, which have not been allocated to the projects.

**IXCHIQ.** Our research and development expenses related to our chikungunya vaccine IXCHIQ decreased by €0.7 million, or 2.2%, to €31.2 million in the year ended December 31, 2024 from €32.0 million in the year ended December 31, 2023. The majority of our research and development activities have shifted towards Phase 4 obligations after the approval of the vaccine by the FDA in November 2023 and adolescents and pediatrics studies.

**VLA1601.** Our research and development expenses related to our Zika vaccine candidate program decreased in the year ended December 31, 2024 by €1.5 million, or 11.9%, to €11.3 million from €12.8 million in the year ended December 31, 2023. In 2023, we re-initiated clinical development of the program, including manufacturing of clinical trial materials, which resulted higher costs than we incurred in 2024.

**VLA2001.** Our research and development expenses related to our COVID-19 vaccine program decreased by €5.7 million, or 98.6%, to €0.1 million in the year ended December 31, 2024 from €5.8 million in the year ended December 31, 2023. This decrease was a result of discontinuing the program.

**IXIARO.** Our research and development expenses related to IXIARO increased to €14.4 million for the year ended December 31, 2024 from €1.2 million for the year ended December 31, 2023. This increase resulted from technology transfer activities performed in Scotland during 2024.

**VLA15.** Our research and development expenses remained relatively unchanged. In 2024, Lyme disease clinical studies for Phase 3 of €7.2 million were included in COGS, since these studies were related to the Pfizer partnership accounted under IFRS15.

***Marketing and Distribution Expenses***

Marketing and distribution expenses for the year ended December 31, 2024 amounted to €52.4 million compared to €48.8 million in 2023, which mainly related to higher staff costs to support product sales growth across the direct markets. The employee-related expenses were positively affected in 2023 by the release of the employer contribution provision and therefore an income to the social security contributions. Marketing and distribution expenses comprised 20% of our total operating expenses for the year ended December 31, 2024, compared to 19% of our total operating expenses for the year ended December 31, 2023.

For the year ended December 31, 2024, marketing and distribution expenses consisted primarily of €17.3 million of employee-related expenses, including salaries, social security contributions, share-based compensation income/expense, and other employee-related expenses, €16.8 million of advertising expenses, including media and public relations expenses, €5.8 million of warehousing and distribution costs, and €6.0 million of expenses related to third-party services.

For the year ended December 31, 2023, marketing and distribution expenses consisted primarily of €13.1 million of employee-related expenses, including salaries, social security contributions, share-based compensation expense and other employee-related expenses, €13.4 million of advertising expenses, including media and public relations expenses, €3.9 million of warehousing and distribution costs, and €11.2 million of costs related to third-party services.

***General and Administrative Expenses***

General and administrative expenses increased by €5.0 million, or 11%, to €42.8 million for the year ended December 31, 2024 from €47.8 million for the year ended December 31, 2023. General and administrative expenses comprised 16% of

our total operating expenses for the year ended December 31, 2024 compared to 19% of our total operating expenses for the year ended December 31, 2023.

For the year ended December 31, 2024, general and administrative expenses consisted primarily of €20.5 million of employee-related expenses (salaries, social security contributions, share-based compensation expense and other employee-related expenses paid to employees), as well as of €16.7 million in costs and fees for professional services, such as consulting, legal and financial services. For the year ended December 31, 2023, general and administrative expenses consisted primarily of €21.1 million of non-research and development employee-related expenses, consisting of salaries, social security contributions, share-based compensation expense, and other employee-related expenses paid to employees in general and administrative functions, as well as of €21.8 million in costs and fees for professional services, such as consulting, legal, and financial services. The employee-related expenses were positively affected in 2023 by the release of the employer contribution provision and therefore an income to the social security contributions.

***Expenses by Nature***

The table in Note 5.6 Expenses by nature summarizes our cost of goods and services, research and development expenses, marketing and distribution expenses, and general and administrative expenses by nature of cost.

***Gain from sale of Priority Review Voucher, net***

The Company sold the PRV received from the FDA for $103 million (€95.0 million) on February 2, 2024.

The Company was awarded a tropical disease PRV in November 2023 following the FDA's approval of IXCHIQ, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus.

The net gain from the sale of the PRV amounted to €90.8 million, after deducting expenses in the amount of €4.2 million, which included transaction fees as well as expenses in connection with contractual payment obligations related to the PRV sale.

***Other Income (Expenses)***

The table in Note 5.8 Other income/(expenses), net summarizes the other operating income (expenses) for the years ended December 31, 2024 and 2023.

***Financial Income (Expense)***

The table in Note 5.9 Finance income/(expenses), net summarizes our financial income (expense) for the years ended December 31, 2024 and 2023.

***Income Tax***

We recorded €0.8 million of income tax expenses for the year ended December 31, 2024 compared to €2.8 million of income tax expenses for the year ended December 31, 2023. This change in income tax was primarily driven by deferred tax income in 2023 due to high impairment charges.

***Profit/(Loss) for the Period***

Our loss for the period ended December 31, 2024 was €12.2 million, decreased from a loss of €101.4 million for the period ended December 31, 2023. The improvement was mainly a result of the sale of the priority review voucher (PRV) received following the licensure of IXCHIQ by the U.S. FDA. The loss in 2023 was primarily driven by one-off expenses of goods and services related to valuation of inventory and onerous agreement provisions for material in connection with our COVID-19 vaccine and the discontinuation of this program.

***Adjusted EBITDA***

Our Adjusted EBITDA loss was €32.9 million for the year ended December 31, 2024 compared to a loss of €65.2 million for the year ended December 31, 2023. The Adjusted EBITDA loss improved by €98.1 million, which was primarily driven

by the lower net loss. A reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure, is set forth below:

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2024** | **2023** |
| PROFIT/(LOSS) FOR THE PERIOD | (12,247) | (101,429) |
| Add: | | |
| Income tax (benefits)/expense | 761 | 2,800 |
| Financing income | (2,362) | (1,210) |
| Financing expenses | 23,984 | 23,325 |
| Foreign currency (gain)/loss – net | 3,193 | (5,574) |
| Amortization | 4,881 | 5,831 |
| Depreciation | 14,705 | 11,753 |
| Impairment | — | (731) |
| **ADJUSTED EBITDA** | **32,916** | **(65,234)** |

## B. Liquidity and Capital Resources.

***Overview***

We have financed our operations primarily through a combination of equity offerings, secured debt, and revenues from product sales. As at December 31, 2025, we had €109.7 million in cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2025 will fund our current operating plans for at least the next 12 months following the publication of the full-year 2025 financial statements.

***Sources and Uses of Cash***

We have financed our operations through revenue from product sales, payments under historical collaborative research alliances, as well as research tax credits and subsidies granted by various public institutions. In addition, we have borrowed secured debt to finance our operations.

During 2025 we increased our capital by a total of 9,333,332 new ordinary shares having a nominal value of €0.15 each. 7,666,666 of the new ordinary shares were issued at a price of €2.74 and an additional 1,666,666 ordinary shares at a price of €3.86. Aggregate gross proceeds of the capital increase, before deducting underwriting commissions and expenses payable by us, were €27.4 million. The €1.2 million transaction costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax resulting in a net proceeds of €26.2 million. For more details as to the private placement, see Note 5.22.1 Share capital and share premium.

On October 6, 2025, we announced a new non-dilutive debt facility of up to $500 million with funds managed by Pharmakon Advisors, LP. This new loan supersedes and fully replaces the previous D&O Loan Agreement. The initial $215 million tranche was used to fully repay Valneva Austria's existing debt with D&O including related fees and expenses, while the remaining $285 million may be drawn later for future business development opportunities subject to mutual agreement between the parties. The new facility extends Valneva's debt maturity from Q1 2026 to Q4 2030, lowers its interest rate, and enhances financial flexibility. For more details, see Note 5.24.1 Principal loan.

As of December 31, 2025, we had borrowings and lease liabilities of €207.2 million, of which €179.2 million were principal loan facility and €28.1 million were lease liabilities.

During the year ended December 31, 2025 €0.1 million (£0.1 million) of grant income was recognized in connection with support received from Scottish Enterprise, Scotland's national economic development agency, to support research and development as well as manufacturing development activities on the Livingston site.This represents the final amount received from the original agreement spanning over 3 years and compared to €3.7 million (£3.1 million) recognized for the year ended December 31, 2024 and €11.1 million (£9.6 million) for the year ended December 31, 2023.

In 2019, we signed a funding agreement with CEPI and received $24.6 million for vaccine manufacturing and late-stage clinical development of its single-dose, live attenuated vaccine against chikungunya. In line with CEPI's commitment to equitable access, the funding underwrote a partnership effort to accelerate regulatory approval of our chikungunya vaccine for use in regions where outbreaks occur and to support World Health Organization prequalification to facilitate broader access in low- and middle-income countries (LMICs). We have to pay CEPI up to $7.0 million as consideration, upon achievement of certain commercial and related milestones, of which $3.0 million was paid in April 2024. The refundable consideration is accounted for as a loan and measured in accordance with IFRS 9 (see Note 5.24). The difference between the proceeds from CEPI and the carrying amount of the loan is treated under IAS 20 and presented as "Borrowings".

The partnership with CEPI was extended in July 2024 when we signed the second funding agreement, which was subsequently amended during 2025. CEPI now provides up to $48.9 million additional funding in the next four years to support broader access to IXCHIQ, in LMICs, as well as post-marketing trials and potential label extensions in children,

adolescents, and pregnant women. For more details please see Note 5.8.1 Grants. Funds received from CEPI, for this second agreement during the year 2025 amounted to $6.6 million, compared to funds received in 2024 of $11.8 million.

In November 2023, we were awarded a Priority Review Voucher (PRV) in connection with the approval of IXCHIQ. The PRV was sold in February 2024 and generated proceeds of $103 million.

As we continue to develop and commercialize our products and product candidates in the coming years, we will likely continue relying on some or all of these sources of financing, as well as potential milestone payments and royalties that may result from licensing agreements for our products and product candidates.

***Cash Flows***

***Comparisons for the Years Ended December 31, 2025 and 2024***

The table below summarizes our cash flows for the years ended December 31, 2025 and 2024:

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2025** | **2024** |
| Net cash generated from/(used in) operating activities | (52,894) | (67,218) |
| Net cash generated from/(used in) investing activities | (1,709) | 76,916 |
| Net cash generated from/(used in) financing activities | (621) | 30,682 |
| **NET CHANGE IN CASH AND CASH EQUIVALENTS** | **(55,224)** | **40,380** |

***Operating Activities***

Net cash used in operating activities for the year ended December 31, 2025 was €52.9 million compared to €67.2 million of net cash used in the year ended December 31, 2024. The outflow primarily reflects the loss for the period of €115.2 million, partially offset by €64.6 million of adjustments to reconcile loss for the period to cash used in operation. These adjustments mainly include depreciation and amortization of tangible and intangible assets (€21.7 million), interest expenses (€41.9 million), and share-based compensation expenses (€9.5 million). These amounts have been partly offset by other non-cash expense of €9.7 million, which mainly consist of currency translation differences.

Net cash used in operating activities for the year ended December 31, 2024 was €67.2 million compared to €202.7 million of net cash used in the year ended December 31, 2023. Net cash used in operating activities for the year ended December 31, 2024 was primarily derived from the loss for the period amounting to €12.2 million and from decreases in working capital in the amount of €11.4 million, which largely were related to payments to Pfizer in conjunction with Valneva's contribution to the Phase 3 costs of the VLA15 R&D program, reducing the refund liability. These amounts have been partly offset by adjustments for non-cash transactions of €49.0 million mostly for depreciation and amortization of tangible and intangible assets of €19.6 million and interest expenses of €24.0 million.

***Investing Activities***

Net cash used in investing activities for the year ended December 31, 2025 was €1.7 million and comprised primarily purchases for property plant and equipment of €4.4 million, partly offset by interest received of €1.8 million. This compared to cash generated from investing activities of €76.9 million for the year ended December 31, 2024, mainly resulting from proceeds received for the sale of the priority review voucher partly offset by €13.9 million purchases of property, plant and equipment.

***Financing Activities***

Net cash used in financing activities decreased to €0.6 million for the year ended December 31, 2025 compared to net cash generated from financing activities of €30.7 million for the year ended December 31, 2024. Net cash used in financing activities during the year ended December 31, 2025 primarily reflected the repayment of the D&O Loan, following its replacement with a new non-dilutive debt facility from Pharmakon Advisors, LP, net of related transaction costs. This was partly offset by €30.0 million of net proceeds from three At-The-Market facility transactions. In addition, interest payments amounting to €30.7 million reduced the net cash generated from financing activities and comprise transaction costs, such as exit fees and repayment premium, incurred with the repayment of the D&O Loan.

Net cash generated from financing activities during the year ended December 31, 2024 was primarily due to €57.1 million of net proceeds from a private placement of ordinary shares. Interest payments amounting to €20.0 million reduced the net cash generated from financing activities.

***Comparisons for the Years Ended December 31, 2024 and 2023***

The table below summarizes our cash flows for the years ended December 31, 2024 and 2023:

| | Year ended December 31, | |
|---|---|---|
| **in € thousand** | **2024** | **2023** |
| Net cash generated from/(used in) operating activities | (67,218) | (202,744) |
| Net cash generated from/(used in) investing activities | 76,916 | (20,585) |
| Net cash generated from/(used in) financing activities | 30,682 | 63,081 |
| **NET CHANGE IN CASH AND CASH EQUIVALENTS** | **40,380** | **(160,248)** |

***Operating Activities***

Net cash used in operating activities for the year ended December 31, 2024 was €67.2 million compared to €202.7 million of net cash used in the year ended December 31, 2023. Net cash used in operating activities for the year ended December 31, 2024 was primarily derived from the loss for the period amounting to €12.2 million and from decreases in working capital in the amount of €11.4 million, which largely were related to payments to Pfizer in conjunction with Valneva's contribution to the Phase 3 costs of the VLA15 R&D program, reducing the refund liability. These amounts have been partly offset by adjustments for non-cash transactions of €49.0 million mostly for depreciation and amortization of tangible and intangible assets of €19.6 million and interest expenses of €24.0 million.

Net cash used in operating activities for the year ended December 31, 2023 was €202.7 million, which derived from the loss for the period, amounting to €101.4 million, and from decreases in working capital in the amount of €145.6 million, which largely were related to payments to Pfizer in conjunction with Valneva's contribution to the Phase 3 costs of the Lyme VLA15 R&D program, reducing the refund liability. These amounts have been partly offset by adjustments for non-cash transactions of €45.0 million mostly for depreciation and amortization of tangible and intangible assets of €17.6 million and interest expenses of €23.3 million.

***Investing Activities***

Net cash generated from investing activities for the year ended December 31, 2024 was €76.9 million mainly resulting from proceeds received for the sale of the priority review voucher partly offset by €13.9 million purchases for property, plant and equipment. This compared to cash used in investing activities of €20.6 million for the year ended December 31, 2023 and was comprised primarily of €14.2 million purchases for property, plant and equipment as well as of the acquisition of the VBC3 building in Vienna.

***Financing Activities***

Net cash generated from financing activities was €30.7 million for the year ended December 31, 2024 compared to €63.1 million for the year ended December 31, 2023. Net cash generated from financing activities during the year ended December 31, 2024 was primarily due to €57.1 million of net proceeds from a private placement of ordinary shares. Interest payments amounting to €20.0 million reduced the net cash generated from financing activities.

Net cash generated from financing activities for the year ended December 31, 2023 consisted primarily of €81.1 million of net proceeds from borrowings, namely the additional tranches from the financing agreement with Deerfield and OrbiMed drawn in the second half of the year. Interest payments amounting to €12.6 million reduced the net cash generated from financing activities.

***Operating and Capital Expenditure Requirements***

We have previously incurred significant operating losses, including in the years discussed in this annual report. As of December 31, 2025 and 2024, we had accumulated a net loss of €679.1 million and €563.9 million, respectively. Our net loss was €115.2 million for the year ended December 31, 2025 and our net loss was €12.2 million, and €101.4 million for the years ended December 31, 2024 and 2023, respectively. We expect to continue to incur significant expenses, and we may incur substantial operating losses over the next several years as we market our approved products, advance clinical development of our product candidates and continue our research and development efforts in the United States, Europe, and endemic markets. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We anticipate that our expenses will increase in connection with our ongoing activities, as we:

- invest in our vaccine candidate programs, including Shigella, and our other pre-clinical and research programs;
- invest into fulfilling Phase 4 post-marketing obligations related to IXCHIQ, our chikungunya vaccine; and
- invest in our working capital and general corporate purposes.

Our present and future funding requirements will depend on many factors, including, among other things:

- costs of continued commercial activities, including product sales, marketing, manufacturing and distribution, for our approved products;
- the scope, progress, timing, and successful completion of our clinical trials of our current or future product candidates, especially the Phase 3 clinical trial for VLA15 and the Phase 4 clinical trials of IXCHIQ;

- the number of potential new product candidates we identify and decide to develop;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates; and
- the amount of revenues, if any, we may derive either directly, or in the form of royalty payments from any current or future collaboration agreements.

For more information as to the risks associated with our future funding needs, see "Item 3.D—Risk Factors".

We expect to finance these expenses and our operating activities through a combination of revenue from sales of our products, grants, milestone and service payments from our collaboration with Pfizer regarding our Lyme disease vaccine candidate, and our existing liquidity. If we are unable to generate sufficient revenue from product sales and through our collaboration agreements in accordance with our expected timeframes, we will need to raise additional capital through the issuance of our shares, through other equity or debt financings or through collaborations with other companies. However, we may be unable to raise additional funds or enter into other funding arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant others rights to develop or market drug candidates that we would otherwise prefer to develop and market ourselves. Our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents as of December 31, 2025 will be sufficient to fund our operations through at least 12 months after publication of this document.

***Contractual Obligations***

The following table discloses aggregate information about our material long-term contractual obligations as of December 31, 2025 and the periods in which payments are due. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

| in € thousand | Less than 1 year | Between 1 and 3 years | Between 3 and 5 years | Over 5 years | Total |
|---|---|---|---|---|---|
| Borrowings | 17,905 | 33,439 | 215,495 | 851 | 267,690 |
| Lease liabilities | 2,739 | 5,572 | 5,414 | 14,357 | 28,082 |
| Refund liabilities | 10,814 | 6,684 | — | — | 17,498 |
| **TOTAL** | **31,458** | **45,695** | **220,909** | **15,208** | **313,270** |

The amounts disclosed in the table above are the contractual undiscounted cash flows.

***Borrowings***

As of December 31, 2025, the carrying amount of bank borrowings and other loans was €179.2 million. Of this, €173.4 million related to the Financing Agreement with Pharmakon Advisors, LP. For more information as to the Financing Agreement, see Note 5.24.1 Principal loan. Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €3.1 million and the CEPI loan in the amount of €2.6 million, which relates to advanced payments received which are expected to be paid back in the future.

As of December 31, 2024, the carrying amount of bank borrowings and other loans was €187.4 million. Of this, €180.8 million related to the Financing Agreement with Deerfield and OrbiMed. Other borrowings related to financing of research and development expenses and CIR (research and development tax credit in France) of €3.5 million and the CEPI loan in the amount of €3.0 million, which relates to advanced payments received which are expected to be paid back in the future.

***Lease Liabilities***

As of December 31, 2025, the outstanding, discounted amount of lease liabilities was €28.1 million. Of this, €26.4 million related to the lease agreements for two premises in Sweden, which we expect will terminate in 2031 and 2037, respectively. Base rent will increase based on an inflation index. Other lease liabilities of €1.7 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

As of December 31, 2024, the outstanding, discounted amount of lease liabilities was €28.9 million. Of this, €26.9 million related to the lease agreements for two premises in Sweden. Base rent will increase based on an inflation index. Other lease liabilities of €2.1 million related to a number of minor agreements with various conditions (interest rates) and terms (maturities).

***Refund Liabilities***

As of December 31, 2025, the carrying amount of refund liabilities was €17.5 million. Of this, €9.0 million (all current) related to the collaboration with Pfizer, as we are funding 40% of Phase 3 clinical trial costs performed by Pfizer, and €6.7 million (all non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreement in 2019, and €1.8 million (all current) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products.

As of December 31, 2024, the carrying amount of refund liabilities was €26.1 million. Of this, €18.6 million related to the collaboration with Pfizer, as we are funding 40% of Phase 3 clinical trial costs performed by Pfizer, and €6.5 million (all non-current) related to the expected payment to GSK related to the termination of the strategic alliance agreement in 2019, and €1.1 million (all current) related to refund liabilities to customers related to rebate and refund programs as well as right to return of commercialized products.

## C. Research and Development, Patents and Licenses

For a discussion of our research and development activities, see "Item 4.B—Business Overview" and "Item 5.A—Operating Results."

## D. Trend Information

For a discussion of trends, see "Item 4.B—Business Overview," "Item 5.1—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

## E. Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. Some of the accounting methods and policies used in preparing our consolidated financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. Critical accounting policies and practices are tailored to specific events in the current year, and the accounting policies and practices that are considered critical might change from year to year. The actual value of our assets, liabilities, and shareholders' equity and of our accumulated deficit could differ from the value derived from these estimates if conditions change and these changes had an impact on the assumptions adopted.

Our management applied judgement and estimates on critical accounting topics:

***Revenue Recognition of Other Revenue and Refund Liabilities***

The recognition of other revenues and refund liabilities involves significant management judgement in estimating and updating the transaction price in accordance with IFRS 15. Management is required to assess the nature and amount of variable consideration and to determine whether such amounts are subject to the constraint on variable consideration. Variable consideration is included in the transaction price only to the extent that it is highly probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Management reassesses the estimated transaction price and the application of the constraint at each reporting date. Revenue is only recognized when it is highly likely that it will not reverse in future, and this is a judgement required from management.

In April 2020, Valneva signed the Collaboration and License Agreement with Pfizer to co-develop and commercialize the Group's Lyme disease vaccine candidate (VLA15). This is classified as an agreement with a customer as defined by IFRS 15 guidance on revenue contracts with customers, and accordingly, amounts received by or payable to Valneva under the Collaboration and License Agreement are accounted for in the Group's revenues.

In 2021 and 2022, several amendments were made to the Collaboration and License Agreement. This resulted in an increase in the expected payments to customer related to Valneva's contribution to Pfizer's future development costs. Therefore, for the year ended December 31, 2022, the accumulated revenue recognized since the inception of the agreement with Pfizer amounting to €45.9 million was reversed as other revenues from contracts with customers. In the years ended December 31, 2023 and December 31, 2024, no revenues were recognized as Valneva determined that entitlement to the consideration was not yet highly probable, due to the possibility of increased payments to customers while R&D activities (including the Phase 3 study) are progressing ahead of possible BLA licensure submission to the FDA.

As of December 31, 2025, Valneva reassessed its entitlement to the consideration and the related refund liability. The Phase 3 clinical trial is nearing completion, and the data readout is expected within the first half of 2026. Based on the updated development budget, Valneva determined the probability and magnitude of any further change in the payment to customer.

Due to project progress, Valneva concluded that a portion of the outstanding refund liability no longer represented an obligation to refund consideration to Pfizer and could therefore be released to revenue. For the year ended December 31, 2025, Valneva recognized revenues for R&D work and additional support services of €10.0 million, corresponding to the amount of the refund liability that the Group no longer expects to settle through future payments to Pfizer. As at December 31, 2025, the remaining refund liability related to the Collaboration and License Agreement with Pfizer amounted to €9.0 million, representing Valneva's best estimate of the portion of consideration that may still need to be refunded through its ongoing contribution to Pfizer's development costs.

While license and equipment performance obligations were fulfilled in prior periods, the R&D activities and additional services were ongoing through 2025 and satisfy the performance obligation over time. During this period, Valneva funded 40% of the ongoing shared development costs.

Items not included in the transaction price as of December 31, 2025 are (i) $143 million from early commercialization milestones, (ii) royalties, ranging from 14% to 22%, and (iii) $100 million in sales based milestones, which will be recognized as and when they occur.

# Item 6. Directors, Senior Management and Employees

## A. Directors and Senior Management

On December 20, 2023, our shareholders approved one-tier governance system under which the Company is led by a Board of Directors. We refer to our senior management as the Executive Committee.

The following table sets forth information concerning the members of our Executive Committee and Board of Directors as of the date of this annual report.

| Name | Age | Position |
|---|---|---|
| **Executive Committee** | | |
| Thomas Lingelbach | 62 | Director, President & Chief Executive Officer |
| Peter Bühler | 56 | Chief Financial Officer |
| Franck Grimaud | 59 | Chief Business Officer (until June 25, 2025) |
| Juan Carlos Jaramillo | 55 | Chief Medical Officer |
| Dipal Patel | 52 | Chief Commercial Officer |
| Vincent Dequenne | 58 | Chief Operating Officer |
| Petra Pesendorfer | 40 | Chief People Officer |
| Hanneke Schuitemaker | 62 | Chief Scientific Officer |
| Kendra Wergin | 40 | General Counsel and Corporate Secretary |
| **Non-Employee Directors** | | |
| Anne-Marie Graffin | 64 | Chair of the Board of Directors |
| James Sulat | 75 | Vice Chair of the Board of Directors |
| James Connolly | 61 | Member of the Board of Directors |
| Maïlys Ferrère | 63 | Representative of Bpifrance Participations SA, member of the Board of Directors (until June 25, 2025) |
| Danièle Guyot-Caparros | 67 | Member of the Board of Directors |
| Kathrin Jansen | 68 | Member of the Board of Directors |
| Gerd Zettlmeissl | 70 | Member of the Board of Directors |

***Executive Committee***

The members of our Executive Committee are appointed by the Board of Directors and are responsible for the day-to-day management of the Company. Certain members of the Executive Committee were also appointed as Associate Managing Officers (*Directeurs Généraux Délégués*) until June 25, 2025, as described further in this Item 6.

*Thomas Lingelbach* has served as our President and Chief Executive Officer (CEO) since 2013. He served as Chairman of our Management Board until December 2023, and in connection with the change to a one-tier governance structure, he was appointed as a member of our Board of Directors alongside his role as President and CEO and as *Directeur Général*. He serves as the Chairman of the Executive Committee. Prior to becoming our founding CEO, Mr. Lingelbach served in a variety of increasingly senior roles, most recently as CEO of Intercell AG from 2011 until its merger with Vivalis SA in 2013. He is an established vaccine industry leader with breadth of experience. Prior to joining Intercell, he served as Vice President and Executive Committee Member, Global Industrial Operations-Vaccines of Chiron Corporation. Upon Chiron's acquisition by Novartis Vaccines & Diagnostics GmbH & Co KG, he served as Managing Director of Chiron Behring GmbH & Co KG and General Manager until he joined Intercell. During his more than 30 years in vaccines, he held a variety of positions from product development to commercialization, with a strong emphasis on technical development and operations. In different capacities, he contributed to the successful development and licensure of more than ten vaccines. Mr. Lingelbach holds an M.S. in Engineering, specialised in bioprocess engineering, from Technische Hochschule Mittelhessen (THM) and complemented his education with a business administration program.

*Peter Bühler* has served as our Chief Financial Officer since January 2022. Mr. Bühler previously served as Chief Financial Officer of Quotient Limited, a position he held from February 2020 until December 2021. From May 2017 to March 2019, Mr. Bühler served as Group Chief Financial Officer at Zaluvida Corporate AG. From April 2013 to April 2017, Mr. Bühler served as Group Chief Financial Officer at Stallergenes Greer SA. Mr. Bühler is a Swiss Chartered Accountant, a member of the Swiss Institute of Certified Accountants and Tax Consultants and received an MBA from SBS Swiss Business School.

*Franck Grimaud* served as our Chief Business Officer from 2013 until June 25, 2025. Prior to joining us, he served as Chief Executive Officer of Vivalis SA from 1999 until its merger with Intercell AG in 2013. Mr. Grimaud has served as Chair of the Governing Board of Fonds Pays de la Loire Participations since September 2016 and as President of the Board

of Directors of Atlanpole Biothérapies since February 2018, where he served as Treasurer from January 2015 to February 2018. Mr. Grimaud holds an M.B.A. from University of Ottawa and received his Licence AES from Université de Poitiers.

*Juan Carlos Jaramillo, M.D.*, has served as our Chief Medical Officer since October 2020. Prior to joining us, Dr. Jaramillo served as Senior Vice President, Market Access & Medical Affairs and then as Senior Vice President, Head of Global Market Access & Pricing at Daiichi Sankyo, GmbH from April 2013 to September 2020. Prior to Daiichi Sankyo, Dr. Jaramillo served as Senior Vice President, Medical Affairs & Clinical Development at Grünenthal, Inc. and prior to that held a variety of positions at GlaxoSmithKline plc. Dr. Jaramillo received his M.D. and B.S. in Pre-Medicine from Universidad Central Del Este.

*Dipal Patel* has served as our Chief Commercial Officer since November 2022. Ms. Patel has over 23 years' experience in the pharmaceutical industry. Prior to joining us, Ms. Patel served as Vice President, Vaccines Commercialization Lead at GlaxoSmithKline, a position she held from January 2020, and as Vice President, Commercial Head (Respiratory) Emerging Markets from August 2017 to January 2020. Prior to that Ms. Patel held multiple roles at GlaxoSmithKline covering commercial strategy, execution, market access and lifecycle management. Over her career, she has held roles of increasing responsibilities across multiple countries including the United States, Australia, Belgium, Singapore, Thailand, and the European and emerging markets regions. Ms. Patel graduated with a B.Sc. (Honors) from Macquarie University, Sydney in 1998 followed by an M.B.A. from Macquarie Graduate School of Management in 2006.

*Vincent Dequenne* has served as our Chief Operating Officer since June 2022 and as a member of our Executive Committee since January 2024. Prior to this position, he served as our Senior Vice President of Global Industrial Operations from July 2021 to May 2022. Prior to that, he served as Managing Director Biologics at Eurogentec from January 2020 to June 2021 and as CDMO Managing Director at Pierre Fabre from October 2017 to January 2020. Before that, he served in roles of increasing responsibility at GSK for more than 10 years and at Eli Lilly for more than 15 years. Mr. Dequenne holds a Master of Engineering, Electromechanical Engineering from *L'institut Supérieur Industriel* in Mons, Belgium.

*Petra Pesendorfer* has served as our Chief People Officer and as a member of our Executive Committee since January 2024. She has more than 18 years' experience in strategic and operational Human Resources, leading large teams across different countries and regions in rapidly growing business environments. During her career, she has held a variety of positions with increasing international responsibilities. Prior to joining us, Ms. Pesendorfer served as Vice President & Global HR Business Unit & Functional Head (2019 - 2023), Regional HR Head for USA and Canada (2022-2023) and Global Head of Human Capital Development & Talent Acquisition (2016-2019) at ams OSRAM. Prior to that, Ms. Pesendorfer held multinational HR leadership roles at Rentokil Initial and Soravia Group from 2006 to 2016. Ms. Pesendorfer holds an International Master of Business Administration from FH Wien University of Applied Sciences, Vienna, and the University of Texas at Brownsville.

*Hanneke Schuitemaker* joined Valneva in June 2024 as our Chief Scientific Officer. She has more than two decades of experience in vaccine discovery and development. She worked at Janssen Vaccines and Prevention, which is part of the Johnson and Johnson group, including as Global Head of Viral Vaccine Discovery and Translational Medicine, with responsibility for the strategy and execution of vaccine programs on COVID-19, HIV, RSV, Ebola, and multiple other viral disease targets. Prior to that, she worked at Sanquin, the Dutch blood supply foundation, as Chair of the Department of Clinical Viro-Immunology, and at the Amsterdam University Medical Center, as Chair of the Department of Experimental Immunology. Dr. Schuitemaker received her Ph.D. in Medicine from the University of Amsterdam.

*Kendra Wergin* has served as our General Counsel and Corporate Secretary and as a member of our Executive Committee since August 2024. Ms. Wergin is admitted to the bars of New York, California, Virginia, and the District of Columbia. She joined Valneva in 2020 as Senior Corporate Counsel and served as Vice President, Legal and Associate General Counsel from March 2023 until her appointment to the Executive Committee. Prior to joining Valneva, Ms. Wergin served as Corporate Counsel at Intuit (2020) and as an Associate in the London and Paris offices of Latham & Watkins LLP (2014-2019), where she practiced corporate law. Ms. Wergin brings additional skills from prior experience in public education, local government, and consulting. Ms. Wergin holds a Juris Doctor from the University of Virginia School of Law, a *Master droit économique* (Master in Economic Law) from l'Institut d'Etudes Politiques de Paris (Sciences Po), a Master of Arts in Teaching from American University, and a Bachelor of Arts from the College of William & Mary.

***Board of Directors***

The Board of Directors is composed of a minimum of three and a maximum of eighteen members. Directors are appointed for a renewable term of three years at the general meeting of shareholders. The general meeting of shareholders may revoke the appointments of directors at any time during the meeting by a simple majority vote. The appointees are selected by the shareholders and may be individuals or entities (represented by a designated individual).

The age limitation for directors is 80 years old, and no more than 20% of the directors may be over 75 years old. The limitations on holding such an appointment concurrently with an appointment in another company are those set forth in the applicable statutory and regulatory provisions.

Our Board of Directors is currently composed of the following non-employee directors, in addition to Thomas Lingelbach:

*Anne-Marie Graffin* joined our Supervisory Board in 2013 and was appointed to the new Board of Directors in December 2023. She was elected Chair of our Board of Directors in December 2023. She served as Chief Executive Officer of the Big Booster Acceleration Program, an international non-profit acceleration program for startups, from 2011 to May 2017. Prior to that, she served in a variety of positions, most recently as Executive Vice President and member of the Executive Committee at Sanofi Pasteur MSD, a European vaccine company, from 1998 to 2011. Ms. Graffin has served on the

supervisory board of Nanobiotix S.A. (Nasdaq: NBTX) since January 2014, on the board of Sartorius Stedim Biotech SA since April 2015, and on the Board of Directors of Vetoquinol SA since 2022. Ms. Graffin received her MBA from ESSEC Business School Paris. We believe Ms. Graffin's experience in the vaccine space and her experience advising biotech companies qualifies her to serve on our Board of Directors.

*James Sulat* joined our Supervisory Board in 2013 and was appointed to the new Board of Directors in December 2023. He is currently Vice Chairman of our Board of Directors. Previously, he served on the Supervisory Board of Intercell AG from 2005 until its merger with Vivalis SA in 2013. From 2009 to 2013, Mr. Sulat served as Chief Executive Officer and Chief Financial Officer of Maxygen, Inc., and as a member of Maxygen's Board of Directors from 2003 to 2013. From 2005 to 2009, Mr. Sulat served in a variety of roles at Memory Pharmaceuticals Corp., including as President and Chief Executive Officer from 2005 to 2008 and as a member of Memory's Board of Directors from 2005 to 2009. Previously, Mr. Sulat served as Chief Financial Officer for Chiron Corporation and Stanford Health Services. He previously served on the Boards of Directors of GS Holdings, Inc. from October 2021 to December 2025, Exicure, Inc. from 2021 until December 2022, Arch Therapeutics, Inc. from 2015 until December 2021, and AMAG Pharmaceuticals, Inc. from 2014 to November 2020. Mr. Sulat received an MBA and an M.S. in Health Services Administration from Stanford University and a B.S. in Administrative Sciences from Yale University. We believe Mr. Sulat's experience in the pharmaceutical industry, expertise in corporate finance and public company board experience qualifies him to serve on our Board of Directors.

*James Connolly* joined our Supervisory Board in June 2022 and was appointed to the new Board of Directors in December 2023. Since 2013, Mr. Connolly has been providing broad based consulting and advisory services to a variety of vaccine, biopharmaceutical and investment organizations. From 2010 to 2013, Mr. Connolly was President and CEO of Aeras (now IAVI). Prior to this, he spent 24 years at Wyeth (now Pfizer) in a series of increasingly senior roles, including Executive Vice President and General Manager, Wyeth Vaccines and President, Wyeth Canada. Mr. Connolly currently serves on the Board of Directors of IAVI. He previously served on the Board of Directors of Vaxess Technologies (2013-2019), Aeras (2013-2018), PaxVax (2014-2018), Tivorsan Pharmaceuticals (2015-2020) and Ambulatus Robotics (2020-2021). Mr. Connolly earned a B.S. in Business Administration from Washington University in St Louis. We believe Mr. Connolly's experience in the vaccines and pharmaceutical industries and his experience advising biotech companies qualifies him to serve on our Board of Directors.

*Maïlys Ferrère* joined our Supervisory Board in June 2022 as representative of Bpifrance Participations, member of the Supervisory Board, and represented Bpifrance Participations on our Board of Directors until June 25, 2025. Ms. Ferrère has served as a Director, Head of the Large Venture Investment Activity at Bpifrance, France's public investment bank, since October 2013. Ms. Ferrère served on the board of directors of Sequans Communications S.A., a publicly traded French designer, developer and supplier of cellular semiconductor solutions, and serves on the Board of DBV Technologies, a publicly traded French company that develops a treatment against peanut allergy. Ms. Ferrère served on the board of directors of Innate Pharma SA., a French global oncology-focused biotech company, from 2017 to 2021. Ms. Ferrère served on the board of directors at Gensight Biologics S.A., a French publicly traded biotechnology company, from 2016 to 2019. She graduated from Institut d'Etudes Politiques Paris and began her career with the Internal Audit of Société Générale before working for multiple French banks in the equity capital markets origination department.

*Danièle Guyot-Caparros* joined our Board of Directors in 2024. She started her career in Audit and Corporate Finance with PWC specializing in the Chemical/Pharma Industry. In 1992, she joined Rhône-Poulenc-Rorer (later Aventis and Sanofi) where she held several senior finance positions (CFO Global R&D, CFO Europe, Group Planning). In 2008, she became Senior Advisor for Deloitte France to support the development of the Life Sciences and Health Care Industry practice. She has supported multiple engagements with a large diversity of clients (big and mid-size pharma companies, biotech, foundations etc.) focusing on transformation, governance issues and M&A. Ms. Guyot-Caparros is also an experienced non-executive director with a focus on Biotech/Medtech. From 2015 to 2017, she was board and audit committee member at Diaxonhit (now Eurobio Scientific) listed on Euronext Growth. She chaired the audit committee of Supersonic Imagine from July 2018 to September 2019 until the acquisition of the company by US group Hologic. From 2013 to June 2022, she chaired the audit committee of ONXEO (listed on Euronext, OMX Copenhagen and now Euronext Growth) and chaired the board from May 2019 to July 2021. In October 2022, she joined the board of DBV Technologies, a company listed on Euronext and Nasdaq, and she is a member of the audit committee and of the compensation committee. In October 2025, she joined the board of ALTEN Group, and she is the chair of its audit committee. Ms. Guyot-Caparros is a graduate from ICN (Institut Commercial de Nancy), with specialization in finance and accounting. She holds a chartered accountant degree and a non-executive director qualification awarded by IFA-Science-Po. We believe that Ms. Guyot-Caparros's experience in finance and business operations qualify her to serve on our Board of Directors.

*Kathrin Jansen* joined our Supervisory Board in June 2023 and was appointed to our new Board of Directors in December 2023. Dr. Jansen has over 30 years of vaccine R&D experience focused on the development of vaccines addressing large unmet medical needs. From 2015 to 2022 she served as Senior Vice President and Head of Vaccine Research and Development at Pfizer Inc, and as a member of Pfizer's Worldwide Research, Development and Medical leadership team. She led a fully integrated, global vaccines research and development organization, with responsibilities ranging from discovery to clinical development, registration, and postmarketing commitments of all of Pfizer's vaccines, including partnered ones. Most notably she led the development of several highly successful and licensed vaccines such as Pfizer/BioNtech's SARS-CoV-2 (COMIRNATY), the first-ever licensed mRNA vaccine, Pfizer's Streptococcus pneumoniae (Prevnar 20), Respiratory syncytial virus (Abrysvo), and Meningococcal B Group B (Trumenba) vaccines. From 2006 to 2015, Dr. Jansen served as Senior Vice President at Wyeth Pharmaceuticals and then Pfizer and was responsible for vaccine discovery, early development, and clinical testing operations. Prior to Wyeth, Dr. Jansen spent 12 years at Merck Research Laboratories supporting several vaccine efforts and leading the R&D activities of Gardasil, the world's first cervical cancer vaccine. Dr. Jansen received her Ph.D. in microbiology, biochemistry & genetics from Phillips

Universitaet, Marburg, Germany, in 1984 followed by postdoctoral training at Cornell University. Dr. Jansen was appointed an Adjunct Professor at the University of Pennsylvania School of Medicine in 2010 and has authored and co-authored over 200 publications. She is a member of the National Academy of Medicine, National Academy of Engineering, a Fellow of the Royal Society of Medicine and recipient of the Albert E Sabin Gold Medal. We believe that Dr. Jansen's experience in the vaccines industry qualifies her to serve on our Board of Directors.

*Gerd Zettlmeissl* joined our Board of Directors in June 2025. Dr. Zettlmeissl has more than 40 years of R&D and General Management leadership experience in the biopharmaceutical industry. Since 2012 he has served on the Board of Directors and Scientific Advisory Boards of a number of non-profit organizations and biotech/vaccine companies. His Board of Directors appointments included chairman of GlycoVaxyn (Switzerland) acquired by GlaxoSmithKline and Themis (Austria) acquired by Merck Sharp and Dohme, chairman of Hilleman Laboratories (India, Singapore) and of Minervax (Denmark). He currently is a member of the Scientific Advisory Board of Biological E. (India). Dr. Zettlmeissl is the former CEO of the vaccine biotech company Intercell (now Valneva). Prior to joining Intercell, he was Managing Director of Chiron-Behring (Germany) and held senior management roles in biopharmaceutical R&D and Technical Operations at Chiron (USA) and Behringwerke (Germany). In 2010, he was named Vaccine Biotech CEO of the Year at the World Vaccine Congress. Dr. Zettlmeissl has authored and co-authored a wide range of patents and publications. He holds a doctoral degree in biochemistry of the University of Regensburg and did a post-doctoral fellowship at the Institut Pasteur Paris in virology. We believe that Dr. Zettlmeissl's experience in the vaccines industry and historical knowledge of Valneva qualify him to serve on our Board of Directors.

***Diversity of the Board of Directors***

As of the date of this annual report, our Board of Directors consists of three women and four men. We therefore comply with the applicable provisions of the French Commercial Code, which requires that the difference between the number of directors of each gender should be no greater than two.

***Family Relationships***

There are no family relationships among any of the members of our Board of Directors and Executive Committee.

## B. Compensation

***Compensation of Members of the Board of Directors***

We pay all our Board members, other than as described below, for their service on our Board of Directors. This compensation consists of base compensation (made up of basic fees and supplements depending on their role on the Board and Committees, except for the Chair) and additional compensation as described below (which is based on the length of their service on the Board). Fees are fixed but may be reduced if meeting attendance is under 75%. At our General Meeting of shareholders held on June 25, 2025, shareholders approved the compensation scheme for base compensation as shown below, payable to our directors in respect of 2025:

| **Member Role** | **Maximum Allowable Compensation (per year)** |
|---|---|
| Chair of the Board | €90,000 |
| Other Board members | €45,000 plus the supplements listed below, as the case may be |
| Vice-Chair supplement | €15,000 |
| Lead Independent Member supplement | €15,000 |
| Committee Chair supplement (includes membership of the chaired Committee) | €15,000 |
| Committee membership supplement (per Committee) | €7,500 |

The shareholders also approved the additional compensation component for each Board member, which is structured as follows (and may be prorated in case the Board member leaves the Board before the date triggering the payment of this compensation):

- €13,300 to be paid approximately one year after the date of appointment;
- €26,600 to be paid approximately two years after the date of appointment;
- €39,900 to be paid approximately three years after the date of appointment and again annually thereafter.

The following table sets forth the total compensation earned by members of the Board during the year ended December 31, 2025 for their service on our Board, in accordance with the principles described above:

| Member | Compensation |
|---|---|
| Anne-Marie Graffin | €129,900 |
| James Sulat | €111,150 |
| James Connolly | €107,400 |
| Kathrin Jansen | €90,350 |
| Danièle Guyot-Caparros | €73,300 |
| Gerd Zettlmeissl | €30,000 |

Ms. Maïlys Ferrère did not receive any compensation in connection with her representation of Bpifrance Participations on the Board of Directors through June 25, 2025, end date of her term, as Bpifrance Participations waived its right to receive such compensation. In addition, in accordance with the decision of the Board of Directors held on December 20, 2023, Mr. Thomas Lingelbach does not receive any compensation for his role on the Board of Directors.

***Compensation of CEO and Associate Managing Officers — 2025***

The Company's general management was represented until June 25, 2025 by our CEO (*Directeur Général*), Mr. Thomas Lingelbach, and the Associate Managing Officers (*Directeurs Généraux Délégués*) listed below, also appointed in order to assist Mr. Lingelbach in the performance of his duties:

- Franck Grimaud, Chief Business Officer;
- Peter Bühler, Chief Financial Officer;
- Juan Carlos Jaramillo, Chief Medical Officer; and
- Dipal Patel, Chief Commercial Officer.

The Board of Directors decided not to renew the appointments of any of the Associate Managing Officers, and therefore although Mr. Bühler, Mr. Jaramillo, and Ms. Patel continue in their respective executive roles, their titles of Associate Managing Officer expired on June 25, 2025. Mr. Grimaud left the Company on June 25, 2025.

The current term of office of Mr. Lingelbach will end at the 2026 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2025. The Board of Directors has agreed to extend Mr. Lingelbach's term as Chief Executive Officer for an additional three years, ending at the 2029 General Meeting called to approve the annual financial statements for the fiscal year ended December 31, 2028.

The method and amount of compensation for the CEO and each Associate Managing Officer (if any) is determined by the Board of Directors, after recommendation by the Nomination, Governance and Compensation Committee.

The following tables set forth compensation earned by the CEO and Associate Managing Officers with respect to the year ended December 31, 2025.

***Mr. Thomas Lingelbach – Chief Executive Officer and member of the Board of Directors since December 20, 2023 (previously Chair of the Management Board)***

Mr. Lingelbach's 2025 compensation is defined in accordance with (a) the provisions of the Management Agreement executed between Mr. Lingelbach and Valneva Austria GmbH, which came into force at the end of our Combined General Meeting held on June 23, 2022 (as amended, notably on December 20, 2023), and (b) the decisions of our Board of Directors, as applicable.

| Type of Compensation | Amount of compensation earned | Description |
|---|---|---|
| **Fixed compensation** | €581,793.00 | According to the decision of the Company's Board of Directors dated March 19, 2025. |
| **Annual variable compensation** | €318,531.67 | (Amount granted with respect to the objectives set for the year 2025, calculated on the basis of 75% of the gross annual salary defined by the Company's Board of Directors on March 19, 2025 and taking into account the validation of 73% of the objectives by the Company's Board of Directors on February 26, 2026). |
| **Exceptional compensation** | €0.00 | |
| **Multi-year variable compensation** | €0.00 | |
| **Compensation in connection with Board membership** | €0.00 | |
| **Fringe benefits :** | | |
| – Car rental | Lease fee: €10,142.77<br>Insurance: €5,239.08<br>Other car related expenses (except fuel) : €11,383.66 | Maximum €1,320 per month for the lease fee as per Mr. Lingelbach's Management Agreement. |
| – Death and endowment insurance policy | €18,000.00 | Long-term life insurance policy as a retirement savings product. |
| – Reimbursement of home workplace journeys made by flights, and associated costs | €5,854.05 | Reimbursement for the costs of weekend flights between Mr. Lingelbach's hometowns in Germany and Austria and sites of Valneva, these costs including the transfers from and to the airport. |
| **Total compensation** | **€950,944.23** | |

***Mr. Franck Grimaud – Chief Business Officer and Associate Managing Officer from December 20, 2023 until June 25, 2025 (previously Management Board member and Managing Director)***

Mr. Grimaud's 2025 compensation is defined in accordance with (a) the provisions of the Management Agreement executed between Mr. Grimaud and Valneva SE, which came into force at the end of our Combined General Meeting held on December 20, 2023 and ended on June 25, 2025, and (b) the decisions of our Board of Directors, as applicable.

| **Type of compensation** | **Amount of compensation earned** | **Description** |
|---|---|---|
| **Fixed compensation** | €142,434.06 | Amount prorated to take account of Mr. Grimaud's departure date. His fixed annual compensation was set at €291,748 by a decision of the Company's Board of Directors on March 19, 2025. |
| **Annual variable compensation** | €0.00 | In accordance with the conditions of termination set for, and agreed by, Mr. Grimaud. |
| **Multi-year variable compensation** | €0.00 | |
| **Exceptional compensation** | €0.00 | |
| **Fringe benefits :** | | |
| – Car rental | Lease fee: €6,417.88<br>Insurance: €986.85<br>French taxes on the use of vehicles: €100.00 | Taking into account the departure date of Mr. Grimaud, the maximum amount allocated for 2025 by Mr. Grimaud's Management Agreement was €1,320 per month, or €15,840 for the year. |
| – Garantie Sociale des Chefs et Dirigeants d'Entreprises | €9,164.00 | A Social Insurance Contract for Company directors and Managers (Convention Garantie Sociale des Chefs et Dirigeants d'Entreprise) has been granted to Mr. Franck Grimaud. The purpose of this contract is to guarantee the payment of compensation in case of unemployment up to 70% of the last professional net income filed with the tax authorities. This GSC was set up pursuant to an authorization of the Board of Directors of October 26, 2000. |
| **Total compensation** | **€159,102.79** | |

***Dr. Juan Carlos Jaramillo – Chief Medical Officer***
***Associate Managing Officer (Directeur Général Délégué) from December 20, 2023 until June 25, 2025 (previously Management Board member )***

Dr. Jaramillo's 2025 compensation is defined in accordance with (a) the provisions of the Management Agreement executed between Dr. Jaramillo and Valneva Austria GmbH, which came into force at the end of the Company's Combined General Meeting held on June 23, 2022 (as amended, notably on December 20, 2023; the agreement was replaced in its entirety by a new Management Agreement effective June 25, 2025, considering the expiry of Mr. Jaramillo's duties as Associate Managing Officer on that same date), and (b) the decisions of our Board of Directors, as applicable.

| Type of compensation | Amount of compensation earned | Description |
|---|---|---|
| **Fixed compensation** | €199,162.08 | Prorated amount based on the execution period of Mr. Jaramillo's duties as Associate Managing Officer in 2025.<br>The officer's fixed annual compensation was set at €413,035 by a decision of the Company's Board of Directors on March 19, 2025. |
| **Annual variable compensation** | €152,822.95 | Amount granted with respect to the objectives set for the year 2025, calculated on the basis of 50% of the gross annual salary defined by the Company's Board of Directors on March 19, 2025 and taking into account the validation of 74% of the objectives by the Company's Board of Directors on February 26, 2026. |
| **Multi-year variable compensation** | €0.00 | |
| **Exceptional compensation** | €0.00 | |
| **Fringe benefits :** | | |
| – Car allowance | €7,920.00 | €1,320 per month as per Mr. Jaramillo's Management Agreement; the amount of compensation earned that is presented takes into account the execution period of his duties as Associate Managing Officer in 2025. |
| – Death and endowment insurance policy | €9,000.00 | Long-term life insurance policy as a retirement savings product; the amount of compensation earned that is presented takes into account the execution period of Mr. Jaramillo's duties as Associate Managing Officer in 2025. |
| – Reimbursement of home workplace journeys made by flights, and associated costs | €7,692.83 | Reimbursement for the costs of weekend flights between Mr. Jaramillo's hometown in Spain and site of Valneva Austria, these costs including the transfers from and to the airport. The amount of compensation earned that is presented takes into account the execution period of Mr. Jaramillo's duties as Associate Managing Officer in 2025. |
| **Total compensation** | **€376,597.86** | |

***Mr. Peter Bühler – Chief Financial Officer***
***Associate Managing Officer (Directeur Général Délégué) from December 20, 2023 until June 25, 2025 (previously Management Board member)***

Mr. Bühler's 2025 compensation is defined in accordance with (a) the provisions of the Management Agreement executed between Mr. Bühler and Valneva Austria GmbH, which came into force at the end of our Company's Combined General Meeting held on June 23, 2022 (as amended, notably on December 20, 2023; the agreement was replaced in its entirety by a new Management Agreement effective June 25, 2025, considering the expiry of Mr. Bühler's duties as Associate Managing Officer on that same date), and (b) the decisions of our Board of Directors, as applicable.

| **Type of compensation** | **Amount of compensation earned** | **Description** |
|---|---|---|
| **Fixed compensation** | €201,139.07 | Prorated amount based on the execution period of Mr. Bühler's duties as Associate Managing Officer in 2025.<br>The officer's fixed annual compensation was set at €417,135 by a decision of the Company's Board of Directors on March 19, 2025. |
| **Annual variable compensation** | €171,025.35 | Amount granted with respect to the objectives set for the year 2025, calculated on the basis of 50% of the gross annual salary defined by the Company's Board of Directors on March 19, 2025 and taking into account the validation of 82% of the objectives by the Company's Board of Directors on February 26, 2026. |
| **Multi-year variable compensation** | €0.00 | |
| **Exceptional compensation** | €0.00 | |
| **Fringe benefits :** | | |
| – Car allowance | €7,920.00 | €1,320 per month as per Mr. Bühler's Management Agreement; the amount of compensation earned that is presented takes into account the execution period of his duties as Associate Managing Officer in 2025. |
| – Death and endowment insurance policy | €9,000.00 | Long-term life insurance policy as a retirement savings product; the amount of compensation earned that is presented takes into account the execution period of Mr. Bühler's duties as Associate Managing Officer in 2025. |
| **Total compensation** | **€389,084.42** | |

***Ms. Dipal Patel – Chief Commercial Officer***
***Associate Managing Officer (Directrice Générale Déléguée) from December 20, 2023 until June 25, 2025 (previously Management Board member)***

Ms. Patel's 2025 compensation is defined in accordance with (a) the provisions of the Management Agreement executed between Ms. Patel and Valneva UK Ltd, which came into force on November 18, 2022 (as amended, notably on December 20, 2023; the agreement was replaced in its entirety by a new Management Agreement effective June 25, 2025, considering the expiry of Ms. Patel's duties as Associate Managing Officer on that same date), and (b) the decisions of our Board of Directors, as applicable.

| Type of compensation | Amount of compensation earned (*) | Description |
|---|---|---|
| **Fixed compensation** | £153,374.12, or €175,304.74 | Prorated amount based on the execution period of Ms. Dipal's duties as Associate Managing Officer in 2025.<br>The officer's fixed annual compensation was set at £318,077 by a decision of the Company's Board of Directors on March 19, 2025. |
| **Annual variable compensation** | £122,459.65, or €139,969.88 | Amount granted with respect to the objectives set for the year 2025, calculated on the basis of 50% of the gross annual salary defined by the Company's Board of Directors on March 19, 2025 and taking into account the validation of 77% of the objectives by the Company's Board of Directors on February 26, 2026. |
| **Multi-year variable compensation** | €0.00 | |
| **Exceptional compensation** | €0.00 | |
| **Fringe benefits :** | | |
| – Car allowance | £6,696.00 or €7,653.45 | £1,116 per month per Ms. Patel's Management Agreement; the amount of compensation earned that is presented takes into account the execution period of her duties as Associate Managing Officer in 2025. |
| – Contribution to UK pension plan | £11,598.38, or €13,256.81 | 7.5% of the gross annual salary; the amount of compensation earned that is presented takes into account the execution period of her duties as Associate Managing Officer in 2025. |
| **Total compensation** | **€336,184.88** | |

*(*) Exchange rate applied: €1 for £0.8749 (average rate for December 2025). This rate will be updated, in particular with regard to the annual variable compensation, at the time of the bonus payment expected in July 2026 (subject to prior approval by the Company's Annual Ordinary General Meeting to be held in June 2026).*

***Compensation of the CEO —2026***

The Board of Directors confirmed in its meeting on January 27, 2026 that Mr. Lingelbach's base salary for his next term of office beginning on June 25, 2026 will be €581,793.

***Adoption of Clawback Policy***

In November 2023, in accordance with Rule 10D-1 promulgated under the Exchange Act and Nasdaq Listing Rule 5608, we adopted an incentive compensation recoupment policy which is filed herewith as Exhibit 97.1.

## Limitations on Liability and Indemnification Matters

Under French law, provisions of bylaws that limit the liability of the members of the Board of Directors, the Chief Executive Officer and Deputy Chief Executive Officer(s) (together with the Chief Executive Officer, the "Executive Officers") are prohibited. However, French law allows *sociétés européennes* to contract for and maintain liability insurance against civil liabilities incurred by members of the Board and Executive Officers involved in a third-party action, provided that they acted in good faith and within their capacities as members of such board or management of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We have liability insurance for our Board members, Executive Officers and other members of our Executive Committee and have obtained insurance coverage for liability under the Securities Act. We also have entered into agreements with our Board members and Executive Officers to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified Board members and Executive Officers.

These agreements may discourage shareholders from bringing a lawsuit against our Board members and Executive Officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our Board members and Executive Officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our Board members and Executive Officers pursuant to these insurance agreements.

## Equity Incentives

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. In accordance with French corporate law, we have historically granted several different equity incentive instruments to our management and our employees, including stock options and free ordinary shares.

Our Board of Directors' authority to grant these stock options and free ordinary shares and the aggregate amount authorized to be granted must be approved by two-thirds of the shareholders voting in the relevant extraordinary shareholders' meeting. Once approved by our shareholders, our Board of Directors can continue to grant such awards for a specified period.

We currently have various long-term incentive plans for our management and employees that have been approved by our shareholders. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the conversion ratio and/or the exercise price of the outstanding stock options.

***Stock Options***

The beneficiaries receive a number of options, depending notably on their job functions, that they can convert into ordinary shares during specific exercise periods that are announced by the management and subject to applicable vesting periods.

Under our plans that are currently in force (or were in force during 2025), each option converts into one ordinary share. Our stock option plans currently in force do not include a discount on the exercise price.

All stock options not exercised within ten years of the grant date lapse without compensation.

The following table sets forth the stock options outstanding as of December 31, 2025 (or which were in force during 2025):

| **Plan name** | **ESOP 2015** | **ESOP 2016** | **ESOP 2017** | **ESOP 2019** | **SLG SOP 2022** | **ESOP 2022** |
|---|---|---|---|---|---|---|
| General Meeting date | June 26, 2014 | June 30, 2016 | June 30, 2016 | June 28, 2018 | June 23, 2022 | June 23, 2022 |
| Grant date | July 28, 2015 | October 7, 2016 | December 7, 2017 | September 30, 2019 | October 10, 2022 | October 10, 2022 |
| Subscription price | €3.92 | €2.71 | €2.85 | €3.05 | €6.47 | €6.47 |
| Option/share conversion ratio | 1: 1 | 1: 1 | 1: 1 | 1: 1 | 1: 1 | 1: 1 |
| Stock options granted to employees and/or corporate officers by the Management Board at launch of plan | 712,000 | 584,250 | 1,269,500 | 2,670,010 | 1,159,751 | 2,154,500 |
| Vesting dates | July 28, 2017 (for 50% of the options)<br>July 28, 2019 (for the remaining 50%) | October 7, 2018 (for 50% of the options)<br>October 7, 2020 (for the remaining 50%) | December 7, 2019 (for 50% of the options)<br>December 7, 2021 (for the remaining 50%) | September 30, 2020 (for 1/3 of the options)<br>September 30, 2021 (for another 1/3 of the options)<br>September 30, 2022 (for the remainder) | October 10, 2023 (for 1/3 of the options)<br>October 10, 2024 (for another 1/3 of the options)<br>October 10, 2025 (for the remainder) | October 10, 2023 (for 1/3 of the options)<br>October 10, 2024 (for another 1/3 of the options)<br>October 10, 2025 (for the remainder) |
| Stock options exercised as of December 31, 2025 | 478,845 | 385,500 | 720,981 | 589,016 | 0 | 0 |
| Shares resulting from exercise of stock options | 478,845 | 385,500 | 720,981 | 589,016 | 0 | 0 |
| Outstanding stock options as of December 31, 2025 | 0 | 8,500 | 202,375 | 892,400 | 790,711 | 1,249,500 |
| Of which outstanding stock options held by corporate officers | 0 | 0 | 0 | 0 | Mr. Thomas Lingelbach: 313,930 | 0 |
| Shares potentially resulting from stock option exercise after December 31, 2025 | 0 | 8,500 | 202,375 | 892,400 | 790,711 | 1,249,500 |
| Stock options having lapsed as of December 31, 2025 | 233,155 | 190,250 | 346,144 | 1,188,594 | 369,040 | 896,000 |

| **Plan name** | **SLG SOP 2023** | **ESOP 2023** | **SLG SOP 2024** | **ESOP 2024** | **ESOP 2025** |
|---|---|---|---|---|---|
| General Meeting date | June 21, 2023 | June 21, 2023 | December 20, 2023 | December 20, 2023 | June 25, 2025 |
| Grant date | December 15, 2023 | December 15, 2023 | October 22, 2024 | October 22, 2024 | July 7, 2025 |
| Subscription price | €5.25 | €5.25 | €2.62 | €2.62 | €2.49 |
| Option/share conversion ratio | 1: 1 | 1: 1 | 1: 1 | 1: 1 | 1: 1 |
| Stock options granted to employees and/or corporate officers by the Management Board at launch of plan | 1,284,519 | 2,156,750 | 2,619,966 (including 1,520,269 to corporate officers) | 2,337,750 | 1,862,610 |
| Vesting dates | December 15, 2024 (for 1/3 of the options)<br>December 15, 2025 (for another 1/3 of the options)<br>December 15, 2026 (for the remainder) | December 15, 2024 (for 1/3 of the options)<br>December 15, 2025 (for another 1/3 of the options)<br>December 15, 2026 (for the remainder) | October 22, 2025 (for 1/3 of the options)<br>October 22, 2026 (for another 1/3 of the options)<br>October 22, 2027 (for the remainder) | October 22, 2025 (for 1/3 of the options)<br>October 22, 2026 (for another 1/3 of the options)<br>October 22, 2027 (for the remainder) | July 7, 2026 (for 1/3 of the options)<br>July 7, 2027 (for another 1/3 of the options)<br>July 7, 2028 (for the remainder) |
| Stock options exercised as of December 31, 2025 | 0 | 0 | 123,109 | 317,921 | 0 |
| Shares resulting from exercise of stock options | 0 | 0 | 123,109 | 317,921 | 0 |
| Outstanding stock options as of December 31, 2025 | 977,705 | 1,655,500 | 2,241,997 | 1,749,658 | 1,757,860 |
| Of which outstanding stock options held by corporate officers | Mr. Thomas Lingelbach: 322,271 | 0 | Mr. Thomas Lingelbach: 581,634 | 0 | 0 |
| Shares potentially resulting from stock option exercise after December 31, 2025 | 977,705 | 1,655,500 | 2,241,997 | 1,749,658 | 1,757,860 |
| Stock options having lapsed as of December 31, 2025 | 306,814 | 501,250 | 254,860 | 270,171 | 104,750 |

***Free Ordinary Shares***

Free ordinary shares (*actions ordinaires gratuites*) are employee equity incentive instruments pursuant to which the beneficiaries are granted, for free, the possibility to receive our ordinary shares under certain conditions.

In 2025, the Company's Board of Directors granted 3,537,321 free ordinary shares for the benefit of Executive Committee and members of the Company's senior management (2024: 991,643). The purpose of these free share plans is to provide a long-term incentive program for the Company's senior management.

The following table shows the free ordinary shares outstanding as of December 31, 2025:

| **Plan name** | **2022-2025 Free Share Plan (terminated on October 10, 2025)** |
|---|---|
| **General Meeting date** | June 23, 2021 |
| **Management Board decision** | October 10, 2022 |
| **Free ordinary shares granted by the Management Board** | 374,390 allocated in three tranches, each amounting to one third of the total individual allocation. If one third is not a whole number, the number of free ordinary shares will be rounded down for the first two tranches and rounded up for the third tranche. |
| **Duration of vesting period** | The vesting period is set at two (2) years as from October 10, 2022 for the first and the second tranches, and three (3) years as from October 10, 2022, for the third tranche. The vesting of free ordinary shares thus becomes final, for each tranche, at the end of the aforementioned vesting period, subject to the fulfillment of the employment condition described below. |
| **Date of availability** | Following free shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees.<br>However, in accordance with Section II (4th paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on June 22, 2022, the Supervisory Board decided that the beneficiaries that are corporate officers should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer. |
| **Free ordinary shares fully vested as of December 31, 2025** | 320,521 |
| **Free ordinary shares being vested as of December 31, 2025** | 0 |
| **Free ordinary shares lapsed as of December 31, 2025** | 53,869 |
| **Performance and employment conditions** | No performance condition. However, the beneficiaries of the plan must, on an ongoing basis, remain corporate officers or employees (full time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the grant of the free ordinary shares allocated to them. |
| **Provisions relating to retirement** | The beneficiaries who retire in accordance with the age requirements of their pension plan prior to full vesting will be entitled to a pro rata number of shares for each unvested tranche based on the period from the date of grant to retirement in relation to the total term of the tranche in question, provided, however, that for purposes of this calculation, the term of the first tranche shall be considered to be one year. |
| **Provisions relating to a change of control** | In the event of a Change of Control, beneficiaries will immediately and definitively receive all of their free ordinary shares in the process of being acquired under all tranches of the plan.<br>"***Change of Control***" means that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L.233-3 of the French Commercial Code. |

| Plan name | 2023-2026 Free Share Plan |
|---|---|
| **General Meeting date** | June 21, 2023 |
| **Management Board decision** | December 15, 2023 |
| **Free ordinary shares granted by the Management Board** | 445,320 allocated in three tranches, each amounting to one third of the total ordinary shares granted by the Management Board. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche. |
| **Duration of vesting period** | The vesting period is set at two (2) years as from December 15, 2023 for the first and the second tranches, and three (3) years as from December 15, 2023, for the third tranche. The vesting of free ordinary shares thus becomes final, for each tranche, at the end of the aforementioned vesting period, subject to the fulfillment of the employment condition described below. |
| **Date of availability** | Following free shares vesting, no compulsory holding period will be applicable to the beneficiaries that are non-executive employees.<br>However, in accordance with section II (fourth paragraph) of Article L.225-197-1 of the French Commercial Code, in their meeting held on March 9, 2023 (confirmed on June 21, 2023), the Supervisory Board decided that the beneficiaries that are corporate officers should keep not less than 20% of the vested free shares of each tranche until termination of their office as Management Board member or corporate officer. |
| **Free ordinary shares fully vested as of December 31, 2025** | 255,218 |
| **Free ordinary shares being vested as of December 31, 2025** | 127,631 (including 27,623 for executive corporate officers) |
| **Free ordinary shares lapsed as of December 31, 2025** | 62,471 |
| **Performance and employment conditions** | No performance conditions.<br>However, the beneficiaries of the plan must, on an ongoing basis, remain corporate officers or employees (full time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the grant of the free ordinary shares allocated to them, except for the retirement provisions described below. |
| **Provisions relating to retirement** | The beneficiaries who retire in accordance with the age requirements of their pension plan prior to full vesting will be entitled to a pro rata number of shares for each unvested tranche based on the period from the date of grant to retirement in relation to the total term of the tranche in question, provided, however, that for purposes of this calculation, the term of the first tranche shall be considered to be one year. |
| **Provisions relating to a change of control** | If a Change of Control takes place before December 14, 2025, and Article L.225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however for the beneficiaries that are corporate officers to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable plan rules will apply to this calculation mutatis mutandis.<br>"***Change of Control***" shall mean that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L.233-3 of the French Commercial Code. |

| Plan name | Free ordinary share plan 2024-2027 |
|---|---|
| **General Meeting date** | December 20, 2023 |
| **Board of Directors decision** | October 22, 2024 |
| **Free ordinary shares granted by the Board of Directors** | 991,643 allocated in three tranches, each amounting to one third of the total ordinary shares granted by the Board of Directors. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche. |
| **Duration of vesting period** | The vesting period is set at two (2) years as from October 22, 2024 for the first and the second tranches, and three (3) years as from October 22, 2024, for the third tranche. The vesting of free ordinary shares thus becomes final, for each tranche, at the end of the aforementioned vesting period, subject to the fulfillment of the employment condition described below. |
| **Date of availability** | In accordance with the decisions of the Board of Directors of June 25, 2024 and October 22, 2024, and pursuant to Section II (5th paragraph) of Article L. 225-197-1 of the French Commercial Code when applicable, the executive corporate officers (CEO - *Directeur Général*, and Associate Managing Officers - *Directeurs Généraux Délégués*) as well as each other members of the Executive Committee, should keep not less than 20% of the vested free shares of each tranche until termination of their Executive Committee membership and, when applicable, their corporate office. |
| **Free ordinary shares fully vested as of December 31, 2025** | 0 |
| **Free ordinary shares being vested as of December 31, 2025** | 946,408 (including 167,012 by executive corporate officers) |
| **Free ordinary shares lapsed as of December 31, 2025** | 45,235 |
| **Performance and employment conditions** | No performance conditions.<br>However, the beneficiaries of the plan must, on an ongoing basis, remain corporate officers or employees (full time or at least 80%) of the Company or of a direct or indirect subsidiary of the Company until the grant of the free ordinary shares allocated to them, except for the retirement provisions described below. |
| **Provisions relating to retirement** | The beneficiaries who retire in accordance with the age requirements of their pension plan prior to full vesting will be entitled to a pro rata number of shares for each unvested tranche based on the period from the date of grant to retirement in relation to the total term of the tranche in question, provided, however, that for purposes of this calculation, the term of the first tranche shall be considered to be one year. |
| **Provisions relating to a change of control** | If a Change of Control takes place before October 22, 2026, and Article L.225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however for the beneficiaries that are corporate officers to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable plan rules will apply to this calculation *mutatis mutandis*.<br>"***Change of Control***" shall mean that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L.233-3 of the French Commercial Code. |

| Plan name | 2025-2028 Performance-based Free Share Plan |
|---|---|
| General Meeting date | June 25, 2025 |
| Board of Directors decision | July 7, 2025 |
| Free ordinary shares granted by the Board of Directors | 3,537,321 allocated in three tranches, each amounting to one third of the total ordinary shares granted by the Board of Directors. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche. |
| Duration of vesting period | The vesting period is set at two (2) years as from July 7, 2025, for the first tranche, and three (3) years as from July 7, 2025, for the second and the third tranches. The vesting of performance-based free ordinary shares thus becomes final, for each tranche, at the end of the aforementioned vesting period, subject to the fulfillment of the employment and performance conditions described below. |
| Date of availability | In accordance with the decision of the Board of Directors of July 7, 2025 and pursuant to Section II (5th paragraph) of Article L. 225-197-1 of the French Commercial Code when applicable, the CEO (Directeur Général) and each of the other members of the Executive Committee must keep not less than 20% of their respective performance-based free shares vested under the plan, until termination of both his/her Executive Committee membership, and as applicable to the CEO, his corporate office. |
| Free ordinary shares fully vested as of December 31, 2025 | 0 |
| Free ordinary shares being vested as of December 31, 2025 | 3,401,001 (including 658,107 by executive corporate officers) |
| Free ordinary shares lapsed as of December 31, 2025 | 136,320 |
| Performance and employment conditions | The final acquisition (“acquisition définitive”), by the Participants, of the PFS under each tranche of the 2025 PFSP will depend on the overall level of performance as assessed and determined by the Board in respect of the Performance Period (as defined below) taking into account the performance metrics and principles as approved by the Board and communicated to the Participants. Performance Period means 2025 and 2026 for all tranches, the performance criteria being assessed cumulatively over these two years.<br><br>In addition, the beneficiaries of the plan must continuously remain a corporate officer or employee (full time or not less than 50%) of the Company or a direct or indirect subsidiary of the Company until the final acquisition of the performance-based free shares, subject to the retirement exception. |

| | |
|---|---|
| **Provisions relating to retirement** | Participants who will retire in accordance with the age requirements of their applicable retirement regime before complete vesting will remain entitled to a prorated amount of shares, for each unvested tranche, based on the period from the date of grant until retirement, as compared to the total duration of the tranche in question; it being specified, that for purposes of this calculation, the duration of the first tranche will be deemed to be one year and the duration of the second tranche will be deemed to be two years.<br>The amount of shares to be definitively acquired with the participant who retired will then be determined by taking into account the overall level of performance, as set by the Board of Directors. The continuous presence condition will cease to apply in respect of all unvested shares of the participant who is retiring, as from the effective date of his/her retirement, it being specified, however, that the continuous presence condition of the concerned participant must have been satisfied between the date of grant and the effective date of his/her retirement. |
| **Provisions relating to a change of control** | If a Change of Control takes place before July 7, 2027, and Article L. 225-197-1, III of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the beneficiaries for the loss of unvested free ordinary shares granted under the canceled plan, subject however for the beneficiaries who are corporate officers to the shareholders' approval to the indemnity so allocated. The gross amount of this indemnity shall be calculated as follows: a) in cases where the performance conditions have not yet been assessed by the Board of Directors in respect of the unvested shares at the time of the Change of Control, the gross amount of indemnity shall be determined as though these shares had been vested with an overall level of performance set at 100% by the Board of Directors; and b) in cases where the performance conditions have already been assessed by the Board of Directors in respect of the unvested shares at the time of the Change of Control, the gross amount of indemnity shall be calculated by taking into account the overall level of performance as determined by the Board of Directors.<br>"Change of Control" shall mean that a person or entity other than the Company's current shareholders has taken control of the Company, "control" having the meaning set forth in Article L. 233-3 of the French Commercial Code. |

***Phantom Shares***

In recent years, we established Phantom Stock Option Programs with terms and conditions similar to the then-existing Employee Stock Option Plans (or "ESOPs") described above, for employees who are U.S. tax citizens.

The Phantom Stock Option Programs are based on our share price and entitle the participants to a potential cash bonus if there has been an increase in our share price compared to the strike price at the grant date. Each employee participating in the program has phantom stock options potentially giving right to a certain number of phantom shares, which will be settled in cash instead of equity.

The overall objectives of the Phantom Stock Option Programs were (i) to retain certain employees who are U.S. citizens, (ii) to create long-term incentive for the participants, because they were not eligible for the ESOPs, and consequently (iii) to align the interests of our employees who are U.S. citizens and our employees eligible for the ESOPs.

The strike price per phantom share for each past program was calculated on the basis of the volume-weighted average closing price of our shares on Euronext Paris during a period of 20 trading days prior to the grant of options under the parallel ESOP. Strike price of the phantom stock option program currently remaining in force is set at €3.05. The phantom shares will be settled in cash until 2030 by subtracting the entry price per share from the market price per share and multiplying the result by the total number of granted phantom shares, but only if our market price per share at that date exceeds the strike price. The market price per share will be based on the closing price of our shares on Euronext Paris on the date of receipt of the exercise notice.

As of December 31, 2025, the remaining Phantom Stock Option Program consisted of an aggregate of 10,000 phantom shares.

The Phantom Stock Option Program does not have any dilutive effect on our shareholders, as the phantom shares do not constitute or qualify for our ordinary shares.

The liability for the phantom plan is measured (initially at the end of each reporting period until settled) at the fair value of the share options rights, by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

## C. Board Practices

We are led by a Board of Directors, with our senior management comprising an Executive Committee. Responsibility for the management of the Company rests with our Executive Committee, notably through our Chief Executive Officer (*Directeur Général*) and (until June 25, 2025) four other members appointed as Associate Managing Officers (*Directeurs Généraux Délégués*) who together formed the Company's General Management.

We present the details of the Board of Directors below.

***Composition***

The Board of Directors is composed of a minimum of three and a maximum of eighteen members. Directors are generally appointed for a renewable term of three years at the general meeting of shareholders. The age limit for the members of the Supervisory Board is 80, and no more than 20% of the directors may be over 75 years old. The limitations on holding such an appointment concurrently with an appointment in another company are subject to the applicable legal and regulatory provisions. Six out of seven of our directors were appointed by our shareholders during our Combined General Meeting on December 20, 2023, and one was newly appointed by our shareholders during our Combined General Meeting on June 26, 2024. The terms of Mr. Connolly, Ms. Graffin, Dr. Jansen, Mr. Lingelbach, and Mr. Sulat will expire at the end of the annual General Meeting of shareholders to be held in June 2026. In February 2026, we announced that the Board had renewed Mr. Lingelbach's appointment as Chief Executive Officer and, subject to confirmation by our shareholders at the annual General Meeting in June 2026, as a member of the Board of Directors, for an additional three years. The term of Ms. Guyot-Caparros will expire at the end of the annual General Meeting of shareholders to be held in June 2027, and the term of Mr. Zettlmeissl will expire at the end of the annual General Meeting of shareholders to be held in June 2028. The Ordinary General Meeting of shareholders may revoke the appointments of directors at any time by a simple majority vote. The directors are appointed by the shareholders and may be individuals or companies (represented by a designated individual). With the exception of Mr. Lingelbach, our Chief Executive Officer and member of the Board of Directors who has a Management Agreement with our subsidiary Valneva Austria GmbH, none of our directors serve pursuant to a service contract providing benefits upon termination of service as a director.

***Role of the Board in Risk Oversight***

Our Board of Directors is primarily responsible for the oversight of our risk management activities and has delegated to the Audit, Compliance and Risk Committee (as defined below) the responsibility to assist the Board in this task. While our Board oversees our risk management, our management, through the Executive Committee, is responsible for day-to-day risk management processes. Our Board expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

***Committees***

The Board of Directors has established three committees, each of which operates pursuant to rules of procedure adopted by the Board. These committees are the Audit, Compliance and Risk Committee, the Nomination, Governance and Compensation Committee, and the Science and Technology Committee. The Board previously also established an ESG Committee to oversee certain matters related to sustainability, but the Board decided in June 2025 to eliminate this committee and transfer its responsibilities to the Audit, Compliance and Risk Committee, which was already responsible for certain matters related to non-financial reporting and audit.

Subject to available exemptions, the composition and functioning of all of our Committees will comply with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq listing rules and SEC rules and regulations.

In accordance with French law, Committees of our Board only have an advisory role and can only make recommendations to our Board of Directors. As a result, decisions are made by our Board of Directors taking into account non-binding recommendations of the relevant Board Committee.

***Audit, Compliance and Risk Committee***

The Audit, Compliance and Risk Committee assists our Board in its oversight of our corporate accounting and financial reporting and oversees the selection of our auditors, their remuneration and independence and keeps the Board informed on control systems, key processes and procedures, security and risks. In accordance with the operating rules adopted by the board, the committee is composed of at least three members (or their permanent representatives) appointed by the Board.

The members of our Audit, Compliance and Risk Committee as of the date of this annual report are Danièle Guyot-Caparros (chair), James Sulat, and James Connolly. Our Board has determined that Ms. Guyot-Caparros, Mr. Sulat, and Mr. Connolly are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Board has further determined that Ms. Guyot-Caparros and Mr. Sulat are "Audit Committee Financial Experts" as defined by the Nasdaq listing rules and that each of the members qualifies as financially sophisticated under the Nasdaq listing rules.

The principal responsibility of our Audit, Compliance and Risk Committee is to monitor matters relating to the preparation and the review of our accounting and financial information in order to ensure the quality of internal control over financial reporting and the reliability of the information provided to shareholders and to the financial markets. Additionally, the Committee assists the Board in fulfilling its responsibilities related to sustainability matters under applicable laws. The Committee also monitors the implementation of proper risk management processes, including related to reporting of sustainability information and compliance with laws applicable to the Company.

Additionally, the committee monitors and discusses the quality and integrity of our financial statements and our reports, including sustainability information included therein, by evaluating and overseeing the qualifications, independence and performance of the firm or firms engaged as our independent external auditors, both for the purpose of preparing or issuing

an audit report or performing financial audit services, and for the purpose of certifying our reporting of sustainability information.

***Nomination, Governance and Compensation Committee***

Our Nomination, Governance and Compensation Committee assists our Board with respect to the appointment and the compensation of the members of our Board and Executive Committee. In accordance with operating rules adopted by the Board, the Nomination, Governance and Compensation Committee is composed of at least three members (or their permanent representatives) appointed by the Board.

The members of our Nomination, Governance and Compensation Committee as of the date of this annual report are James Connolly (chair), Anne-Marie Graffin, and Gerd Zettlmeissl, all of whom are independent. James Sulat also served as a member of this committee until June 25, 2025.

Our Board of Directors has assigned the following duties specifically to the Nomination, Governance and Compensation Committee:

- reviewing our compensation policy, in particular the description of our collective objectives (applicable company-wide) and individual objectives (for members of the Executive Committee),
- reviewing the compensation of the members of our Executive Committee,
- examining and making proposals with respect to the various components of corporate officers' compensation, the policy concerning the distribution of equity such as warrants, stock options, grants and capital increases reserved for members of our savings plan the allocation of incentive bonuses and all the provisions relating to retirement benefits and any other kind of benefit,
- examining the amount of attendance fees among Board members,
- assisting the Board in the selection of directors, the members of the Executive Committee, and the members of Board committees, and
- making recommendations with respect to the independence of the members of the Board and committees.

***Science and Technology Committee***

Our Science and Technology Committee assists our Board in oversight of the Company's research and development programs, portfolio strategy and capital allocation, and scientific and technological expertise.

In accordance with operating rules adopted by the Board, the Science and Technology Committee is composed of at least two members (or their permanent representatives) appointed by the Board. The members of our Science and Technology Committee are Kathrin Jansen (chair), Thomas Lingelbach, and Gerd Zettlmeissl.

## D. Employees

As of December 31, 2025, we had a headcount of 674 employees located in Austria, Canada, France, Sweden, the United Kingdom and the United States. The table below shows the number of employees employed by us and each of our subsidiaries:

| Location | Number of Employees |
|---|---|
| Valneva Austria GmbH | 305 |
| Valneva Canada Inc. | 8 |
| Valneva France SAS | 12 |
| Valneva Scotland Ltd | 139 |
| Valneva SE | 51 |
| Valneva Sweden AB | 124 |
| Valneva UK Ltd | 13 |
| Valneva USA, Inc. | 22 |
| **Total** | **674** |

Of these employees, approximately 45% were primarily engaged in manufacturing, 21% in research and development, 25% in general and administrative functions, and 9% in commercial operations.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. The principal purposes of our equity incentive plans are to attract, retain, and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Pursuant to local laws, including the laws of France and Austria, some of our employees are covered by collective bargaining agreements.

### E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

### F. Disclosure of Action to Recover Erroneously Awarded Compensation

Not applicable.

## Item 7. Major Shareholders and Related Party Transactions

### A. Major Shareholders

The following table and accompanying footnotes sets forth, as of December 31, 2025, information regarding beneficial ownership of our ordinary shares by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our ordinary shares;
- each of the members of our Board of Directors (including the former Chair of the Management Board) and our Executive Committee, individually or as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including free ordinary shares that vest within 60 days of December 31, 2025 and options that are currently exercisable or exercisable within 60 days of December 31, 2025. Ordinary shares subject to free ordinary shares that vest within 60 days of December 31, 2025, and options currently exercisable or exercisable within 60 days of December 31, 2025 are deemed to be outstanding for computing the percentage ownership of the person holding these free ordinary shares or options and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all ordinary shares shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

Unless otherwise indicated in the notes under the table, the address of each beneficial owner listed in the table below is c/o Valneva SE, Îlot Saint-Joseph, Bureaux Convergence, Bât. A, 12 ter Quai Perrache, 69002 Lyon, France.

| | Number of Ordinary Shares Owned | Percentage of Ordinary Shares Beneficially Owned |
|---|---|---|
| **5% Shareholders:** | | |
| CDC (Bpifrance Participations and CDC Croissance) [(1)] | 12,957,389 | 7.47 |
| Including Bpifrance Participations SA (legal entity member of the Board of Directors) | 8,406,577 | 4.84 |
| Pfizer Inc.[(2)] | 9,554,395 | 5.51 |
| **Members of the Board of Directors:** | | |
| Mr. Thomas Lingelbach | 1,134,927 | * |
| Ms. Anne-Marie Graffin | 39,000 | * |
| Mr. James Sulat | 97,367 | * |
| Mr. James Connolly | 20,000 | * |
| Ms. Danièle Guyot-Caparros | — | — |
| Ms. Kathrin Jansen | — | — |
| Mr. Gerd Zettlmeissl | — | — |
| **Executive Committee members [(3)]:** | | |
| Mr. Peter Bühler | 388,902 | * |
| Mr. Juan Carlos Jaramillo | 345,560 | * |
| Ms. Dipal Patel | 198,385 | * |
| Ms. Petra Pesendorfer | 36,102 | * |
| Mr. Vincent Dequenne | 128,168 | * |
| Dr. Hanneke Schuitemaker | 46,532 | * |
| Ms. Kendra Wergin | 49,866 | * |
| **All members of our Board of Directors and Executive Committee as a group** | 2,484,809 | 0.43 % |

* Represents beneficial ownership of less than 1%.

(1) As reported in a notification of legal threshold crossing addressed to the Company on October 7, 2025. As of October 1, 2025, (i) Bpifrance Participations held directly 8,459,764 Ordinary Shares and 16,919,528 Voting Rights, and (ii) CDC Croissance held 4,658,812 Ordinary Shares and 4,658,812 Voting Rights. Neither Bpifrance nor EPIC held any Ordinary Shares directly. Bpifrance may be deemed to be the beneficial owner of 8,459,764 Ordinary Shares and 16,919,528 Voting Rights indirectly through its 100% ownership of Bpifrance Participations. EPIC may be deemed to be the beneficial owner of 8,459,764 Ordinary Shares and 16,919,528 Voting Rights indirectly through its joint ownership and control of Bpifrance. CDC may be deemed to be the beneficial owner of (x) 8,459,764 Ordinary Shares and 16,919,528 Voting Rights, indirectly through its joint ownership and control of Bpifrance and (y) 4,658,812 Ordinary Shares and 4,658,812 Voting Rights, indirectly through its ownership of CDC Croissance. This information is completed by a change in balance of quantities of securities for Bpifrance Participations after transactions on October 3 and 7, 2025.

(2) As reported in a notification of statutory threshold crossing addressed to the Company on September 23, 2024. The principal address for Pfizer Inc. is 235 E. 42nd Street, New York, NY 10017.

(3) As described in Item 6A of this Annual Report, certain members of our Executive Committee were designated as Associate Managing Officers until June 25, 2025.

***Significant Changes in Percentage Ownership***

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2022 were primarily the result of (i) our issuance and sale of 8,145,176 ordinary shares (including in the form of ADSs) in our May 2021 U.S. public offering and European private placement, (ii) our issuance and sale of 5,175,000 ordinary shares (including in the form of ADSs) in our November 2021 U.S. public offering and European private placement, (iii) our issuance and sale of 9,549,761 ordinary shares to Pfizer in June 2022, (iv) our issuance and sale of 21,000,000 ordinary shares (including in the form of ADSs) in our October 2022 U.S. public offering and European private placement, (v) our issuance and sale of 23,000,000 ordinary shares in our September 2024 Private Placement, (vi) our issuance and sale of 4,750,000 ordinary shares in our April 2025 Private Placement, (vii) our issuance and sale of 2,916,666 ordinary shares in

our May 2025 Private Placement and (viii) our issuance and sale of 1,666,666 ordinary shares in our August 2025 Private Placement.

***Voting Rights***

A double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years, starting from the registration of the Company in the form of a European company.

***Shareholders in the United States***

To our knowledge, as of October 31, 2025, 47,785,653 shares, or 27.48% of our ordinary shares outstanding at that date, were held of record by 42 residents of the United States.

## B. Related Party Transactions

## Related Person Transaction Policy

We comply with French law regarding approval of transactions with related parties.

The latest version of our Related Person Transaction Policy was adopted by the Board of Directors in December 2023. This policy sets forth our procedures for the identification, review, consideration and approval or ratification of Related Person Transactions (as defined below). For purposes of our policy only, a related person transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and (a) the amount involved in the transaction exceeds $120,000 or (b) certain transactions that fall within the scope of the relevant provisions of the French Commercial Code, with the exception of usual transactions concluded under normal conditions. A related person is any member of the Board of Directors, a *Directeur Général Délégué* (previously, certain members of our Executive Committee), or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to the Board of Directors for review, consideration, assessment, and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction, and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our Board of Directors and Executive Committee and, to the extent feasible, significant shareholders to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy.

In addition, under our Code of Conduct, our employees and the members of our Board of Directors and Executive Committee have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, the Board of Directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on the independence of a member of the Board of Directors in the event the related person is a member of the Board of Directors, an Immediate Family Member of a member of the Board or an entity with which a member of the Board of Directors or a *Directeur Général Délégué* is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a Related Person Transaction, the Board of Directors must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as the Board of Directors determines in the good faith exercise of its discretion.

## Related Person Transactions

Since January 1, 2025, we have engaged in the following Related Person Transactions:

**Indemnification Agreements**

We entered into an indemnification agreement in 2025 with Mr. Gerd Zettlmeissl, who became a member of our Board of Directors on June 25, 2025, under which he qualified as a Related Person.

We first entered into indemnification agreements with each of member of our then-existing Management Board (now members of the Executive Committee) and Supervisory Board (now the Board of Directors) in connection with our global offerings in 2021 and 2022, and we have since entered into new agreements with each of our new directors and officers.

With certain exceptions and subject to limitations on indemnification under French law, indemnification agreements provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We have liability insurance for the members of our Executive Committee and Board of Directors. We believe that this insurance and these agreements are necessary to attract qualified members of the Executive Committee and Board of Directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Acknowledgment Agreement with Mr. Franck Grimaud, former Associate Managing Officer (*Directeur Général Délégué*) of our Company**

We entered into an agreement to acknowledge the non-renewal of the term of office of our former Chief Business Officer, Mr. Franck Grimaud, regarding his retirement from Valneva on July 31, 2024.

Pursuant to the terms of the agreement and in accordance with his Management Agreement, Mr. Grimaud received a gross termination indemnity of €291,748, equal to his 2025 annual base salary less the salary paid during his notice period (four months).

The Settlement Agreement further provides that Mr. Grimaud will keep the benefit of four tranches of free ordinary shares granted to him under Valneva's 2022-2025 Free Share Plan.

## C. Interests of Experts and Counsel

Not applicable.

# Item 8. Financial Information

## A. Consolidated Statements and Other Financial Information

***Consolidated Statements***

Our consolidated financial statements are included as part of this Annual Report, starting at page F-1.

***Legal Proceedings***

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For a description of certain legal matters, see the Notes to our consolidated financial statements included elsewhere in this Annual Report.

***Dividend Policy***

We have never declared or paid any dividends on our ordinary shares. Under our credit facility, except with respect to certain permitted dividend distributions, we are generally not permitted to declare or make any dividend with respect to our share capital. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business, given our state of development.

Subject to the requirements of French law and our bylaws, dividends may only be distributed from our distributable profits, plus any amounts held in our available reserves which are reserves other than legal and statutory and revaluation surplus. Dividend distributions, if any in the future, will be made in euro and converted into U.S. dollars with respect to the ADSs, as provided in the deposit agreement.

## B. Significant Changes

Not applicable.

# Item 9. The Offer and Listing

## A. Offer and Listing Details

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "VALN" since May 6, 2021. Our ordinary shares have been trading on Euronext Paris under the symbol "VAL" since May, 2013. Prior to that date, there was no public trading market for our ADSs or our ordinary shares.

## B. Plan of Distribution

Not applicable.

## C. Markets

Our ADSs have been listed on Nasdaq under the symbol "VALN" since May 6, 2021. Our ordinary shares have been trading on Euronext Paris under the symbol "VAL" May, 2013.

## D. Selling Shareholders

Not applicable.

## E. Dilution

Not applicable.

## F. Expenses of the Issue

Not applicable.

# Item 10. Additional Information

## A. Share Capital

Not applicable.

## B. Memorandum and Articles of Association

The information set forth in Exhibit 2.3 "Description of Securities" is incorporated herein by reference.

## C. Material Contracts

## Finance Agreements

***Pharmakon Loan Agreement***

On October 6, 2025, Valneva Austria GmbH entered into a loan agreement (the "Loan Agreement") with, among others, BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership (the "Lenders"), that provides for a senior term loan facility of an aggregate principal amount of $500.0 million, divided into the following tranches: (i) a Tranche A Loan in an aggregate principal amount of $215.0 million, which was funded on October 17, 2025; and (ii) one or more uncommitted Subsequent Tranche Loans in an aggregate principal amount of $285.0 million (the "Subsequent Tranche Loans", and together with the Tranche A Loan, the "Term Loans"), which will be available subject to certain conditions including the consent of the Collateral Agent and all Lenders. The proceeds of the Tranche A Loan were used, together with cash on hand, to repay all amounts owed under our credit agreement with Deerfield and OrbiMed.

The Term Loans mature on October 17, 2030 (the "Maturity Date") and bear interest at a fixed rate equal to 9.00% per annum, payable quarterly in arrears. Our obligations under the Loan Agreement are secured by substantially all of our assets, including our intellectual property. Additionally, certain of our subsidiaries have guaranteed our obligations under the Loan Agreement.

The Loan Agreement requires we pay an amount equal to 2.00% of the principal amount of the Term Loans funded by the Lenders, payable with respect to each Term Loan on the funding date of such Term Loan. We may elect to prepay the Term Loans in part or in whole prior to the Maturity Date, with such prepayments being subject to a prepayment premium equal to the principal amount so prepaid multiplied by 3.00% if made prior to the third anniversary of the funding date of the applicable Term Loan, 2.00% if made on or after the third anniversary of the funding date of the applicable Term Loan but prior to the fourth anniversary of the funding date of the applicable Term Loan, and 1.00% if made on or after the fourth anniversary of the funding date of the applicable Term Loan but prior to the Maturity Date. In addition to the prepayment premium, prepayments of any Term Loan prior to the second anniversary of the funding date of such Term Loan are subject to a make-whole amount equal to the sum of all interest that would have accrued through such second anniversary. In connection with any prepayment, repayment at maturity or acceleration of any Term Loan, we are obligated to pay an exit fee equal to 2.00% of the principal so prepaid or repaid.

The Loan Agreement contains customary affirmative and restrictive covenants. During the term of the Loan Agreement, we may not, subject to specified exceptions, (i) sell or dispose of assets, (ii) amend, modify, or waive our rights under material agreements, (iii) incur additional indebtedness, (iv) incur non-permitted liens or encumbrances on our or our subsidiaries' assets, or (v) make payments on subordinated indebtedness, among other restrictions. The Loan Agreement also requires that our annual and quarterly financial statements be free of any "going concern" qualification. The Loan Agreement contains customary events of default, including in connection with a material adverse change. The occurrence of an event of default would enable the Lenders to, among other things, accelerate our obligations under the Loan Agreement, and in case of an event of default relating to certain insolvency, liquidation, bankruptcy or similar events, all outstanding obligations will be immediately accelerated.

## Agreements Relating to Product Sales

***Department of Defense Contracts***

In January 2025, the Defense Logistics Agency, or DLA, of the U.S. Department of Defense awarded us a new contract for the supply of IXIARO, following previous contracts we have had with the DLA since January 2019. This 2025 contract one-year contract included a minimum value of approximately $32.8 million of IXIARO doses and the possibility for additional purchases over the term of the contract.

The previous contract, executed in September 2023, also provided for a one-year supply of IXIARO and had a minimum value of approximately $32.3 million for approximately 200,000 doses.

Since 2009, we have also had a Federal supply schedule contract with the Department of Veterans Affairs listing IXIARO.

***Seqirus Distribution Agreements***

In June 2025, Valneva Austria GmbH, or Valneva Austria, entered into an exclusive agreement, or the IXCHIQ/IXIARO Distribution Agreement, with Seqirus GmbH, or Seqirus, pursuant to which Valneva Austria granted Seqirus the exclusive right to import, market, promote, distribute, and sell IXIARO and IXCHIQ in Germany. In parallel, Valneva Sweden AB, or Valneva Sweden, entered into a distribution agreement, or the DUKORAL Distribution Agreement, with Seqirus pursuant to which Valneva Sweden granted Seqirus an exclusive right to import, market, promote, distribute, and sell DUKORAL in Germany. The IXCHIQ/IXIARO Distribution Agreement and the DUKORAL Distribution Agreement together are referred to as the Seqirus Distribution Agreements.

Pursuant to the Seqirus Distribution Agreements, Seqirus is required to purchase the products as agreed between the parties, and Valneva Austria or Valneva Sweden may terminate the agreement if Seqirus fails to meet its commitments. Unless terminated earlier, the Seqirus Distribution Agreements will continue for an initial term until December 31, 2028. Either party may terminate the agreements in case of the uncured material breach of the other party. Additionally, each party shall have the right, after December 31, 2027, to terminate the agreements without cause

***Bavarian Nordic Distribution Agreements***

In November 2020, Valneva Austria GmbH, or Valneva Austria, entered into a distribution agreement, or the IXIARO Distribution Agreement, with Bavarian Nordic A/S, or BN, pursuant to which Valneva Austria granted BN an exclusive right to import, market, promote, distribute, and sell IXIARO in Germany. In parallel, Valneva Sweden AB, or Valneva Sweden, entered into a distribution agreement, or the DUKORAL Distribution Agreement, with BN pursuant to which Valneva Sweden granted BN an exclusive right to import, market, promote, distribute, and sell DUKORAL in Germany. The IXIARO Distribution Agreement and the DUKORAL Distribution Agreement together are referred to as the BN Distribution Agreements.

In connection with BN's purchase of the Vaxchora cholera vaccine, the DUKORAL Distribution Agreement was amended with effect in May 2023 to convert BN's exclusive right to distribute DUKORAL to a non-exclusive distribution right and to terminate the agreement on December 31, 2025. The IXIARO Distribution Agreement also terminated on December 31, 2025.

***VBI Distribution Agreement***

In December 2022, Valneva Austria GmbH entered into an agreement, or the VBI Distribution Agreement, with VBI Vaccines B.V., or VBI, relating to Valneva's distribution of VBI's hepatitis B vaccine PreHevbri, or the Product. The VBI Distribution Agreement had an initial term until December 31, 2025, with the possibility of renewal for an additional two years.

In July and August 2024, VBI's parent company, VBI Vaccines Inc., commenced bankruptcy proceedings in Canada under the Companies' Creditors Arrangement Act and in the United States under Chapter 15 of the Bankruptcy Code, and delisted from the Nasdaq Stock Market. In connection with these proceedings, VBI voluntarily withdrew PreHevbri from the market and Marketing Authorization for the product in the European Union was withdrawn. In light of these events, we consider the agreement to be terminated, and Valneva has taken steps to destroy any remaining stock of the product.

## Agreements Relating to Product Development and Manufacturing

***Pfizer License Agreement***

In April 2020, we entered into a research collaboration and license agreement, or the Pfizer License, with Pfizer. In June 2022, Valneva Austria and Pfizer amended the Pfizer License. In connection with the Pfizer License, as amended, we granted to Pfizer (a) an exclusive, worldwide, sublicensable license under certain patents, know-how, and materials and (b) a non-exclusive, worldwide, sublicensable license under all patents, know-how or other intellectual property rights controlled by us, in each case to use, have used, develop, have developed, manufacture, have manufactured, commercialize, have commercialized and otherwise exploit VLA15 and related products for all therapeutic, diagnostic and prophylactic human and veterinary use. Under the Pfizer License, we also obtained, during the development term, a non-exclusive, royalty-free, fully paid-up, worldwide license with the right to sublicense to subcontractors under certain patents and know-how controlled by Pfizer and patents and know-how developed under the Pfizer License to perform development activities relating to VLA15 and related products.

We are obligated to grant licenses or sublicenses that are consistent with the Pfizer License directly to affiliates of Pfizer upon Pfizer's written request. Each party also granted the other a non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up worldwide license for research purposes with the right to sublicense to affiliates under its know-how, materials, and confidential information disclosed under the agreement.

In connection with the Pfizer License, we may not develop or exploit a competing product, and we must use commercially reasonable efforts to perform assigned obligations under a development plan. As partial consideration for the license grant, Pfizer paid us a one-time upfront payment of $130 million on June 15, 2020. We and Pfizer will each contribute towards development costs, and Pfizer is obligated to pay us up to $178 million in development milestones and low double-digit tiered royalties starting at 14% on net sales of licensed products, subject to specified offsets and reductions. Of this $178 million, (i) $143 million is comprised of additional payments related to the first stages of commercialization of VLA15 in the United States and Europe as well as the approval of the vaccine, (ii) $10 million is comprised of payments linked to development milestones related to the initiation of the VLA15-221 clinical study and was received in 2021, and (iii) $25 million related to the initiation of the Phase 3 clinical trial and was received in 2022. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed

product in such country and ending on the last to occur of the date on which the sale, offer for sale or importation of such licensed product in such country would infringe, but for the license granted here, a valid claim covering such licensed product in such country and fifteen years after the first commercial sale of such licensed product in such country. In addition, the royalties will be supplemented by milestone payments of up to $100 million, payable to Valneva based on cumulative sales.

According to the terms of the Pfizer License, Pfizer is responsible for regulatory submissions and subsequent commercialization of the licensed product, if it is approved. Pfizer has sole discretion regarding if and when to submit applications for regulatory approval and if, how and where to commercialize the licensed product, if approved.

The Pfizer License expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term for any licensed product in such country. Pfizer may terminate the agreement (a) on a licensed product-by-licensed product and country-by-country basis or in its entirety for convenience or any uncured material breach by us, (b) in whole or relevant part for certain violations of global trade control laws prior to the first regulatory approval of a licensed product, or (c) for our breach of certain representations and warranties or other failure to comply with specified laws. We may terminate the agreement on a licensed product-by-licensed product and country-by-country basis for any uncured material breaches by Pfizer of any of its diligence obligations, or in its entirety for any uncured material breach of the agreement by Pfizer.

Following the signature of the amendment to the Pfizer License in June 2022, Valneva will finance 40% of the costs of Phase 3 costs, compared to 30% in the initial agreement. In addition, Pfizer is paying Valneva royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement.

On June 22, 2022, Pfizer invested €90.5 million ($95 million), or 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase designed to strengthen the strategic partnership between the two companies in Lyme disease. Valneva used the proceeds of this investment to finance a portion of its contribution to the Phase 3 Lyme program.

***CEPI Funding Agreements***

In July 2019, we entered into a funding agreement, or the CEPI Agreement, with CEPI. In connection with the CEPI Agreement, we were awarded up to $23.4 million in funding (paid in a series of six-month tranches) to further develop a chikungunya vaccine, or the product, and we are obligated to provide equitable access to project results on the terms and conditions of the CEPI Agreement. Under the CEPI Agreement, equitable access means the regular supply of chikungunya vaccines in all Non-Traveler's Market Countries (as defined in the CEPI Agreement, covering mostly low and middle income countries) that have a demand for the vaccines at an affordable price (as defined in the CEPI Agreement) and, in the context of an outbreak or increased outbreak preparation need, means that vaccines are first available to populations in the affected territory when and where they are needed. In addition, we granted CEPI a limited non-exclusive, fully paid-up, sublicensable license, referred to as the Public Health License, under the project results and other intellectual property necessary to enable CEPI or a third party designated by CEPI to develop, manufacture, market, and/or supply the product worldwide solely to end users in an affected territory in preparation for or response to an outbreak. Such Public Health License shall only be effective upon specified license triggers.

Under the agreement, we were obligated to pay CEPI up to $7.0 million in commercial and related milestones, of which $3.0 million was paid in 2024, and to supply CEPI with specified quantities of the chikungunya drug product or investigational product in case of an outbreak or increased outbreak preparation need. This includes maintaining at our cost a one-year rolling safety stock comprised of not less than 200,000 doses of chikungunya vaccine, referred to as the Safety Stock. In case the Safety Stock is used to address an outbreak or increased outbreak preparation need, and CEPI wishes to replenish such Safety Stock, CEPI shall pay us the related production costs.

In July 2024, we entered into a further funding agreement, or the 2024 CEPI Agreement, with CEPI, under which we will receive an additional $41.3 million in funding over the next five years from CEPI, with support from the European Union's Horizon Europe program. This funding will be paid in a series of six-month tranches in advance of agreed milestones, and is intended to support post-marketing trials for IXCHIQ and potential label extensions to enable the vaccine to be administered to children, adolescents and pregnant women, including retroactive funding for certain activities commenced prior to the entry into the agreement.

The 2024 CEPI Agreement sets up a framework that applies to our relationships with Butantan and the Serum Institute of India (SII), which are further discussed below. Under the CEPI framework, we are required to prioritize the public health systems in Non Traveler's Market Countries, taking into consideration public sector demand, production capacity and contractual obligations existing prior to any public sector purchase agreements. CEPI also retains the first right to provide additional funding and support for the further development, manufacture and deployment of the IXCHIQ vaccine in Non-Traveler's Market Countries.

The 2024 CEPI Agreement sets up a governance structure that enables CEPI to be further involved in meetings with our partners, namely Instituto Butantan, as well as in meetings with regulatory authorities to the extent permitted by such authorities.

The two CEPI Agreements share the same termination provisions. Either agreement may be terminated by one party upon an uncured material breach of the agreement or insolvency of the other party. CEPI may also terminate the agreements if we are unable to discharge our obligations, for safety, regulatory, or ethical issues, if we do not satisfy specified criteria for funding, if there are material changes to the development plan without CEPI's prior written consent, or during the terms any affiliate to whom we have assigned or transferred the agreement ceases to be our affiliate. We may also terminate the

agreements (in whole or with respect to certain markets) for convenience at any time after 10 years following the grant of U.S. marketing approval for the product, at any time after three years following the grant of U.S. marketing approval for the product if we are unable to sell the product at a viable price, or if CEPI transfers or assigns the agreement other than to specified entities. Following the last to occur of (a) the granting of U.S. marketing approval for the product and (b) such approval in the first low income country, in the event we undergo a change of control or sell the entire chikungunya business, we may also terminate the agreement. In each of these terminations by Valneva, we have obligations to collaborate with CEPI for two years to find a third party supplier to whom our obligations under the CEPI Agreement will be assigned and to transfer the drug substance and drug product technology and related intellectual property (with the exception of trademarks) to such third party supplier. In lieu of such transfer, after two years following termination, the CEPI Agreement will be suspended, except for certain continuing obligations, until we and CEPI agree to continue the program appropriate to the circumstances.

***Instituto Butantan and Fundação Butantan Master Collaboration Agreement and Project Agreements***

Following the execution of a binding term sheet in May 2020, in January 2021 we entered into the master collaboration agreement and related project agreements, which we refer to collectively as the definitive agreements, with Instituto Butantan, a Brazilian public institute, and Fundação Butantan, a Brazilian non-profitable private foundation of the Instituto Butantan, which we refer to jointly as Butantan, engaged in the research, development, manufacture, and commercialization of vaccines in Brazil, pursuant to which we and Butantan intend to collaborate to obtain regulatory approval of our chikungunya vaccine candidate VLA1553, secure supply of the chikungunya vaccine in Latin America and other regions where outbreaks occur, and obtain WHO prequalification in accordance with the aims of the CEPI Agreement.

Pursuant to the definitive agreements, we have transferred our drug product technology and supplied drug substance to Butantan to enable Butantan to develop, manufacture, and commercialize our chikungunya vaccine in Latin America and in certain low and middle income countries and obtain regulatory approval and WHO prequalification. We and Butantan have agreed to conduct certain clinical trials and Phase 4 observational studies with VLA 1553 as co-sponsors in specified countries in Latin America that we will use to meet regulatory requirements with the EMA. We have granted Butantan an exclusive, non-transferable, sublicensable, royalty-bearing license to commercialize the product in the specified countries within the Butantan territory, provided that we shall have the right to convert such license into a non-exclusive right to commercialize the product if Butantan fails to fully comply with specified obligations in the definitive agreements. Butantan will also have to comply with certain CEPI requirements, among others, equitable access to the product and outbreak related obligations, including maintaining a Safety Stock.

Under the definitive agreements, we received an upfront payment and have received certain milestone payments in consideration for the drug product technology transfer. We will be eligible to receive royalties on the sale of product in the Butantan Territory during the applicable royalty term. The level of royalty payments varies between sales in the private market and public market.

The definitive agreements will remain in effect for so long as any Project Agreement is in effect. Each party has the right to terminate an agreement if the other party has committed a material breach or default that remains uncured for a specified period of time or if the other party has become insolvent. We also retain the right to terminate for Butantan's failure to comply with the CEPI requirements, assign foreground intellectual property rights to us, obtain regulatory approval in accordance with the definitive agreements, or build up the necessary manufacturing capacity for the supply of the product. Additionally, we have the right to terminate the definitive agreements in case of any certain material manufacturing concerns or if the CEPI Agreement is terminated.

***Serum Institute of India Master Collaboration and License Agreement***

In December 2024, we entered into an exclusive license agreement with the Serum Institute of India (SII) to expand access to our chikungunya vaccine to low and medium income countries in Asia. The agreement fell within the framework of the 2024 CEPI Agreement. Under the agreement, the parties agreed to conduct a technology transfer of the drug product manufacturing process to SII, which would establish its own drug product manufacturing process and along with the drug substance from us, would manufacture its own vaccine and be responsible for seeking and maintaining regulatory approval of the vaccine in India and certain other countries in Asia.

In December 2025 we and SII mutually agreed to discontinue the Master Collaboration and License Agreement. We expect that any future agreements related to the manufacturing, marketing, and distribution of our chikungunya vaccine in India and other Asian markets, as originally contemplated by the agreement with SII, would also be situated within the framework of our agreements with CEPI.

***LimmaTech Development, Collaboration, License and Commercialization Agreement***

In July 2024, Valneva Austria GmbH entered into an exclusive agreement with LMBT Biologics AG, or LimmaTech, to develop, manufacture and commercialize globally Shigella4V, or S4V, a vaccine candidate for the prevention of shigellosis. In May 2025, Valneva Austria and LimmaTech amended the agreement. Under the terms of the agreement, as amended, LimmaTech received an upfront payment of €10 million, and LimmaTech is also eligible to receive regulatory, development, and sales-based milestone payments over the course of the product candidate's development and low double-digit royalties on sales of the product, if approved. The level of royalty payments varies between developed countries, where the vaccine will be marketed to travelers, and low and middle income countries, or LMICs.

LimmaTech is responsible for the development of the product until the first Phase 2 controlled human infection model, or CHIM study, and we are responsible for subsequent development of the product candidate, as well as filing for regulatory approvals and commercialization. LimmaTech will be responsible for development costs up to a capped amount, and we will assume all subsequent development costs.

LimmaTech will retain ownership of its own IP assets under the agreement. After the end of Phase 2 trials, we have the right to take over the prosecution and maintenance of any of LimmaTech's patent rights that solely cover S4V.

The agreement expires on a country-by-country basis, upon the expiration of the last royalty term for any licensed product in such country, up to the end of 2046 at the latest. Either party may terminate the agreement if there is a material breach of the terms which is not cured within the specified time period. LimmaTech is also permitted to terminate the agreement if we challenge the patent rights licenced under the agreement. Finally, by the end of the Phase 2 trials, if we are not in ongoing negotiations, or fail to enter into a sub-licence agreement with a partner to commercialize the product through publicly funded or other not-for-profit channels in LMIC territories within six months of the end of the Phase 2 trials, LimmaTech has the right to terminate the agreement only with respect to such LMIC territories.

After the completion of the Phase 2 CHIM study, we have the right to terminate the agreement, either with respect to the LMIC territory or in its entirety. We also have the right to terminate the agreement if the expected results in the Phase 2 trials is not met.

***IDT Commercial Manufacturing Services Agreement and VLA1553 Product Schedule***

In November 2021, Valneva Austria GmbH entered into a non-exclusive commercial manufacturing services agreement, or the IDT Agreement, with IDT Biologika GmbH, or IDT, pursuant to which IDT would provide contract manufacturing services under separate product schedules. The IDT Agreement will expire in November 2026 unless previously terminated. We may terminate the IDT Agreement for convenience. Either party may terminate the IDT Agreement or the separate product schedules, in whole or in part, in case of material breach, insolvency, or certain compliance failures.

Valneva and IDT entered into a product schedule pertaining to the manufacturing of our chikungunya vaccine, or the VLA1553 Product Schedule, in December 2022. In September 2025, Valneva Austria and IDT amended the VLA1553 Product Schedule. Pursuant to the VLA1553 Product Schedule, as amended, IDT performs the fill and finish and lyophilization of the drug product of our chikungunya vaccine (VLA1553) using bulk drug substance batches received from us. The VLA1553 Product Schedule will remain in place until December 31, 2029 and will automatically renew thereafter unless previously terminated.

***Manufacturing Agreement with Vetter Pharma International***

In April 2023, Valneva Austria GmbH entered into a non-exclusive commercial manufacturing services agreement, or the Vetter Agreement, with Vetter Pharma International GmbH, or Vetter, pursuant to which Vetter will provide syringes pre-filled with sterilized water in connection with the manufacturing of IXCHIQ. The maximum estimated value of the Vetter Agreement during the initial term is approximately €26.9 million. The Vetter Agreement will expire in April 2028 unless previously terminated and may be renewed for subsequent terms. Either party may terminate the Vetter Agreement in case of breach or insolvency on the part of the other party, and Vetter may terminate in case of a change of control of Valneva involving a Vetter competitor or in case the parties cannot agree on changes to manufacturing processes or prices that may be requested by us.

## D. Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

## E. Taxation

***Material U.S. federal income tax considerations for U.S. Holders***

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire our securities. This discussion applies only to a U.S. Holder that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax considerations that may be relevant in light of a U.S. Holder's particular circumstances, including state, local, and non-U.S. tax considerations, estate and gift tax considerations, the impact of special tax accounting rules under Section 451(b) of the Code or the alternative minimum tax provisions of the Code, the potential application of the Medicare contribution tax, and tax considerations applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;

- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction, or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers, or traders in securities, commodities, or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding shares or ADSs in connection with a trade or business outside the United States;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between France and the United States, or the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a position different from what is described below concerning the tax consequences of the acquisition, ownership and disposition of ordinary shares or ADSs or that such a position would not be sustained by a court.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

(1) an individual who is a citizen or resident of the United States;

(2) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local, and non-U.S. tax consequences of owning and disposing of ordinary shares or ADSs in their particular circumstances.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

***Passive Foreign Investment Company rules***

Under the Code, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the value of our assets (generally determined on the basis of a weighted quarterly average) consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property, and certain rents and royalties. Cash and cash-equivalents are generally passive assets for these purposes. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation or partnership is treated as holding and receiving directly its proportionate share of assets and income of such corporation or partnership. If we are a PFIC for any taxable year during which a U.S. Holder holds our shares, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

We do not believe that we were characterized as a PFIC for the year ended December 31, 2025. However, the determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year. In addition, the total value of our assets for PFIC testing purposes (including goodwill) may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Accordingly, if our market capitalization declines while we hold a substantial amount of cash and cash equivalents for any taxable year we may be a PFIC for that taxable year. Under the income test, our status as a PFIC depends on the composition of our income for the relevant taxable year which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current, or future taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules. If such a deemed sale election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs that the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we are a PFIC and cease to be a PFIC.

For each taxable year that we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including a pledge) of ordinary shares or ADSs, unless our ordinary shares or ADSs constitute "marketable stock" and such U.S. Holder makes a mark-to-market election (as discussed below). Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the taxable year of the disposition or distribution (as applicable), and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries or any other entities in which we hold equity interests that also are PFICs, or lower-tier PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to lower-tier PFICs.

U.S. Holders can avoid the rules described above by making an effective QEF Election. However, a U.S. Holder can only make a QEF election with respect to ordinary shares or ADSs in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. We do not presently intend to provide the information required to allow a U.S. Holder to make a QEF election if we are a PFIC.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are "marketable stock." Ordinary shares or ADSs will be marketable stock if they are "regularly traded" on certain U.S. stock exchanges or on a non-U.S. stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be listed on the Nasdaq Global Select Market, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq Global Select Market and are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to U.S. Holders if we are a PFIC. It should be noted that only the ADSs and not its ordinary shares are listed on the Nasdaq Global Select Market. Consequently, its ordinary shares may not be marketable If Euronext Paris (where its ordinary shares are listed) does not meet the applicable requirements. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs in any year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ordinary shares or ADSs cease to be marketable stock.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable stock." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an Annual Report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the Annual Report may result in substantial penalties and extend the statute of limitations with respect to the U.S. Holder's federal income tax return. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

**WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.**

***Taxation of distributions***

Subject to the discussion above under "Passive Foreign Investment Company rules," distributions paid on ordinary shares or ADSs, other than certain *pro rata* distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment will not apply if we are treated as a PFIC for the taxable year of the distribution or the preceding taxable year. The amount of a dividend will include any amounts withheld by us in respect of French income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain *pro rata* distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit purposes, our dividends will generally be treated as passive category income. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, any French income taxes withheld from dividends on ordinary shares or ADSs at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. U.S. Treasury regulations may in some circumstances prohibit a U.S. Holder from claiming a foreign tax credit with respect to certain foreign taxes that are not creditable under applicable tax treaties. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any French withholding tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

***Sale or other taxable disposition of ordinary shares and ADSs***

Subject to the discussion above under "Passive Foreign Investment Company rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition.

However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

***Information reporting and backup withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

***Information with respect to foreign financial assets***

Certain U.S. Holders who are individuals and certain closely-held entities may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by financial institutions, in which case the accounts themselves may have to be reported if maintained by non-U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

**Material French Tax Considerations**

The following describes the material French income tax consequences to U.S. holders of purchasing, owning, and disposing of our ADSs.

This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership, or disposition of our ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

The following discussion does not address the French tax consequences applicable to securities (including ADSs) held in trusts. If ADSs are held in trust, the grantor, trustee, and beneficiary are advised to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of such securities.

The description of the French income tax and real estate wealth tax consequences set forth below is based on the double tax treaty entered into between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, or the Treaty, which came into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax guidelines issued by the French tax authorities in force as of the date of this Annual Report, or the Treaty.

If a partnership holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership is urged to consult its own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of ADSs.

This discussion applies only to investors that hold ADSs as capital assets that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the ADSs is not effectively connected to a permanent establishment or a fixed base in France. Certain U.S. holders may be subject to special rules not discussed below, and are advised to consult their usual tax advisor regarding the specific tax consequences which may apply to their particular situation.

U.S. holders are advised to consult their own tax advisor regarding the tax consequences of the purchase, ownership, and disposition of ADSs in light of their particular circumstances, especially with regard to the "Limitations on Benefits" provision contained in the Treaty.

***Tax on Sale or Other Disposals***

As a matter of principle, under French tax law, a U.S. holder should not be subject to any French tax on any capital gain from the sale, exchange, repurchase, or redemption by us of ADSs, provided such U.S. holder is not a French resident for French tax purposes and has not held more than 25% of our dividend rights, known as "*droits aux bénéfices sociaux*," at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives (as an exception, a U.S. holder resident, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the French tax code ("*Code général des impôts*," or the FTC), other than those mentioned in Article 238-0 A, 2 bis-2° of the FTC, may be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds). The list of non-cooperative States or territories is published by decree and is in principle updated annually. This list was last updated on 18 April 2025, and currently includes American

Samoa, Anguilla, Antigua and Barbuda, Fiji, Guam, Palaos, Panama, Russia, Samoa, Trinidad and Tobago, Turks and Caicos Islands, the United States Virgin Islands and Vanuatu. States referred to in Article 238-0 A, 2 bis-2° of the FTC, and thus outside of the scope of Article 244 bis B of the FTC, are currently American Samoa, Fiji, Guam, Panama, Russia, Samoa, Trinidad and Tobago, and the United States Virgin Islands.

Under application of the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty and is entitled to Treaty benefits will not be subject to French tax on such capital gain unless the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. U.S. holders who own ADSs through U.S. partnerships that are not resident for Treaty purposes are advised to consult their own tax advisor regarding their French tax treatment and their eligibility for Treaty benefits in light of their own particular circumstances. A U.S. holder that is not a U.S. resident for Treaty purposes or is not entitled to Treaty benefits (and in both cases is not resident, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC) and has held more than 25% of our dividend rights, known as "*droits aux bénéfices sociaux*" at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives may be subject to a levy in France (i) at the rate of 12.8% for individuals, and (ii) a rate of 25% for legal persons. Pursuant to Article 244 *bis* B of the FTC, such legal persons, whatever their form, may obtain a refund of the portion of such withholding tax which exceeds the corporate income tax which they would have been liable to pay if their registered seat had been located in France, provided that (i) they do not effectively either participate in our management or our control and (ii) their registered office is located in a State or territory that has concluded a tax treaty with France that contains an administrative assistance clause on the exchange of information and the fight against tax fraud and tax evasion and that is not a non-cooperative State or territory within the meaning of Article 238-0 A of the FTC.

***Financial Transactions Tax and Registration Duties***

Pursuant to Article 235 ter ZD of the FTC, purchases of ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the AMF are subject to a 0.3% French tax on financial transactions for purchases made before April 1, 2025 and 0.4% as from this date provided that the issuer's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year, within the meaning of Article 235 *ter* ZD of the FTC, is published annually by the French tax authorities in their official guidelines.

As at December 1, 2025, our market capitalization did not exceed 1 billion euros, pursuant to BOI-ANNX-000467-17/12/2025.

As a result, the acquisition of ADSs is currently out of the scope of the tax on financial transactions, but this may change in the future. Purchases of our ADSs may, however, become subject to the tax on financial transactions as from January 1, 2027, provided that our market capitalization exceeds 1 billion euros as at December 1, 2026 and that the Nasdaq Global Market is acknowledged by the French AMF.

In the case where Article 235 *ter* ZD of the FTC is not applicable, the French tax code provides that transfers of shares—issued by a French company which are listed on a regulated or organized market within the meaning of Articles L421-1 and L424-1 of French monetary code (*Code monétaire et financier*) or, pursuant to French tax administrative doctrine (BOI-ENR-DMTOM-40-10 24/04/2024 # 30), listed on another similar regulated or organized market operating under similar conditions—are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written deed (acte) executed either in France or outside France.

However neither the French tax code, nor case law or official guidelines published by the French tax authorities indicate if the transfer of ADSs should be in the scope of the above-mentioned registration duties. As a result, transfer of ADSs should remain outside of the scope of such registration duties. U.S. Holders are urged to consult their own tax advisor about the possible application of the registration duty upon the transfer of ADSs.

***Taxation of Dividends***

Dividends paid by a French corporation to non-residents of France are generally subject to French withholding tax at a rate of currently (i) 25% for payment benefiting legal entities which are not French tax residents, and (ii) 12.8% for payment benefiting individuals who are not French tax residents. Dividends paid by a French corporation in non-cooperative States or territories, as defined in Article 238-0 A of the FTC other than those mentioned in Article 238-0 A, 2 bis, 2° of the FTC, will generally be subject to French withholding tax at a rate of 75% unless the company which pays the dividend proves that the distribution of such proceeds in that State or territory has neither the object nor the effect of permitting their location in such State or territory for the purpose of tax evasion).

However, eligible U.S. holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to this 12.8% or 25%, or 75% withholding tax rate, but may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is generally reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuer; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any.

For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complex, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisor regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that:

- such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Forms 5000 and 5001) in accordance with French guidelines (BOI-INT-DG-20-20-20-20-12/09/2012); or
- the depositary or other financial institution managing the securities account in the U.S. of such holder provides the French paying agent with a document listing certain information about the U.S. holder and its ADSs and a certificate whereby the financial institution managing the U.S. holder's securities account in the United States takes full responsibility for the accuracy of the information provided in the document.

Otherwise, dividends paid to a U.S. holder, if such U.S. holder is a legal person, will be subject to French withholding tax at the rate of 25%, or 75% if paid in certain non-cooperative States or territories (as defined in Article 238-0 A of the FTC other than those mentioned in Article 238-0 A, 2 bis-2° of the FTC), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Certain qualifying pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary. The depositary will arrange for the filing with the French tax authorities of all such forms properly completed and executed by U.S. holders of ADSs and returned to the depositary in sufficient time so that they may be filed with the French tax authorities before the distribution in order to immediately obtain a reduced withholding tax rate. Otherwise, the depositary must withhold tax at the full rate of 25% or 75% as applicable. In that case, the U.S. holders may claim a refund from the French tax authorities of the excess withholding tax.

***Estate and Gift Taxes***

In general, a transfer of securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the double tax treaty entered into between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978 which came into force on October 1, 1980 (as amended by any subsequent protocols, including the protocol of December 8, 2004), unless (i) the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or (ii) the ADSs were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

***Wealth Tax***

Since January 1, 2018, the French wealth tax (*impôt de solidarité sur la fortune*) has been repealed and replaced by the French real estate wealth tax (*impôt sur la fortune immobilière*). Its scope is narrowed to real estate assets (and certain assets deemed to be real estate assets) or rights, held directly or indirectly through one or more legal entities and whose net taxable assets amount at least to €1,300,000.

Broadly, subject to provisions of double tax treaties and to certain exceptions, individuals who are not residents of France for tax purposes within the meaning of Article 4 B of the FTC, are subject to real estate wealth tax (*impôt sur la fortune immobilière*) in France pursuant to French official guidelines BOI-INT-CVB-USA-10 19/02/2020 # 25) in respect of the portion of the value of their shares of our company representing real estate assets (Article 965, 2° of the FTC). Some exceptions are provided by the FTC. For instance, any participations representing less than 10% of the share capital of an operational company and shares representing real estate for the professional use of the company considered shall not fall within the scope of the French real estate wealth tax (*impôt sur la fortune immobilière*).

Under the Treaty (the provisions of which should be applicable to this real estate wealth tax (*impôt sur la fortune immobilière*) in France), the French real estate wealth tax (*impôt sur la fortune immobilière*) will however generally not apply to securities held by an eligible U.S. holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that such U.S. holder (i) does not own directly or indirectly more than 25% of the issuer's financial rights and (ii) that the ADSs do not form part of the business property of a permanent establishment or fixed base in France.

U.S. holders are advised to consult their own tax advisor regarding the specific tax consequences which may apply to their particular situation with respect to such French real estate wealth tax (*impôt sur la fortune immobilière*).

**THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL FRENCH AND U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE**

**INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.**

## F. Dividends and Paying Agents

Not applicable.

## G. Statement by Experts

Not applicable.

## H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with an opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.valneva.com. We intend to post our Annual Report on Form 20-F on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

## I. Subsidiary Information

Not applicable.

## J. Annual Report to Security Holders.

Not applicable.

# Item 11. Quantitative and Qualitative Disclosures about Market Risk

We operate internationally and are exposed to foreign exchange risks arising from various currencies, primarily with respect to the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK) and the U.S. Dollar (USD). The foreign exchange risks from the exposure to other currencies, including the Danish Krone, the Swiss Franc and the Norwegian Krone, are relatively limited. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations. Our objective is to limit the potential negative impact of the foreign exchange rate changes, for example by currency conversion of cash and cash equivalents denominated in foreign currency and by using foreign currency options. We have certain investments in foreign operations, the net assets of which are exposed to foreign currency translation risk.

With all other variables held constant, the impact from changes in exchange rates are illustrated in the table referenced in Note 5.16.3 Foreign currency sensitivity analysis.

## A. Interest Rate Risk

We are exposed to market risks in connection with hedging both of our liquid assets and of our medium and long-term indebtedness and borrowings subject to variable interest rates. Borrowings issued at variable rates expose us to cash flow interest rate risks, which are offset by cash and financial assets held at variable rates. During 2025, as well as 2024 and 2023, the Group's investments at variable rates, as well as the borrowings at variable rates, were denominated in EUR, SEK, USD, CAD, and GBP. We analyze our interest rate exposure on a dynamic basis. Based on this analysis, we calculate the impact on profit and loss of a defined interest rate change. The same interest rate change is used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As at December 31, 2025 and December 31, 2024, no material interest risk was identified. In case of increasing interest rates, the positive effect from cash in banks will be higher than the negative effect from variable interest-bearing liabilities. In case of decreasing interest rates, there will be no material negative impact.

## B. Credit Risk

We are exposed to credit risk. We hold bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of our counterparts, we rely on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. We have policies that limit the amount of credit exposure to any single financial institution. We are also exposed to credit risks from our trade debtors, as our income from product sales, collaborations, licensing, and services arises from a small number of transactions. We have policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits as set by the Board of Directors.

## C. Interim Periods

Not applicable.

## D. Safe Harbor

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See "Special Note Regarding Forward-Looking Statements."

# Item 12. Description of Securities Other than Equity Securities

## A. Debt Securities

Not applicable.

## B. Warrants and Rights

Not applicable.

## C. Other Securities

Not applicable.

## D. American Depositary Shares

Citibank, as depositary, registers and delivers our ADSs. Each ADS represents two ordinary shares deposited with Citibank Europe plc, located at 1 North Wall Quay, Dublin 1 Ireland or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The depositary's corporate trust offices at which the ADSs will be administered are located at 388 Greenwich Street, New York, New York 10013.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

**Fees and Charges**

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

| Service | Fees |
|---|---|
| Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-ordinary share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares | Up to U.S. 5¢ per ADS issued |
| Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to ordinary share ratio, or for any other reason) | Up to U.S. 5¢ per ADS cancelled |
| Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements) | Up to U.S. 5¢ per ADS held |
| Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs | Up to U.S. 5¢ per ADS held |
| Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off) | Up to U.S. 5¢ per ADS held |
| ADS Services | Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary |
| Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason) | Up to U.S. 5¢ per ADS (or fraction thereof) transferred |
| Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and vice versa). | Up to U.S. 5¢ per ADS (or fraction thereof) converted |

ADS holders are also responsible for paying certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary, or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex, and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes, and other charges of the depositary and/or service providers (which may be a division, branch or affiliate of the depositary) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs, and expenses incurred by the depositary, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom the ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS

cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

**Taxes**

ADS holders are responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary, and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You are liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split, and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary, and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

# PART II

## Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

## Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

**A. Not applicable.**

**B. Not applicable.**

**C. Not applicable.**

**D. Not applicable.**

**E. Not applicable.**

# Item 15. Controls and Procedures

## A. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and our chief financial officer (principal financial officer), has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13(a)-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended, the "Exchange Act"), as of December 31, 2025. Based on such evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective as of December 31, 2025, because of the material weakness described below.

After giving full consideration to this material weakness, and the additional analyses and other procedures that we performed to ensure that our consolidated financial statements included in this Annual Report on Form 20-F were prepared in accordance with IFRS, management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with IFRS.

## B. Internal Control Over Financial Reporting

***Management's Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13(a)-15(f) and 15(d)-15(f) under the "Exchange Act") and for the assessment of the effectiveness of our internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS).

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), management conducted an assessment of the effectiveness of our internal control over financial reporting based upon the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, and as a result of the material weakness described below, management has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2025.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The Company did not design and operate effective controls to ensure that all instances of complex, judgmental, and non-recurring transactions were (i) timely identified, (ii) subjected to a level of technical accounting analysis and review commensurate with their complexity, and (iii) supported by sufficiently detailed documentation evidencing management's evaluation of applicable IFRS recognition and measurement criteria.

Specifically, the deficiencies identified relate to controls over: (i) the determination of product costs to be excluded from inventory cost—particularly costs related to idle capacity—in connection with a non-recurring transfer of manufacturing activities; (ii) the possibility to recognize assets relating to claims arising from non-recurring operational incidents at contract manufacturing organizations; and (iii) the estimation and recognition of revenue and associated refund liabilities under a specific research collaboration arrangement.

These deficiencies in internal control led to various adjustments made prior to the issuance of the financial statements. Additionally, these control deficiencies could result in a misstatement of the aforementioned or other account balances or disclosures that would result in a material misstatement to the consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies, in the aggregate, constitute a material weakness.

***Remediation Plan***

Management is in the process of designing and implementing the remediation plans to address the material weakness discussed above, which we believe will address the underlying causes of each deficiency. Remediation activities are intended to strengthen the design and operating effectiveness of controls over complex and judgmental accounting matters, and will include, among other actions:

i. Enhancing risk identification procedures for non-recurring transactions and estimates, including required escalation protocols and accounting position memos.

ii. Implementing standardized documentation requirements for significant accounting judgments.

iii. Strengthening review controls over the application of IFRS in judgmental areas, including revenue recognition under the specific research collaboration arrangement, assets relating to claims and inventory valuation regarding the consideration of idle capacities in production cost; and

iv. Establishing clearer governance and escalation protocols for complex accounting matters.

Where appropriate, we may engage external advisors with subject matter expertise to support management's evaluation of complex accounting matters and to assist in reinforcing the design and documentation of controls over technical accounting assessments.

We will continue to evaluate the effectiveness of these enhanced controls, including a structured process for ensuring such transactions receive timely technical accounting analysis and that any identified deficiencies are remediated promptly.

However, remediation will not occur until the plans are implemented and there has been appropriate time for us to conclude through testing that the controls operate effectively.

## C. Attestation Report of the Registered Public Accounting Firm

PricewaterhouseCoopers Audit and Deloitte & Associés, independent registered accounting firms, have issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2025, which expressed an adverse opinion thereon.

## D. Changes in Internal Control Over Financial Reporting

As noted above in "Management's Annual Report on Internal Control over Financial Reporting", there were changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Item 16. [Reserved]

## A. Audit Committee Financial Expert

Our Board of Directors has determined that Ms. Guyot-Caparros, Mr. Sulat, and Mr. Connolly are independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our Board of Directors has further determined that Ms. Guyot-Caparros and Mr. Sulat are "audit committee financial experts" as defined by the Nasdaq listing rules and that each of the members of the Audit, Compliance and Risk Committee qualifies as financially sophisticated under the Nasdaq listing rules.

## B. Code of Ethics

We have adopted a Code of Conduct & Ethics applicable to all of our employees and members of our Board of Directors and Executive Committee. Our Code of Conduct & Ethics is available on our website. We expect that any amendments to the Code of Conduct & Ethics, or any waivers of its requirements, will be disclosed on our website. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Conduct & Ethics applies to our principal executive officer, principal financial officer, principal accounting officer, or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not incorporated by reference into this Annual Report and does not constitute a part of this Annual Report.

## C. Principal Accountant Fees and Services

PricewaterhouseCoopers Audit and Deloitte & Associés served as our independent auditors for the year ended December 31, 2025 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Valneva and consolidated subsidiaries in the years ended December 31, 2025, 2024 2023.

**Principal Accountant Fees and Services:**

| | Year ended December 31, | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | PricewaterhouseCoopers | | | | | | Deloitte & Associés | | | | | |
| in € thousand | 2025 | % | 2024 | % | 2023 | % | 2025 | % | 2024 | % | 2023 | % |
| **Audit fees** | **1,182** | **74%** | **1,710** | **89%** | **2,076** | **98%** | **1,029** | **100%** | **1,311** | **89%** | **1,902** | **99%** |
| provided by the statutory auditor | 1,082 | 68% | 1,272 | 66% | 1,539 | 73% | 939 | 91% | 1,185 | 80% | 1,622 | 84% |
| provided by the statutory auditor's network | 100 | 6% | 439 | 23% | 537 | 25% | 90 | 9% | 126 | 9% | 280 | 15% |
| **Audit-related Fees** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** |
| provided by the statutory auditor | 0 | % | — | % | — | % | — | % | — | % | — | % |
| provided by the statutory auditor's network | 0 | % | — | % | — | % | — | % | — | % | — | % |
| **Tax Fees** | **122** | **8%** | **45** | **2%** | **40** | **2%** | **0** | **%** | **—** | **%** | **—** | **%** |
| provided by the statutory auditor's network | 122 | 8% | 45 | 2% | 40 | 2% | 0 | % | — | % | — | % |
| **All Other Fees** | **292** | **18%** | **163** | **8%** | **0** | **%** | **—** | **%** | **163** | **11%** | **19** | **1%** |
| **Total** | **1,596** | **100%** | **1,918** | **100%** | **2,116** | **100%** | **1,029** | **100%** | **1,474** | **100%** | **1,921** | **100%** |

**"Audit fees"** are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that PricewaterhouseCoopers and Deloitte & Associés provides, such as consents and assistance with and review of documents filed with the SEC.

**"Audit-related Fees"** are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

**"Tax fees"** are the aggregate tax fees billed for services related to the production of certification in the context of the declaration of expenses to obtain grants and prepare special reports relating to certain operations on the Company's capital.

**"All other fees"** are the aggregate fees billed for the limited assurance review of sustainability reporting and verification of disclosure requirements set out in article 8 of Regulation (EU) 2020/852.

| Auditor Name | Auditor Location | Auditor Firm ID |
|---|---|---|
| **PricewaterhouseCoopers Audit** | **Neuilly-sur-Seine, France** | **1347** |
| **Deloitte & Associés** | **Paris, France** | **1756** |

***Audit and Non-Audit Services Pre-Approval Policy***

French law requires that audit committees pre-approve any non-audit services to be performed by a company's statutory auditors. Additionally, French law requires audit committees to ensure that such non-audit services will not affect the independence of the statutory auditors in performing their audit services, and the fees received for non-audit services cannot exceed 70% of the total fees for audit services.

Accordingly, our Audit and Governance Committee, or the Committee, has authority to propose the retention and compensation of the Company's registered public accounting firms and oversees the independence and performance of such firms with respect to both audit-related and non-audit-related services. The Committee may approve the provision of services other than the certification of financial statements by the auditors following an analysis of the potential impact of providing such services on the auditors' independence and the approval of any safeguards that may be required to mitigate such impact.

Prior to engagement of any prospective auditors, the Committee reviews a written disclosure by the prospective auditors of all relationships between the prospective auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and discusses with the prospective auditors the potential effects of such relationships on the independence of the prospective auditors, consistent with Ethics and Independence Rule 3526, Communication with Audit Committees Concerning Independence ("Rule 3526"), of the Public Company Accounting Oversight Board (United States). Consistent with Rule 3526, at least annually, the Committee receives and reviews written disclosures from the auditors delineating all relationships between the auditors, or their affiliates, and the Company, or persons in financial oversight roles at the Company, that may reasonably be thought to bear on independence and a letter from the auditors affirming their independence, and considers and discusses with the auditors any potential effects of any such relationships on the independence of the auditors as well as any compensation or services that could affect the auditors' objectivity and independence.

The Committee has considered the non-audit services provided by PricewaterhouseCoopers and Deloitte & Associés as described above and believes that they are compatible with maintaining PricewaterhouseCoopers and Deloitte & Associés's independence as our independent registered public accounting firms.

## D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

## E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

## F. Changes to Certifying Accountant

Not applicable.

## G. Corporate Governance

As a French *société européenne*, we are subject to various corporate governance requirements under French law. We are a "foreign private issuer" under the U.S. federal securities laws and the Nasdaq listing rules. The foreign private issuer exemption will permit us to follow home country corporate governance practices instead of certain Nasdaq listing requirements. A foreign private issuer that elects to follow a home country practice instead of Nasdaq listing requirements must submit to Nasdaq a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws.

We apply the Middlenext code, which recommends that a majority of the members of the Board of Directors be independent (as such term is defined under the code). Neither the corporate laws of France nor our bylaws requires that (i) our compensation committee include only independent members of the Board of Directors, (ii) each committee of the Board of Directors have a formal written charter, or (iii) our independent members of the Board of Directors hold regularly scheduled meetings at which only independent members of the Board of Directors are present. We intend to continue to follow French corporate governance practices in lieu of Nasdaq listing requirements for each of the foregoing.

These exemptions do not modify the independence requirements for the audit and governance committee, and we intend to comply with the requirements of the Sarbanes-Oxley Act and the Nasdaq listing rules, which require that our audit and governance committee be composed of at least three independent members. Rule 10A-3 under the Exchange Act provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as

well as control over the performance of their duties, management of complaints made, and selection of consultants. Under Rule 10A-3, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or our shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by our shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least $33^1/_3$% of the outstanding shares of the company's ordinary voting shares. We intend to continue to follow our French home country practice rather than complying with this Nasdaq rule. Consistent with French law, when first convened, general meetings of shareholders may validly convene only if the shareholders present or represented hold at least (i) 20% of the voting shares in the case of an ordinary general meeting or of an extraordinary general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits, or share premium (the ordinary general meeting shall make its decision on a majority of half of the votes cast by the shareholders present or represented), or (ii) 25% of the voting shares in the case of any other extraordinary general meeting (the general meeting shall make its decision on a majority of two thirds of the votes cast by the shareholders present or represented). If such quorum required by French law is not met, the meeting is adjourned. There is no quorum requirement under French law when an ordinary general meeting or an extraordinary general meeting is reconvened where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, but the reconvened meeting may consider only questions that were on the agenda of the adjourned meeting. When any other extraordinary general meeting is reconvened, the required quorum under French law is 20% of the shares entitled to vote. If a quorum is not met at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Furthermore, Nasdaq's corporate governance rules require listed U.S. companies to seek shareholder approval for the implementation of certain equity compensation plans and issuances of securities, which we are not required to, and do not intend to, follow as a foreign private issuer.

## H. Mine Safety Disclosure.

Not applicable.

## I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

## J. Insider Trading Policy

We have adopted an insider trading policy governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees that is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and the listing standards of Euronext Paris and the Nasdaq Global Select Market. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 20-F.

## K. Cybersecurity

***Risk management and strategy***

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical systems and information (collectively, our "Information Systems and Data").

Our Information Technology department, with support from members of our Legal and Compliance teams and our Head of Risk Management, helps identify and assess cybersecurity risks and prepare the Company to respond to these risks. We use various methods for monitoring and evaluating threats to our environment including, for example: using manual and automated tools to detect anomalies and attempted attacks, subscribing to reports and services that identify cybersecurity threats, evaluating our and our industry's risk profile, analyzing reports of threats and actors, conducting scans of our environment, evaluating threats reported to us, conducting internal and external audits, conducting threat assessments for internal and external threats, and conducting vulnerability assessments, including penetration tests.

Depending on the environment and system, we implement and maintain various technical, organizational, and physical measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. These include, in addition to others discussed in this Item 16K, system monitoring, an incident detection and response plan, a disaster recovery plan, encryption and segregation of certain data, network security controls, and measures for the physical security of our technology infrastructure. We provide an annual information security awareness training to our employees and ask them to review certain information security policies on an annual basis.

Our identification, assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, we include information on cybersecurity risk evaluations conducted by management in reports provided to our internal Risk Management Committee, elements of which are shared with the Audit, Risk, and Compliance Committee ("the Audit Committee") of our Board of Directors. Additionally, our Executive Committee may discuss cybersecurity risks and mitigation activities as part of its general risk management

oversight. Our Chief Financial Officer (CFO) is the member of our Executive Committee with functional responsibility for cybersecurity and may elevate cybersecurity topics for the attention of the Executive Committee, Audit Committee, and Board of Directors.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants, threat intelligence service providers, cybersecurity software and service providers, penetration testing firms, dark web monitoring services, forensic investigators, and professional services firms, including legal counsels.

Support elements for a variety of functions across our business are performed by third parties, such as distributors, contract manufacturing organizations, contract research organizations, application providers, and supply chain resources. We consider cyber risks in evaluating third parties and services, and our vendor management processes are tailored to our assessment of a particular vendor's risk profile and criticality to our operations. Those processes may include, for example, some combination of the following: performing a risk assessment or issuing a security questionnaire, reviewing written security programs, performing certain vulnerability scans, conducting security assessment calls with the vendor's security personnel, performing audits on the vendor's compliance with our security requirements, or imposing contractual obligations relating to information security. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify and manage cybersecurity risks associated with a provider.

We have not identified risks from any known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may be reasonably likely to materially affect the Company and how they may do so, see our risk factors under Item 3D. Risk Factors in this Annual Report, including those described in "Risks Related to our Business Operations, Employee Matters and Managing Growth".

***Governance***

Our Board of Directors considers the Company's cybersecurity risk as part of its general oversight function. The Audit Committee is responsible for overseeing the Executive Committee's implementation and enforcement of our cybersecurity risk management processes.

Our cybersecurity risk assessment and management processes are implemented and maintained by a management team comprised of our Vice President of Information Technology and Analytics ("VP of IT/Analytics") and our CFO, to whom our VP of IT/Analytics reports. This management team is responsible for hiring appropriate personnel, managing spending relating to cybersecurity, providing information on cybersecurity risks, preparing for cybersecurity incidents, reviewing security assessments, approving cybersecurity processes and resources, and managing our response to significant cybersecurity incidents. The management team stays informed about and monitors efforts to prevent, detection, mitigate and remediate cybersecurity incidents through various means, which may include briefings with operational cybersecurity team members, outside threat intelligence sources, and from tooling described above that is deployed in our IT environment.

Individuals responsible for cybersecurity at an operational level within the Company have a minimum of five years experience in the field of information technology. For example, our Head of Information Security and Audit is certified within the TÜV Austria as a Manager and Auditor according to ISO 27001 & ISO 27002. We also have a Cyber Incident Response Team that includes the Head of Information Security, Data Protection Officer, and Director of Information Technology Infrastructure. This group may be expanded as needed to include representatives from our Legal and Corporate Communications teams as well as our Executive Committee, which is responsible for communicating with the Audit Committee or full Board of Directors as needed.

The Audit Committee receives regular reports from the VP of IT/Analytics concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them, as well as cybersecurity incidents deemed significant by the management team. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

# Item 17. Financial Statements

See the financial statements beginning on page F-1 of this Annual Report.

# Item 18. Financial Statements

Not applicable.

# Item 19. Exhibits

| Exhibit Number | Description of Document | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule/ Form | File Number | Exhibit | Filing Date |
| 1.1* | Articles of Association (statuts) of the Registrant (English translation) | 20-F | | | |
| 2.1 | Form of Deposit Agreement | F-1/A | 333-255155 | 4.1 | April 29, 2021 |
| 2.2 | Form of American Depositary Receipt (included in Exhibit 4.1) | F-1/A | 333-255155 | 4.2 | April 29, 2021 |
| 2.3* | Description of Securities | 20-F | | | |
| 4.1† | Research Collaboration and License Agreement, dated April 29, 2020, by and between Pfizer Inc. and Valneva Austria GmbH. | F-1 | 333-255155 | 10.1 | April 9, 2021 |
| 4.2† | Amendment No. 1 to Research Collaboration and License Agreement dated July 14, 2021, by and between Valneva Austria GmbH and Pfizer Inc. | 6-K | 001-40377 | 10.5 | August 15, 2022 |
| 4.3† | Amendment No. 2 to Research Collaboration and License Agreement dated November 10, 2021, by and between Valneva Austria GmbH and Pfizer Inc. | 6-K | 001-40377 | 10.6 | August 15, 2022 |
| 4.4† | Amendment No. 3 to Research Collaboration and License Agreement dated June 19, 2022, by and between Valneva Austria GmbH and Pfizer Inc. | 6-K | 001-40377 | 10.7 | August 15, 2022 |
| 4.5† | Amendment No. 4 to Research Collaboration and License Agreement dated November 22, 2022, by and between Valneva Austria GmbH and Pfizer Inc. | 20-F | 001-40377 | 4.3 | March 30, 2023 |
| 4.6† | Master Supply and Commercial Manufacturing Services Agreement, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 10.3 | March 24, 2022 |
| 4.7† | Product Schedule, dated November 26, 2021, by and between IDT Biologika GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 10.7 | March 24, 2022 |
| 4.8† | Product Schedule, dated December 16, 2022, by and between IDT Biologika GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 4.9 | March 30, 2023 |
| 4.9† | Funding Agreement, dated April 1, 2019, by and between Coalition for Epidemic Preparedness Innovations and Valneva SE. | F-1 | 333-255155 | 10.4 | April 9, 2021 |
| 4.10† | Funding Agreement, dated July 19, 2024, by and between Coalition for Epidemic Preparedness Innovations and Valneva Austria GmbH | 20-F | 001-40377 | 4.10 | March 24, 2025 |
| 4.11† | Master Collaboration and License Agreement, dated December 16, 2024, by and between the Serum Institute of India Private Limited and Valneva Austria GmbH | 20-F | 001-40377 | 4.11 | March 24, 2025 |
| 4.12† | Development, Collaboration, License and Commercialization Agreement, dated July 31, 2024, by and between LimmaTech Biologics AG and Valneva Austria GmbH | 20-F | 001-40377 | 4.12 | March 24, 2025 |
| 4.13† | Contract dated September 9, 2020, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc. | F-1 | 333-255155 | 10.8 | April 9, 2021 |

| | | | | | |
|---|---|---|---|---|---|
| 4.14† | Amendment, dated August 23, 2021, to Contract dated September 9, 2020 by and between the U.S. Defense Logistics Agency and Valneva USA, Inc. | F-1 | 333-260507 | 10.9 | October 26, 2021 |
| 4.15† | Contract dated September 21, 2023, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc. | 20-F | 001-40377 | 4.1 | March 22, 2024 |
| 4.16† | Contract dated January 29, 2025, by and between the U.S. Defense Logistics Agency and Valneva USA, Inc. | 20-F | 001-40377 | 4.16 | March 24, 2025 |
| 4.17*† | Distribution Agreement (IXIARO and IXCHIQ) dated June 23, 2025 by and between Valneva Austria GmbH and Seqirus GmbH | 20-F | | | |
| 4.18*† | Amendment to Distribution Agreement (IXIARO and IXCHIQ) dated September 2, 2025 by and between Valneva Austria GmbH and Seqirus GmbH | 20-F | | | |
| 4.19*† | Distribution Agreement (DUKORAL) dated June 23, 2025 by and between Valneva Sweden AB and Seqirus GmbH | 20-F | | | |
| 4.20*† | Master Collaboration Agreement, dated January 25, 2021, by and between Valneva Austria GmbH and lnstituto Butantan | 20-F | | | |
| 4.21*† | Amendment 1 to Master Collaboration Agreement, dated May 4, 2021, by and between Valneva Austria GmbH and lnstituto Butantan | 20-F | | | |
| 4.22*† | Amendment 2 to Master Collaboration Agreement, dated August 18, 2022, by and between Valneva Austria GmbH and lnstituto Butantan | 20-F | | | |
| 4.23*† | Amendment 3 to Master Collaboration Agreement dated January 22, 2024, by and between Valneva Austria GmbH and lnstituto Butantan | 20-F | | | |
| 4.24† | Distribution Agreement (IXIARO), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Austria GmbH. | F-1 | 333-255155 | 10.10 | April 9, 2021 |
| 4.25† | Distribution Agreement (DUKORAL), dated November 18, 2020, by and between Bavarian Nordic A/S and Valneva Sweden AB, as amended to date. | F-1 | 333-255155 | 10.11 | April 9, 2021 |
| 4.26† | Amendment to Distribution Agreements, dated May 15, 2023, by and between, *inter alios*, Bavarian Nordic A/S, Valneva Austria GmbH and Valneva Sweden AB. | 20-F | 001-40377 | 4.15 | March 22, 2024 |
| 4.27† | Distribution Agreement, dated December 15, 2022, by and between Valneva SE and VBI Vaccines Inc. | 20-F | 001-40377 | 4.3 | March 30, 2023 |
| 4.28† | Amendment, dated January 1, 2024, to the Distribution Agreement dated December 15, 2022, by and between Valneva SE and VBI Vaccines Inc. | 20-F | 001-40377 | 4.2 | March 22, 2024 |
| 4.29† | Sublicense Agreement, dated April 14, 2003, by and between VaccGen International LLC and Intercell AG, as assigned to the Registrant and as amended. | F-1 | 333-255155 | 10.6 | April 9, 2021 |
| 4.30† | Supply Agreement, dated March 1, 2008, by and among Intercell AG, Vetter Pharma-Fertigung GmbH & Co. KG and Intercell Biomedical Ltd., as assigned to the Registrant. | F-1 | 333-255155 | 10.7 | April 9, 2021 |

| | | | | | |
|---|---|---|---|---|---|
| 4.31† | Commercial Supply Agreement, dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 4.20 | March 22, 2024 |
| 4.32† | First Amendment, dated November 16, 2023, to the Commercial Supply Agreement dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 4.21 | March 22, 2024 |
| 4.33† | Second Amendment, dated January 1, 2024, to the Commercial Supply Agreement dated April 1, 2023, by and between Vetter Pharma International GmbH and Valneva Austria GmbH. | 20-F | 001-40377 | 4.22 | March 22, 2024 |
| 4.34† | Sales Agreement, dated as of August 12, 2022, by and between Valneva SE and Jefferies LLC. | 6-K | 001-40377 | 1.1 | August 15, 2022 |
| 4.35† | Asset Purchase Agreement, dated February 2, 2024, by and between Valneva Austria GmbH and Novartis Pharma AG. | 20-F | 001-40377 | 4.25 | March 22, 2024 |
| 4.36*†# | Loan Agreement, dated October 6, 2025, by and among Valneva Austria GmbH, Valneva SE, Biopharma Credit Plc, BPCR Limited Partnership, and Biopharma Credit Investments V (Master) LP | 20-F | | | |
| 4.37 | Terms and Conditions Applicable to BSA 27 Equity Warrants and Form of Exercise Notice | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.38+ | Employee Stock Option Plan 2013 | F-1 | 333-255155 | 10.1 | April 9, 2021 |
| 4.39+ | Employee Stock Option Plan 2015 | F-1 | 333-255155 | 10.1 | April 9, 2021 |
| 4.40+ | Employee Stock Option Plan 2016 | F-1 | 333-255155 | 10.1 | April 9, 2021 |
| 4.41+ | Employee Stock Option Plan 2017 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.42+ | Employee Stock Option Plan 2019 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.43+ | Employee Stock Option Plan 2022 | 20-F | 001-40377 | 4.32 | March 22, 2024 |
| 4.44+ | Employee Stock Option Plan 2023 | 20-F | 001-40377 | 4.33 | March 22, 2024 |
| 4.45+ | Employee Stock Option Plan 2024 | 20-F | 001-40377 | 4.38 | March 24, 2025 |
| 4.46+* | Employee Stock Option Plan 2025 | 20-F | | | |
| 4.47+ | Senior Leadership Group Stock Option Plan 2022 | 20-F | 001-40377 | 4.38 | March 30, 2023 |
| 4.48+ | Senior Leadership Group Stock Option Plan 2023 | 20-F | 001-40377 | 4.35 | March 22, 2024 |
| 4.49+* | Senior Leadership Group Stock Option Plan 2024 | 20-F | 001-40377 | 4.41 | March 24, 2025 |
| 4.50+ | Free Convertible Preferred Share Plan 2017-2021 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.51+ | Free Share Plan 2019-2023 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.52+ | Free Share Plan 2023-2026 | 20-F | 001-40377 | 4.38 | March 22, 2024 |
| 4.53+* | Free Share Plan 2024-2027 | 20-F | 001-40377 | 4.45 | March 24, 2025 |
| 4.54+* | Performance Free Share Plan 2025-2028 | 20-F | | | |
| 4.55+ | Special Free Ordinary Share Plan 2022-2025 N°2 | 20-F | 001-40377 | 4.4 | March 22, 2024 |
| 4.56+ | Phantom Stock Option Plan 2017 and Form of Exercise Notice | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.57+ | Phantom Stock Option Plan 2019 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 4.58+ | Phantom Stock Plan 2020 | F-1 | 333-255155 | 10.2 | April 9, 2021 |
| 8.1 | Subsidiaries of the Registrant | 20-F | 001-40377 | 8.1 | March 22, 2024 |
| 12.1* | Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | |
| 12.2* | Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 13.1** | Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 13.2** | Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 15.1* | Consent of Deloitte et Associés, independent registered public accounting firm | | | | |
| 15.2* | Consent of PricewaterhouseCoopers Audit, independent registered public accounting firm | | | | |
| 19.1* | Insider Trading Policy | | | | |
| 97.1 | Clawback Policy | 20-F | 001-40377 | 97.1 | March 22, 2024 |
| 101.INS* | XBRL Instance Document | | | | |
| 101.SCH* | XBRL Taxonomy Extension Schema Document | | | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document | | | | |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document | | | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document | | | | |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document | | | | |

* Filed herewith.

** Furnished herewith.

\+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

# Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

## SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing this Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

**VALNEVA SE**

By: /s/ Thomas Lingelbach

Thomas Lingelbach

Chief Executive Officer

Date: March 17, 2026

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Shareholders and the Board of Directors of Valneva SE

### Opinions on the Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated statement of financial position of Valneva SE and its subsidiaries (together the "Company") as of December 31, 2025 and 2024, and the related consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity, and statement of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We have also audited the internal control over financial reporting of the Company as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO because a material weakness in internal control over financial reporting existed as of that date as the Company did not design and operate effective controls to ensure that all instances of complex, judgmental, and non-recurring transactions were (i) timely identified, (ii) subjected to a level of technical accounting analysis and review commensurate with their complexity, and (iii) supported by sufficiently detailed documentation evidencing management's evaluation of applicable IFRS recognition and measurement criteria.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in the Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 15B. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2025 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements.

### Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in management's report referred to above. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are public accounting firms registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

### Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and

that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**Critical Audit Matters**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Other Revenues and Refund Liabilities – Research Collaboration and License Agreement with Pfizer*

As described in Notes 5.3.1 Critical Accounting Policies, Practices, and Estimate, 5.5.2 Other Revenues, and 5.29 Refund Liabilities to the Consolidated Financial Statements, in April 2020, the Company signed the Collaboration and License Agreement (the "Agreement") with Pfizer to co-develop and commercialize a Lyme disease vaccine candidate. The Agreement is within the scope of IFRS 15 "Revenue from Contracts with Customers" and includes an exclusive license as well as research and development ("R&D") and support services.

The considerations for this Agreement include a variable part. Variable considerations derive from upfront and milestone payments received and to be received from Pfizer, contributions from Valneva to Pfizer in shared development costs (all together, the "Net contributions") and circumstances that could potentially increase future payments to Pfizer. At the end of each reporting period, Valneva updates the estimated transaction price and its assessment of whether an estimate of variable consideration is constrained. Revenue is recognized when the variable consideration constraint is removed and it is highly probable that a significant revenue reversal will not occur.

As of December 31, 2025, Valneva reassessed its entitlement to the consideration and the related refund liability. As the Phase 3 clinical trial was largely completed, and based on the updated development budget, Valneva concluded that both the estimated probability and the potential magnitude of any further increase in payments to the customer had decreased, and that a portion of the outstanding refund liability no longer represented an obligation to refund consideration to Pfizer. As a result, as of and for the year ended December 31, 2025, Valneva recognized other revenues of €10.0 million, and refund liabilities of €9.0 million.

The principal considerations for our determination that performing procedures relating to other revenues and refund liabilities – research collaboration and license agreement with Pfizer - is a critical audit matter are (i) the significant judgment by management when estimating the transaction price and assessing whether an estimate of variable consideration is constrained and (ii) a high degree of auditor subjectivity in performing procedures in evaluating management's estimates. As described in the "Opinions on the Financial Statements and Internal Control over Financial Reporting" section, a material weakness was identified that impacted this matter.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the estimate of the transaction price. These procedures also included, among others, (i) evaluating the reasonableness of management's assessment of whether the variable consideration is constrained and it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur; (ii) testing the refund liability by recalculating the Net contributions and evaluating 'management's assumptions related to potential future R&D contributions; (iii) confirming with Pfizer the current terms of the Agreement and relevant positions; and (iv) evaluating the sufficiency of the disclosure in the consolidated financial statements.

/s/ PricewaterhouseCoopers Audit /s/ Deloitte & Associés

Neuilly-sur-Seine and Paris-La-Défense, France

March 17, 2026

PricewaterhouseCoopers Audit and Deloitte & Associés have served as the Company's auditors since 2013 and 2007, respectively.

# Evolving with Purpose, Transforming the Future

## 2025
CONSOLIDATED
FINANCIAL STATEMENTS

valneva

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# 1 CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

## 1.1 Consolidated Statement of Profit or Loss

| | | Year ended December 31, | | |
|---|---|---|---|---|
| *in € thousand* | Note | 2025 | 2024 | 2023 |
| Product sales | *5.5* | 157,908 | 163,253 | 144,624 |
| Other revenues | *5.5* | 16,750 | 6,325 | 9,088 |
| **REVENUES** | | **174,659** | **169,579** | **153,713** |
| Cost of goods and services | *5.6* | (107,139) | (98,538) | (100,875) |
| Research and development expenses | *5.6* | (85,303) | (74,143) | (59,894) |
| Marketing and distribution expenses | *5.6* | (37,356) | (52,356) | (48,752) |
| General and administrative expenses | *5.6* | (37,322) | (42,750) | (47,799) |
| Gain from sale of Priority Review Voucher, net | *5.8* | — | 90,833 | — |
| Other income and expenses, net | *5.8* | 10,400 | 20,706 | 21,520 |
| **OPERATING PROFIT/(LOSS)** | | **(82,060)** | **13,330** | **(82,087)** |
| Finance income | *5.9* | 2,644 | 2,362 | 1,210 |
| Finance expenses | *5.9* | (41,898) | (23,984) | (23,325) |
| Foreign exchange gain/(loss), net | *5.9* | 7,196 | (3,193) | 5,574 |
| **PROFIT/(LOSS) BEFORE INCOME TAX** | | **(114,119)** | **(11,486)** | **(98,629)** |
| Income tax benefit/(expense) | *5.10* | (1,073) | (761) | (2,800) |
| **PROFIT/(LOSS) FOR THE PERIOD** | | **(115,192)** | **(12,247)** | **(101,429)** |
| | | | | |
| **EARNINGS/(LOSSES) PER SHARE** | | | | |
| for profit/(loss) for the period attributable to the equity holders of the Company *(expressed in € per share)* | | | | |
| Basic | *5.11* | (0.68) | (0.08) | (0.73) |
| Diluted | *5.11* | (0.68) | (0.08) | (0.73) |

The accompanying Notes form an integral part of these financial statements.

## 1.2 Consolidated Statement of Comprehensive Income

| | | Year ended December 31, | | |
|---|---|---|---|---|
| *in € thousand* | Note | 2025 | 2024 | 2023 |
| **PROFIT/(LOSS) FOR THE PERIOD** | | **(115,192)** | **(12,247)** | **(101,429)** |
| **OTHER COMPREHENSIVE INCOME/(LOSS)** | | | | |
| **Items that may be reclassified to profit or loss** | | | | |
| Currency translation differences | *5.22.2* | 520 | (1,329) | 3,300 |
| **Items that will not be reclassified to profit or loss** | | | | |
| Defined benefit plan actuarial gains/(losses) | *5.30.1* | 68 | 49 | (130) |
| **Other comprehensive income/(loss) for the period, net of tax** | | **588** | **(1,281)** | **3,170** |
| **TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD** | | **(114,604)** | **(13,527)** | **(98,258)** |

The accompanying Notes form an integral part of these financial statements.

# 2 CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| | | December 31 | |
|---|---|---|---|
| *in € thousand* | Note | 2025 | 2024 |
| **ASSETS** | | | |
| **Non-current assets** | | **176,296** | **201,020** |
| Intangible assets | *5.12* | 22,349 | 25,258 |
| Right of use assets | *5.13* | 18,558 | 19,232 |
| Property, plant and equipment | *5.14* | 119,474 | 138,883 |
| Deferred tax assets | *5.10.2* | 8,326 | 9,605 |
| Other non-current assets | *5.19* | 7,590 | 8,041 |
| **Current assets** | | **222,540** | **299,012** |
| Inventories | *5.17* | 50,232 | 53,663 |
| Trade receivables | *5.18* | 27,813 | 35,205 |
| Other current assets | *5.19* | 34,846 | 41,874 |
| Cash and cash equivalents | *5.20* | 109,650 | 168,271 |
| **TOTAL ASSETS** | | **398,836** | **500,032** |
| **EQUITY** | | | |
| Share capital | *5.22* | 26,031 | 24,378 |
| Share premium | *5.22* | 675,940 | 647,600 |
| Other reserves | *5.22.2* | 83,318 | 73,203 |
| Retained earnings/(Accumulated deficit) | | (563,928) | (551,682) |
| Profit/(Loss) for the period | | (115,192) | (12,247) |
| **TOTAL EQUITY** | | **106,168** | **181,253** |
| **LIABILITIES** | | | |
| **Non-current liabilities** | | **199,334** | **204,199** |
| Borrowings | *5.24* | 161,261 | 166,521 |
| Lease liabilities | *5.27* | 25,343 | 26,432 |
| Refund liabilities | *5.29* | 6,684 | 6,491 |
| Provisions | *5.30* | 1,392 | 546 |
| Deferred tax liabilities | *5.10.2* | 4,409 | 4,162 |
| Other non-current liabilities | *5.31* | 246 | 46 |
| **Current liabilities** | | **93,334** | **114,580** |
| Borrowings | *5.24* | 17,905 | 20,852 |
| Trade payables and accruals | *5.25* | 24,540 | 35,522 |
| Income tax liability | | 1 | 1,742 |
| Tax and Employee-related liabilities | *5.26* | 19,555 | 19,458 |
| Lease liabilities | *5.27* | 2,739 | 2,508 |
| Contract liabilities | *5.28* | 432 | 3,010 |
| Refund liabilities | *5.29* | 10,814 | 19,650 |
| Provisions | *5.30* | 11,659 | 6,686 |
| Other current liabilities | *5.31* | 5,689 | 5,152 |
| **TOTAL LIABILITIES** | | **292,668** | **318,779** |
| **TOTAL EQUITY AND LIABILITIES** | | **398,836** | **500,032** |

The accompanying Notes form an integral part of these financial statements.

# 3 CONSOLIDATED STATEMENT OF CASH FLOWS

| *in € thousand* | Note | Year ended December 31, 2025 | 2024 | 2023 |
|---|---|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | | | |
| Profit/(Loss) for the period | | (115,192) | (12,247) | (101,429) |
| Gain from sale of Priority Review Voucher, net | *5.8* | — | (90,833) | — |
| Adjustments to reconcile profit/(loss) for the period to cash generated from/(used in) operations | *5.32.1* | 64,649 | 48,979 | 44,984 |
| Changes in non-current operating assets and liabilities | *5.32.1* | 1,323 | (180) | 514 |
| Changes in working capital | *5.32.1* | (1,471) | (11,394) | (145,578) |
| **Cash used in operations** | *5.32.1* | **(50,691)** | **(65,674)** | **(201,509)** |
| Income tax paid | | (2,203) | (1,545) | (1,236) |
| **NET CASH GENERATED FROM/(USED IN) OPERATING ACTIVITIES** | | **(52,894)** | **(67,218)** | **(202,744)** |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | | | |
| Acquisition of subsidiaries, net of cash acquired | *5.1.2* | — | — | (10,951) |
| Purchases of property, plant and equipment | | (4,420) | (13,865) | (14,231) |
| Proceeds from sale of property, plant and equipment | | 128 | 165 | 111 |
| Purchases of intangible assets | | (61) | (2,579) | (81) |
| Proceeds from assets classified as held for sale | *5.32.1* | — | — | 3,358 |
| Proceeds from sale of Priority Review Voucher | | — | 90,833 | — |
| Proceeds from sale and purchase of MMF investments | | 841 | — | — |
| Interest received | | 1,803 | 2,362 | 1,210 |
| **NET CASH GENERATED FROM/(USED IN) INVESTING ACTIVITIES** | | **(1,709)** | **76,916** | **(20,585)** |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | | | |
| Proceeds/(payments) from issuance of common stock, net of costs of equity transactions | *5.22* | 30,003 | 57,139 | (240) |
| Proceeds from borrowings, net of transaction costs | *5.24* | 174,401 | (34) | 81,111 |
| Repayment of borrowings | *5.24* | (171,632) | (3,734) | (2,097) |
| Payment of lease liabilities | *5.27* | (2,708) | (2,719) | (3,127) |
| Interest paid [(1)] | | (30,686) | (19,969) | (12,567) |
| **NET CASH GENERATED FROM FROM/(USED IN) FINANCING ACTIVITIES** | | **(621)** | **30,682** | **63,081** |
| **NET CHANGE IN CASH AND CASH EQUIVALENTS** | | (55,224) | 40,380 | (160,248) |
| Cash and cash equivalents at beginning of the year | *5.20* | 168,271 | 126,080 | 286,532 |
| Exchange gains/(losses) on cash | | (3,397) | 1,811 | (204) |
| **CASH AND CASH EQUIVALENTS AT END OF THE PERIOD** | | **109,650** | **168,271** | **126,080** |

*(1) Cash flows relating to the interest on the lease liabilities amounted to €0.8 million as at* December 31, 2025 *(2024: €0.8 million and 2023: €1.2 million)*

The accompanying Notes form an integral part of these financial statements.

# 4 CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| *in € thousand* | Note | Share capital | Share premium | Other reserves | Retained earnings/ (Accumulated deficit) | Profit/ (loss) for the period | Total equity |
|---|---|---|---|---|---|---|---|
| **BALANCE AS AT JANUARY 1, 2025** | | **24,378** | **647,600** | **73,203** | **(551,682)** | **(12,247)** | **181,253** |
| Total comprehensive income/(loss) | | — | — | 588 | — | (115,192) | (114,604) |
| Income appropriation | | — | — | — | (12,247) | 12,247 | — |
| Share-based compensation expense: | | | | | | | |
| Value of services | *5.23* | — | — | 9,527 | — | — | 9,527 |
| Exercises | *5.23* | 253 | 3,543 | — | — | — | 3,796 |
| Capital Increase | *5.22* | 1,400 | 26,035 | — | — | — | 27,435 |
| Cost of equity transaction, net of tax | *5.22* | — | (1,239) | — | — | — | (1,239) |
| **BALANCE AS AT DECEMBER 31, 2025** | | **26,031** | **675,940** | **83,318** | **(563,928)** | **(115,192)** | **106,168** |

| *in € thousand* | Note | Share capital | Share premium | Other reserves | Retained earnings/ (Accumulated deficit) | Profit/ (loss) for the period | Total equity |
|---|---|---|---|---|---|---|---|
| **BALANCE AS AT JANUARY 1, 2024** | | **20,837** | **594,003** | **65,088** | **(450,253)** | **(101,429)** | **128,247** |
| Total comprehensive income/(loss) | | — | — | (1,281) | — | (12,247) | (13,527) |
| Income appropriation | | — | — | — | (101,429) | 101,429 | — |
| Share-based compensation expense: | | | | | | | |
| Value of services | *5.23* | — | — | 9,395 | — | — | 9,395 |
| Exercises | *5.23* | 91 | (91) | — | — | — | — |
| Capital Increase | *5.22* | 3,450 | 57,730 | — | — | — | 61,180 |
| Cost of equity transaction, net of tax | *5.22* | — | (4,041) | — | — | — | (4,041) |
| **BALANCE AS AT DECEMBER 31, 2024** | | **24,378** | **647,600** | **73,203** | **(551,682)** | **(12,247)** | **181,253** |

| *in € thousand* | Note | Share capital | Share premium | Other reserves | Retained earnings/ (Accumulated deficit) | Profit/ (loss) for the period | Total equity |
|---|---|---|---|---|---|---|---|
| **BALANCE AS AT JANUARY 1, 2023** | | **20,755** | **594,043** | **55,252** | **(306,974)** | **(143,279)** | **219,797** |
| Total comprehensive income/(loss) | | — | — | 3,170 | — | (101,429) | (98,258) |
| Income appropriation | | — | — | — | (143,279) | 143,279 | — |
| Share-based compensation expense: | | | | | | | |
| Value of services | *5.23* | — | — | 6,666 | — | — | 6,666 |
| Exercises | *5.23* | 82 | (39) | — | — | — | 42 |
| **BALANCE AS AT DECEMBER 31, 2023** | | **20,837** | **594,003** | **65,088** | **(450,253)** | **(101,429)** | **128,247** |

The accompanying Notes form an integral part of these financial statements.

# 5 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## 5.1 General information

### 5.1.1 Corporate Information

Valneva SE (the Company) together with its subsidiaries (the Group or Valneva) is a company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical needs. The Company takes a highly specialized and targeted approach, applying deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions. Valneva has a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently markets three proprietary travel vaccines as well as certain third-party vaccines leveraging the Group's established commercial infrastructure. Revenues from the growing commercial business help fuel the continued advancement of the vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against other global public health threats.

As at December 31, 2025, the Group's portfolio includes three commercial vaccines:

- IXIARO, (or JESPECT in Australia and New Zealand), is an inactivated Vero cell culture-derived Japanese encephalitis vaccine;
- DUKORAL is an oral vaccine containing four inactivated strains of the bacterium Vibrio cholerae serotype O1, and part of a toxin from one of these strains as active substances.; and
- IXCHIQ is the world's first licensed chikungunya vaccine available to address this unmet medical need and the third vaccine we brought from early R&D to approval.

The Company is registered at Îlot Saint-Joseph, Bureaux Convergence, Bât. A, 12 ter Quai Perrache, 69002 Lyon (France). Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada, and the United States and had an average of 694 employees in the year ended December 31, 2025

Valneva SE is a public company listed on the Euronext Paris (symbol: VLA) and on the Nasdaq Global Select Market (symbol: VALN) since May 2021.

#### Significant events of the period and significant agreements

***IXCHIQ – Regulatory Updates***

In 2025 and early 2026, Valneva reported several regulatory updates regarding its chikungunya vaccine, IXCHIQ. The impact of all the IXCHIQ related events have been reflected on the financial statements. For more information please see Note 5.15 Impairment testing and 5.17 Inventories.

***European Medicines Agency (EMA)***

EMA granted a marketing authorization for IXCHIQ for the prevention of chikungunya virus disease in individuals aged 12 years and older in the European Union in April 2025. This approval expanded the vaccine's prior authorization for adult use and was supported by data demonstrating sustained antibody responses in 97% of participants for up to 24 months, with consistent immune durability across age groups.

In May 2025, EMA's safety committee (PRAC) initiated a review of IXCHIQ following reports of serious adverse events (SAEs), mainly in individuals 65 years of age and older with several underlying medical conditions, during an outbreak vaccination campaign on the French island of La Réunion. EMA suspended the use of the vaccine for individuals over 65 years old while the review was ongoing.

In November 2025, EMA announced the lifting of the temporary restriction after concluding its review.

***United States Food & Drug Administration (FDA)***

In August 2025, the FDA suspended the license for IXCHIQ following additional reports of SAEs, requiring the Company to cease shipments and sales of the vaccine in the United States.

In January 2026, the Company decided to voluntarily withdraw the biologics license application (BLA) and investigational new drug (IND) application for IXCHIQ in the United States. The Company had been awaiting further information with respect to its formal response to the license suspension and was informed in January 2026 of the FDA's decision to place the IND on clinical hold pending an investigation of a newly reported SAE in a patient who had received three concomitant vaccines, including IXCHIQ.

***United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA)***

On February 5, 2025, the MHRA granted marketing authorization for IXCHIQ for the prevention of chikungunya virus disease in adults aged 18 and older.

In June 2025, the UK MHRA implemented a temporary suspension on the use of IXCHIQ in elderly adults and in February 2026 updated its recommendation for the use of IXCHIQ in the UK by including a restriction for individuals 60 years of age and older, for people with specified health conditions as well as timing of vaccination prior to travel. The MHRA

confirmed that the benefit–risk profile of IXCHIQ remains favorable for individuals aged 18 to 59 years who are at risk of chikungunya infection and do not have the contraindicated underlying medical conditions.

### *Brazilian National Health Surveillance Agency (ANVISA)*

In April 2025, Brazil's health regulator, ANVISA, granted marketing authorization for IXCHIQ, representing the first approval of a chikungunya vaccine in an endemic country and supporting Valneva's strategy to expand access to the vaccine with support from the Coalition for Epidemic Preparedness Innovations and the European Union.

### *Health Canada*

In August 2025, Health Canada granted marketing authorization for IXCHIQ for the prevention of chikungunya virus disease in individuals aged 12 years and older. This approval expanded the vaccine's prior authorization for adult use and aligned with the adolescent label extension approved in Europe in April 2025.

### *Commercial Agreements and Market Access*

During 2025, Valneva strengthened its commercial partnerships to support the distribution and supply of its commercial vaccines.

In January 2025, Valneva USA, Inc. signed a new $32.8 million supply contract with the United States Department of Defense (DoD) for the supply of Valneva's Japanese encephalitis vaccine, IXIARO. Under the one-year contract, the DoD committed to purchase a minimum of $32.8 million worth of IXIARO vaccines.

In June 2025, Valneva, through its subsidiaries Valneva Austria GmbH and Valneva Sweden AB, entered into exclusive marketing and distribution agreements with CSL Seqirus for the commercialization of Valneva's vaccines in Germany. In July 2025, CSL Seqirus started to commercialize IXCHIQ, followed by IXIARO and the cholera vaccine DUKORAL in 2026. The agreement has a term of three years and replaces the previous partnership with Bavarian Nordic.

### *Research and Clinical Development*

Valneva continued to advance its vaccine development pipeline during the period.

In April 2025, Valneva and LimmaTech Biologics announced the vaccination of the first participant in a Phase 2 study evaluating S4V2, the most clinically advanced tetravalent bioconjugate vaccine candidate against shigellosis. The study is assessing the safety and immunogenicity of S4V2 in approximately 110 nine-month-old infants in Kenya and aims to identify the optimal dose for a future Phase 3 trial.

Shigellosis remains a major global health concern, particularly among children under five years of age. The study is funded by the Gates Foundation, with results expected in the year 2026.

### *Financing Activities*

During 2025, Valneva also strengthened its financial position through capital markets activities and debt refinancing. The Company issued 9.3 million shares under the ATM program, raising €27.4 million, offset by €1.2 million in transaction costs.

In March 2025, Valneva filed a prospectus supplement with the U.S. Securities and Exchange Commission as part of the renewal of its registration statement on Form F-3 related to its existing At-the-Market (ATM) offering program. Originally established in August 2022, the ATM program allows the Company to offer and sell up to $75 million in American Depositary Shares (ADS), each representing two ordinary shares. The Company is not obligated to sell any ADS under the program, and the renewed agreement retains terms similar to the original arrangement.

In October 2025, Valneva entered into a non-dilutive debt refinancing agreement with funds managed by Pharmakon Advisors providing a facility of up to $500 million. The initial tranche of $215.0 million (€183.0 million equivalent as at December 31, 2025) was used to fully repay the existing debt with Deerfield Management and OrbiMed, including related fees and expenses. The remaining $285.0 million may be drawn in the future to support business development opportunities.

The new facility extends Valneva's debt maturity from Q1 2026 to Q4 2030, lowers the interest rate and enhances financial flexibility.

### *Strategic and Operational Updates*

As part of the Group's ongoing efforts to improve operational efficiency, Valneva announced a strategic initiative in November 2025 to optimize its organizational footprint in France. Valneva decided to consolidate its French operations at its Lyon site and close the facility in Saint-Herblain, Nantes, which included operational activities as well as certain pre-clinical research and development functions.

This consolidation is expected to streamline operations in France while centralizing all research and development activities at the Group's site in Vienna.

In December 2025, Valneva and Serum Institute of India mutually agreed to discontinue the license agreement for Valneva's chikungunya vaccine, IXCHIQ. For more information please see Note 5.5 Revenues and 5.28 Contract liabilities.

## 5.1.2 Group information

The following list shows all subsidiaries held by the Company directly or indirectly:

| Name | Country of incorporation | Consolidation Method | Interest held as at December 31, 2025 | Interest held as at December 31, 2024 |
|---|---|---|---|---|
| Vaccines Holdings Sweden AB | SE | Full Consolidation | 100 % | 100 % |
| Valneva Austria GmbH | AT | Full Consolidation | 100 % | 100 % |
| Valneva Canada Inc. | CA | Full Consolidation | 100 % | 100 % |
| Valneva France SAS | FR | Full Consolidation | 100 % | 100 % |
| Valneva Scotland Ltd. | UK | Full Consolidation | 100 % | 100 % |
| Valneva Sweden AB | SE | Full Consolidation | 100 % | 100 % |
| Valneva UK Ltd. | UK | Full Consolidation | 100 % | 100 % |
| Valneva USA, Inc. | US | Full Consolidation | 100 % | 100 % |
| VBC 3 Errichtungs GmbH | AT | Full Consolidation | 100 % | 100 % |

The closing date for the consolidated financial statements is December 31 of each year.

The Company previously maintained a site in Saint-Herblain, Nantes (France) with general and administrative functions as well as research and development facilities with a site in Lyon. During the first part of 2026, the Company will consolidate its French operations at its Lyon location, which serves as a base for commercial activities, and close the Saint-Herblain, Nantes (France) site, This consolidation is intended to streamline operations and improve efficiency in France, while all research and development activities are centralized at the Group's site in Vienna.

Vaccines Holdings Sweden AB, located in Solna, Sweden, is the holding company of Valneva Sweden AB, also located in Solna, which manufactures DUKORAL and commercializes DUKORAL, IXIARO, and IXCHIQ in the Nordic countries.

Valneva Austria GmbH, located in Vienna, Austria, focuses on pre-clinical and clinical development activities of vaccines. The facilities accommodate departments for pre-clinical R&D, technical/clinical product development, quality and regulatory affairs, general and administrative as well as commercial functions. In addition to using its latest-stage laboratory facilities for R&D activities, the site holds a certificate of Good Manufacturing Practice from the Austrian Agency for Health and Food Safety (AGES) for its Quality Control laboratories, and was licensed by the U.S. Food and Drug Administration (FDA). Valneva Austria GmbH commercializes IXIARO, DUKORAL,and IXCHIQ and third-party products such as Rabipur/RabAvert and Encepur. Additionally, Valneva Austria GmbH is involved in external manufacturing steps of IXCHIQ.

Valneva Canada Inc., located in Kirkland, Canada, focuses on commercializing IXIARO, DUKORAL, IXCHIQ, and third-party products such as KAMRAB.

Valneva France SAS, located in Lyon, France, focuses on commercializing IXIARO, DUKORAL, IXCHIQ, and previously also commercialized third-party products such as Rabipur/RabAvert and Encepur.

Valneva Scotland Ltd., located in Livingston, Scotland (United Kingdom) is primarily involved in the production of IXIARO and IXCHIQ and provides R&D support to the business as and when required.

Valneva UK Ltd., located in Fleet, England (United Kingdom), focuses on commercializing DUKORAL, IXIARO, and IXCHIQ in the United Kingdom.

Valneva USA, Inc., located in Bethesda, Maryland (USA), focuses on the commercialization of IXIARO to the U.S. military and the U.S. private market and previously also commercialized IXCHIQ in the U.S.

VBC 3 Errichtungs GmbH (Vienna, Austria), owns the Laboratory and Office building used by Valneva Austria GmbH.

## 5.2 Summary of significant accounting policies

The principal accounting policies applied in preparing these consolidated financial statements are outlined below. These policies have been consistently applied to all years presented.

### 5.2.1 Basis of preparation

These 2025 Consolidated Financial Statements have been prepared in accordance with the International financial reporting standards, which comprise IFRS (International Financial Reporting Standards), IAS (International Accounting Standard) and their interpretations, and IFRIC (International Financial Reporting Interpretations Committee), as issued by the International Accounting Standards Board (IASB).

The preparation of financial statements in conformity with IFRS as issued by the IASB requires the use of certain critical accounting estimates. It also requires the Group's management to exercise its judgement in applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 5.3.

The accounting policies are disclosed in Note 5.1 General information to Note 5.35 Events after the reporting period. The accounting policies that management considered critical are disclosed in Note 5.5.2 Other revenues.

For ease of presentation, numbers have been rounded and, where indicated, are presented in thousands of Euros. Calculations, however, are based on exact figures. Therefore, the sum of the numbers in a column of a table may not conform to the total figure displayed in the column.

These consolidated financial statements were approved and authorized for issuance by the Board of Directors on March 17, 2026.

### 5.2.2 Impact of new, revised or amended Standards and Interpretations

#### Standards, amendments to existing standards and interpretations issued by IASB whose application has been mandatory since January 1, 2025

| New standards, Interpretations and amendments adopted by the Group | | Effective date | Effects |
|---|---|---|---|
| IAS 21 | Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability | January 1, 2025 | none |
| Editorial Corrections (various) | Periodically issued IASB Editorial Corrections and changes to IFRSs and other pronouncements. | March 31, 2025 | none |
| Disclosures about Uncertainties in the Financial Statements (Illustrative Examples) | A set of examples that illustrate the reporting of the effects of uncertainties in financial statements through climate-related fact patterns | November 28, 2025 | none |

The amendments listed above did not have any material impact on the amounts recognized in prior periods and are not expected to affect the current or future periods.

#### Standards, amendments to existing standards and interpretations whose application is not yet mandatory.

The Group did not elect to apply early the following new standards, amendments, and interpretations which were issued but not mandatory as at January 1, 2025.

| New standards, Interpretations and amendments | | Effective date | Effects |
|---|---|---|---|
| IFRS 18 | New standard, IFRS 18 Presentation and Disclosures in Financial Statements | January 1, 2027 | under assessment |
| IFRS 19 | New standard, IFRS 19 Subsidiaries without Public Accountability: Disclosures | January 1, 2027 | none |
| IFRS 7 & IFRS 9 | Amendments IFRS 9 and IFRS 7 regarding the classification and measurement of financial instruments | January 1, 2026 | none |
| Annual improvements to IFRS – Volume 11 | Amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards: Hedge accounting by a first-time adopter | January 1, 2026 | none |
| | Amendments to IFRS 7 Financial Instruments: Disclosures: Gain or loss on derecognition, Disclosure of deferred difference between fair value and transaction price, Introduction and credit risk disclosures | January 1, 2026 | none |
| | Amendments to IFRS 9 Financial Instruments: Lessee derecognition of lease liabilities, Transaction price | January 1, 2026 | none |
| | Amendments to IFRS 10 Consolidated Financial Statements: Determination of a 'de facto agent' | January 1, 2026 | none |
| | Amendments to IAS 7 Statement of Cash Flows: Cost method | January 1, 2026 | none |
| IFRS 7 & IFRS 9 | Amendments IFRS 9 and IFRS 7 regarding the application of the 'own use' exemption to Power Purchase Agreements (PPAs) | January 1, 2026 | none |
| IFRS 19 | The amendments cover new or amended IFRS Accounting Standards issued between 28 February 2021 and 1 May 2024 that were not considered when IFRS 19 Subsidiaries without Public Accountability: Disclosures was first issued. | January 1, 2027 | none |
| IAS 21 | The amendments clarify how companies should translate financial statements from a non-hyperinflationary currency into a hyperinflationary one. | January 1, 2027 | none |

These standards and amendments are not expected to have a material impact on the entity in the current reporting periods and on foreseeable future transactions, except IFRS 18 which is currently under assessment.

## 5.2.3 Consolidation

### Subsidiaries

Subsidiaries are entities over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date that control ceases.

The Group applies the acquisition method of accounting for all business combinations. The consideration transferred for the acquisition of a subsidiary is the fair value of assets transferred, the liabilities incurred, and the equity interests issued by the Company. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Acquisition-related costs, other than those associated with the issue of debt or equity securities, are expensed as incurred. Identifiable assets acquired, liabilities, and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the consideration transferred over the fair value of the Company's share of the identifiable net assets acquired is recorded as goodwill. If the fair value of the net assets of the acquired subsidiary exceeds the consideration, the difference is recognized directly in the income statement as a bargain purchase gain. Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated.

## 5.2.4 Foreign currency translation

### Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Euros, which is Valneva SE's functional and presentation currency.

### Transactions and balances

Foreign currency transactions are converted into the functional currency using exchange rates applicable on the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in the income statement.

### Subsidiaries

The results and financial position of all subsidiaries (none of which have the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are converted into the presentation currency as follows:

- assets and liabilities presented for each balance sheet are converted according to the exchange rate valid on the balance sheet date;

- income and expenses for each income statement are converted at monthly average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are converted on the dates of the transactions); and
- all resulting exchange differences are recognized as other comprehensive income and are shown as other reserves.

When a foreign operation is partially disposed of or sold, exchange differences that had been recorded in equity are recognized in the income statement as part of the gain or loss on sale.

### 5.2.5 Financial risk management

The Group's activities expose it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk, and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

Financial risk management is carried out under the responsibility of the CFO. The Group's risk management systems identify, evaluate, and manage financial risks. The Audit Committee of the Group's Board of Directors receives regular reports on the Group's risk management systems, including the management of financial risks.

#### Market risk

##### *Foreign exchange risk*

The Group operates internationally and is exposed to foreign exchange risks arising from various currencies, primarily with respect to the British Pound (GBP), the Canadian Dollar (CAD), the Swedish Krona (SEK), and the U.S. Dollar (USD). The foreign exchange risks from the exposure to other currencies are relatively limited. Foreign exchange risks arise from future commercial transactions, recognized assets and liabilities, and net investments in foreign operations.

The objective of the Group is to limit the potential negative impact of the foreign exchange rate changes, for example by currency conversion of cash and cash equivalents denominated in foreign currency and by balancing foreign currency assets and liabilities to the extent possible. The Group has certain investments in foreign operations, the net assets of which are exposed to foreign currency translation risk. Please refer to Note 5.16.3 for an analysis of the impact from changes in exchange rates on the pre-tax result.

##### *Interest rate risk*

The Group analyzes its interest rate exposure on a dynamic basis. Based on this analysis, the Group calculates the impact on profit and loss of a defined interest rate change. The same interest rate change is used for all currencies. The calculation only includes investments in financial instruments and cash in banks that represent major interest-bearing positions. As at December 31, 2025 and December 31, 2024, no material interest risk was identified. In case of increasing interest rates the positive effect from cash in banks will be higher than the negative effect from variable interest-bearing liabilities; in case of decreasing interest rates there will be no material negative impact.

#### Credit risk

The Group is exposed to credit risk which is the risk of financial loss if customers or counterparties to a financial instrument fail to meet their contractual obligations.

Valneva holds bank accounts, cash balances, and securities at sound financial institutions with high credit ratings. To monitor the credit quality of its counterparts, the Group relies on credit ratings as published by specialized rating agencies such as Standard & Poor's, Moody's, and Fitch. The Group has policies that limit the amount of credit exposure to any single financial institution. The Group is also exposed to credit risks from its trade debtors, as its income from product sales, collaborations, licensing, and services arises from a small number of transactions. The Group has policies in place to enter into such transactions only with highly reputable, financially sound counterparts. If customers are independently rated, these ratings are used. Otherwise, when there is no independent rating, a risk assessment of the credit quality of the customer is performed, taking into account its financial position, past payment experience and other relevant factors. Individual credit limits are set based on internal or external ratings in accordance with signature authority limits. The credit quality of financial assets is described in Note 5.16.4.

#### Liquidity risk

The Group is exposed to liquidity risk due to the maturity of its financial liabilities and the fluctuations of its operating cash flow, and the potential implementation of early repayment clauses in the grant agreements (see Note 5.8.1). Furthermore, fluctuations in the Group's operating cash flow during accounting periods also generate liquidity risks. Prudent liquidity risk management therefore implies maintaining sufficient cash resources, cash equivalents, and short-term deposits in order to satisfy ongoing operating requirements and the ability to close out market positions. Extraordinary conditions on the financial markets may, however, temporarily restrict the possibility to liquidate certain financial assets.

Although it is difficult to predict future liquidity requirements, the Group considers that the existing cash and cash equivalents as at December 31, 2025 will be sufficient to fund its operations for at least 12 months from the date of authorization for issuance of these consolidated financial statements. The Pharmakon Loan Agreement signed in 2025 does not include any financial covenants and this new facility extends repayment from Q1 2026 to Q4 2030, has a more favorable interest rate, and enhances financial flexibility. The previous loan agreement (the D&O Loan Agreement) with U.S. healthcare investment firms Deerfield Management Company and OrbiMed contained covenants related to minimum liquidity and minimum revenue (see Note 5.24.1). No adjustments were made to the D&O Loan Agreement covenants in 2024 or 2025. If the primary endpoint of the VLA 15 Phase 3 trial is not met, the Group will be required to undergo

restructuring and implement cost-containment measures that would allow the Group to meet its financial obligations for the foreseeable future but would significantly impact its operations and prospects. These restructuring measures would require alignment with Pharmakon to avoid an event of default. The Company cannot guarantee such measures would be sufficient in the long term and renegotiation of existing debt terms or alternative measures to refinance or repay the debt may be required.

The table below analyzes the Group's financial liabilities into relevant maturity groupings based on the remaining period from the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

**Balance as at December 31, 2025**

| *in € thousand* | Less than 1 year | Between 1 and 3 years | Between 3 and 5 years | Over 5 years | Total |
|---|---|---|---|---|---|
| Borrowings | 17,905 | 33,439 | 215,495 | 851 | 267,690 |
| Lease liabilities | 2,739 | 5,572 | 5,414 | 14,357 | 28,082 |
| Refund liabilities | 10,814 | 6,684 | — | — | 17,498 |
| Trade payables and accruals | 24,540 | — | — | — | 24,540 |
| Tax and employee-related liabilities (1) | 12,642 | — | — | — | 12,642 |
| Other liabilities | 7 | — | — | — | 7 |
| **TOTAL** | **68,648** | **45,696** | **220,908** | **15,208** | **350,460** |

*(1) Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required for financial instruments only.*

**Balance as at December 31, 2024**

| *in € thousand* | Less than 1 year | Between 1 and 3 years | Between 3 and 5 years | Over 5 years | Total |
|---|---|---|---|---|---|
| Borrowings | 20,852 | 132,489 | 33,349 | 683 | 187,373 |
| Lease liabilities | 2,508 | 5,203 | 5,083 | 16,147 | 28,941 |
| Refund liabilities | 19,650 | 6,491 | — | — | 26,141 |
| Trade payables and accruals | 35,522 | — | — | — | 35,522 |
| Tax and employee-related liabilities (1) | 13,107 | — | — | — | 13,107 |
| Other liabilities | 79 | — | — | — | 79 |
| **TOTAL** | **91,719** | **144,183** | **38,432** | **16,829** | **291,163** |

*(1) Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required for financial instruments only.*

The fair values as well as the book values of the Group's borrowings are disclosed in Note 5.24. To manage liquidity risk, the Group holds a combination of cash, cash equivalents and short-term deposit balances.

## 5.2.6 Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide benefits for shareholders and for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. The Group actively manages its funds to primarily ensure liquidity and principal preservation while seeking to maximize returns. The Group's cash and short-term deposits are located at several different banks. In order to maintain or adjust the capital structure, the Group may issue new shares or sell assets to reduce debt.

In order to pursue its business strategy to grow into a major, self-sustained vaccine company through organic growth and opportunistic mergers & acquisitions, the Group may rely on additional equity and debt financing. Capital consists of "Equity" as shown in the consolidated balance sheet.

## 5.2.7 Fair value estimation

The carrying value less impairment provision of trade receivables and payables are assumed to approximate their fair values due to the relatively short maturity of the respective instruments.

## 5.3 Critical accounting judgements and key sources of estimation uncertainty

In applying the Group's accounting policies, which are described in Note 5.2: Summary of significant accounting policies, management is required to make judgements (other than those involving estimations) that have a significant impact on the amounts recognized and to make estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

### 5.3.1 Critical Accounting Policies, Practices, and Estimate

The following is the critical judgement, apart from those involving estimations (which are presented separately below), that management has made in the process of applying the Group's accounting policies and that has the most significant effect on the amounts recognized in financial statements:

- Note 5.5.2 Other revenues and Note 5.29 Refund liabilities: The recognition of other revenues and refund liabilities involves significant management judgement in estimating and updating the transaction price in accordance with IFRS 15. Management is required to assess the nature and amount of variable consideration and to determine whether such amounts are subject to the constraint on variable consideration. Variable consideration is included in the transaction price only to the extent that it is highly probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Management reassesses the estimated transaction price and the application of the constraint at each reporting date. Revenue is only recognized when it is highly likely that it will not reverse in future, and this is a judgement required from management. In particular, Note 5.5.2 underlines the judgements made in applying accounting policies, which are most relevant with respect to the Research Collaboration and License Agreement with Pfizer.

### 5.3.2 Key sources of estimation uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty in the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below:

- Note 5.15 Impairment testing: Impairment test of intangible and tangible assets and right of use assets: key assumptions underlying recoverable amounts. Budgets comprise forecasts of revenue, staff costs, and overheads based on current and anticipated market conditions that have been considered and approved by the Executive Committee and the Board of Directors. The revenue projections are inherently uncertain due to the short-term nature of the business and unstable market conditions. If the Group does not successfully develop vaccine candidates and receive regulatory approval, or if Valneva fails to successfully manufacture or commercialize approved vaccines, an impairment may be required. For the main estimates and sensitivities related to the impairment test regarding the CGU, see Note 5.15;
- Note 5.17 Inventories: Write-down analysis for inventories: For the assessment of write-down of raw material the current production plans have been taken into account. Raw material which will not be used before its expiry date is written down. For the assessment of write-downs of work in progress, finished goods, and purchased goods, the forecasted sales plans and a minimum shelf life at the time of the most current sales expectation are taken into account. In addition, inventories are assessed on the likelihood of the release of the relevant products. The Group manufactures inventories through a number of production sites and allocates production overheads to inventories on the basis of normal operating capacity, in line with IAS 2. Where actual production is below normal capacity, the related unallocated fixed overheads are recognised as an expense and excluded from inventory valuation. The assessment of what constitutes normal capacity, and whether under-absorption of overheads arises from below normal idle capacity rather than ordinary production variability, involves significant judgement. This assessment is based on expected production volumes, historical utilization levels, scheduled maintenance, temporary shutdowns, market conditions and other plant-specific factors.
- Note 5.23 Share-based compensation: Share-based payments and related expected employer contribution costs: assumption for fair value determination, including performance conditions, as well as the determination of accelerated vesting in the event of a change of control (as considered remote);
- Note 5.29 Refund liabilities: Recognition of the refund obligation related to the Pfizer Collaboration and License Agreement;
- Notes 5.30 Provisions and 5.33 Commitments and contingencies: Recognition and measurement of provisions and contingencies: key assumptions about the likelihood and magnitude of an outflow of resources. In estimating the provision for onerous contracts, management makes assumptions regarding the likelihood of termination costs for certain agreements. In estimating the restructuring provisions management assesses the timing and amount of expected costs, including employee termination benefits, contract termination penalties, and other direct expenditures. In accordance with IAS 37, the Company recognizes contingent assets only when the inflow of economic benefits is virtually certain. Management applies significant judgment in evaluating whether claims for indemnities or reimbursements from Contract Manufacturing Organizations relating to the disposal of the Company's products during manufacturing activities meet this threshold; accordingly, receivables and related income for claims

associated with accidental disposal and spillage events are recognized only once formal acknowledgment of liability has been obtained.;

- Note 5.8.2 Research and development tax credits: The recognition of Research and development tax credits on other income integrated assumptions on the eligible expenses, reflecting the management's best estimate of the final submission to the tax authority.

### 5.3.3 Measurements of fair values

A number of the Group's accounting policies and disclosures require the measurement of fair values, for both financial and non-financial assets and liabilities.

When measuring the fair value of an asset or a liability, the Group uses observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

Further information about the assumptions made in measuring fair values is included in the following Notes:

- Note 5.16: Financial instruments and
- Note 5.23: Share-based compensation.

## 5.4 Segment information

The Executive Committee, as the Company's chief operating decision maker ("CDM"), considers Valneva's operating business in its entirety to allocate resources and assess performance. The Executive Committee evaluates all vaccine candidates and vaccine products together as a single operating segment, "development and commercialization of prophylactic vaccines". Therefore, the split used to allocate resources and assess performance is based on a functional view, thus correlating to the income statement.

## 5.5 Revenues

Revenues include both revenues from contracts with customers and other non-IFRS 15 revenues (mainly subleases) which are out of scope from IFRS 15:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | **2025** | **2024** | **2023** |
| Product sales | 157,908 | 163,253 | 144,624 |
| Other revenues from contracts with customers | 16,097 | 5,622 | 8,075 |
| Other non-IFRS 15 revenue | 653 | 704 | 1,014 |
| **REVENUES** | **174,659** | **169,579** | **153,713** |

### 5.5.1 Product sales

The Group mostly generates product sales revenues from the sale of its commercialized travel vaccines and from the sale of third-party products.

The Group's product sales contracts generally include one type of performance obligation. Revenue is recognized at the point in time when the identified performance obligation is transferred to the customer, either when the customer obtains control over the goods at the time of shipment or when the product is received by the customer, which generally happens within a few days, depending on the terms of the agreement. Sales contracts with retailers and the U.S. Department of Defense (DoD) are shown as "direct product sales", whereas sales to the other distributors are reported as "indirect sales - sales through distributors".

Some of the Group's product sales agreements include retrospective rebates, charge-back clauses, discounts, and under certain conditions return rights, which give rise to variable consideration under IFRS 15. The constraints on variable consideration (expected rebates, discounts and considerations for product returns) are taken into account and

recognized on an accrual basis and reported as refund liabilities or as contract liabilities (for replacement doses) in the consolidated balance sheet.

In most cases, Valneva sells its products through distributors. Valneva is acting as principal given that it controls such products before transferring them to the final customer. More specifically, Valneva assumes the inventory risk before the goods are transferred to customers and has discretion in establishing prices for such goods. Revenue is recognized when the product is delivered to the end customers.

Valneva also sells products acquired from third parties. Valneva considers that it is acting as principal given that it controls such products before transferring them to the final customer. More specifically, Valneva assumes the inventory risk before the goods are transferred to customers and has discretion in establishing prices for such goods. Revenue is recognized when the product is delivered to the customers. Products purchased from third parties are recognized as "inventory" in the balance sheets and when sold as "cost of goods" in the statements of income.

### 5.5.2 Other revenues

The Group generates other revenues from its products, product candidates, and proprietary technologies. The contracts in place often include several different promised goods or services such as research licenses, commercial licenses, and further R&D services. The terms of such agreements include license fees received as initial fees, annual license maintenance fees, and fees to be paid upon achievement of milestones, as well as license option fees and fees for the performance of research services. In addition, the Group's licensing arrangements generally provide for royalties payable on the licensee's future sales of products developed within the scope of the license agreement. Furthermore, revenue recognized due to the termination of agreements is recognized in other revenues.

The Group's existing license contracts provide distinct right to use licenses, and therefore revenue is recognized at the point in time at which the licensee is able to direct the use of and benefit from the license. The consideration for licensing contracts may consist of fixed and variable parts. In case of right-to-use licenses, the fixed part of the consideration is recognized at the point in time when the licensee is able to direct the use and benefit from the license. For any variable consideration, revenue is recognized at the point in time when the variable consideration constraint is removed.

Revenue for research and development services within the Group's contracts currently in place is recognized over time. The progress is measured on an input basis (costs incurred related to total costs expected). This input method is considered an appropriate measure of the progress towards complete satisfaction of these performance obligations under IFRS 15.

Variable considerations are included in revenues only to the extent that it is highly probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the end of each reporting period, the Group updates the estimated transaction price and its assessment of whether an estimate of variable consideration is constrained. Amounts allocated to a satisfied performance obligation are recognized as revenue, or as a reduction of revenue, in the period in which a change in estimate of variable consideration occurs. Revenues from license royalties are recognized when the underlying product sales occur.

#### Lyme - Pfizer Collaboration and License Agreement

In April 2020, Valneva signed the Collaboration and License Agreement with Pfizer to co-develop and commercialize the Group's Lyme disease vaccine candidate (VLA15). This is classified as an agreement with a customer as defined by IFRS 15 guidance on revenue contracts with customers, and accordingly, amounts received by or payable to Valneva under the Collaboration and License Agreement are accounted for in the Group's revenues.

The considerations for this Agreement include a variable part. Variable considerations derive from upfront and milestone payments received and to be received from Pfizer, contributions from Valneva to Pfizer in shared development costs and circumstances that could potentially increase future payments to Pfizer. At the end of each reporting period, Valneva updates the estimated transaction price and its assessment of whether an estimate of variable consideration is constrained. Revenue is recognized when the variable consideration constraint is removed and it is highly probable that a significant revenue reversal will not occur.

In 2021 and 2022, several amendments were made to the Collaboration and License Agreement. This resulted in an increase in the expected payments to customer related to Valneva's contribution to Pfizer's future development costs. Therefore, for the year ended December 31, 2022, the accumulated revenue recognized since the inception of the agreement with Pfizer amounting to €45.9 million was reversed as other revenues from contracts with customers. In the years ended December 31, 2023 and December 31, 2024, no revenues were recognized as Valneva determined that entitlement to the consideration was not yet highly probable, due to the possibility of increased payments to customers while R&D activities (including the Phase 3 study) are progressing ahead of possible BLA licensure submission to the FDA.

As of December 31, 2025, Valneva reassessed its entitlement to the consideration and the related refund liability. The Phase 3 clinical trial is nearing completion, and the data readout is expected within the first half of 2026. Based on the updated development budget, Valneva determined the probability and magnitude of any further change in the payment to customer.

Due to project progress, Valneva concluded that a portion of the outstanding refund liability no longer represented an obligation to refund consideration to Pfizer and could therefore be released to revenue. For the year ended December 31, 2025, Valneva recognized revenues for R&D work and additional support services of €10.0 million, corresponding to the amount of the refund liability that the Group no longer expects to settle through future payments to Pfizer. As at

December 31, 2025, the remaining refund liability related to the Collaboration and License Agreement with Pfizer amounted to €9.0 million, representing Valneva's best estimate of the portion of consideration that may still need to be refunded through its ongoing contribution to Pfizer's development costs.

While license and equipment performance obligations were fulfilled in prior periods, the R&D activities and additional services were ongoing through 2025 and satisfy the performance obligation over time. During this period, Valneva funded 40% of the ongoing shared development costs.

Items not included in the transaction price as of December 31, 2025 are (i) $143 million from early commercialization milestones, (ii) royalties, ranging from 14% to 22%, and (iii) $100 million in sales based milestones, which will be recognized as and when they occur.

### 5.5.3 Disaggregated revenue information

The Group's revenues are disaggregated as follows:

#### Type of goods or service

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | **2025** | **2024** | **2023** |
| IXIARO® | 98,419 | 94,069 | 73,483 |
| DUKORAL® | 31,909 | 32,303 | 29,775 |
| Third party products | 19,159 | 33,185 | 35,675 |
| IXCHIQ® | 8,421 | 3,696 | — |
| VLA2001 | — | — | 5,691 |
| **PRODUCT SALES** | **157,908** | **163,253** | **144,624** |
| Royalties received | 2,124 | 2,410 | 2,129 |
| Revenues from shipping and handling | 481 | 1,368 | 21 |
| R&D work and additional support services | 9,985 | — | — |
| Milestone payment - licenses | 3,421 | 712 | 3,637 |
| Other services | 87 | 1,133 | 2,288 |
| thereof COVID-19 | — | — | 1,973 |
| **OTHER REVENUES FROM CONTRACTS WITH CUSTOMERS** | **16,097** | **5,622** | **8,075** |
| Other non-IFRS 15 revenue | 653 | 704 | 1,014 |
| **REVENUES** | **174,659** | **169,579** | **153,713** |

In the year ended December 31, 2025, product sales for all active products decreased by €5.3 million compared to the same period in 2024.

IXIARO sales showed a 5% increase, which was mainly driven by the increased order volume in the UK due to the limited supply in the prior year, as well as increased order volumes in France and other European markets as the result of the growth in the travel market.

DUKORAL sales in 2025 were 1% lower compared to 2024. This decrease resulted from lower market demand in Germany, which is partly offset by an increased demand due the cholera outbreak in Mayotte, France.

IXCHIQ sales were €8.4 million in 2025 compared to €3.7 million in 2024, as the vaccine was launched at the end of the first quarter of 2024. Sales in 2025 included all doses Valneva supplied to France's island La Réunion to respond to the chikungunya outbreak and were adversely impacted by the suspension of the license by the FDA in August 2025.

Third-party product sales in 2025 were 42% lower compared to 2024, which was mainly driven by discontinuation of distribution of Rabipur®/RabAvert® and Encepur® in UK and Canada as well the termination of the distribution agreement of FLUAD in Austria.

Revenues from shipping and handling decreased in 2025 to €0.5 million. In 2024, revenues included an additional one time revenue for freight costs due to a revised customer agreement.

Revenues from milestone payments and licenses increased by €2.7 million in 2025 compared to 2024, mainly related to the exclusive license agreement with Serum Institute of India for Valneva's single-shot chikungunya vaccine amounting to €2.5 million.

R&D work and additional support services shows revenues recognized under the Collaboration and License Agreement with Pfizer amounting to €10.0 million.

Other service revenues decreased by 92% to €0.1 million in 2025. This change is mainly due to fewer services being provided by the Group in 2025 compared to the prior year.

### Sales channels for product sales

Products are sold via the following sales channels:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| Direct product sales | 130,755 | 137,889 | 119,305 |
| Indirect product sales | 27,153 | 25,365 | 25,320 |
| **TOTAL PRODUCT SALES** | **157,908** | **163,253** | **144,624** |

### Geographical markets

In presenting information on the basis of geographical markets, revenue is based on the final location where Valneva's distribution partner sells the product or where the customer/partner is located.

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| United States | 53,610 | 48,593 | 32,964 |
| Canada | 30,125 | 32,321 | 28,193 |
| Germany | 17,468 | 18,374 | 13,503 |
| France | 14,668 | 7,220 | 5,866 |
| Nordics | 13,898 | 13,937 | 12,695 |
| Other Europe | 13,877 | 9,056 | 9,335 |
| United Kingdom | 12,644 | 19,489 | 20,266 |
| Austria | 9,473 | 15,897 | 14,583 |
| Rest of World | 8,897 | 4,691 | 16,308 |
| **REVENUE TOTAL** | **174,659** | **169,579** | **153,713** |

*Nordics includes Finland, Denmark, Norway and Sweden and Rest of World includes India, Israel, Australia, Peru, Japan, Brazil and New Zealand.*

In the year ended December 31, 2025, total revenues increased by €5.1 million compared to the year ended December 31, 2024. Revenues from the U.S. market increased by €5.0 million, primarily due to the recognition of variable consideration relating to the research collaboration and licensing agreement with Pfizer for the Lyme disease program amounting to €10.0 million. This increase was partly offset by the decline in product sales to the U.S. military by 4%, which is primarily due to the timing of the DoD contract.

### Information about major customers

The concentration risk from the customer portfolio of the Group is limited. In 2025, there were three customers with a contribution exceeding 10% of the annual revenue.

Sales to customers representing more than 10% of the total revenues amounted to €77.9 million in 2025 (2024: €76.0 million, 2023: €67.1 million) and consisted solely of product sales.

## 5.5.4 Assets and liabilities related to contracts with customers

See Note 5.18 for details on trade receivables, Note 5.19 for details on costs to obtain a contract, Note 5.28 for details of contract liabilities and Note 5.29 for details of refund liabilities.

## 5.6 Expenses by nature

The consolidated income statement line items cost of goods and services, research and development expenses, marketing and distribution expenses, and general and administrative expenses include the following items by nature of cost:

| | | Year ended December 31, | | |
|---|---|---|---|---|
| *in € thousand* | ***Note*** | **2025** | **2024** | **2023** |
| Consulting and other purchased services | | 68,638 | 65,783 | 80,988 |
| Cost of services and change in inventory | | 15,001 | 13,681 | 11,417 |
| Employee benefit expense other than share-based compensation | *5.7* | 89,386 | 83,028 | 72,997 |
| Share-based compensation expense | *5.7* | 9,571 | 8,710 | 6,276 |
| Raw materials and consumables used | | 15,253 | 21,982 | 14,113 |
| Depreciation and amortization and impairment | *5.12/13/14* | 22,645 | 19,586 | 16,853 |
| Building and energy costs | | 15,662 | 13,908 | 13,088 |
| Supply, office and IT costs | | 9,711 | 7,682 | 11,663 |
| License fees and royalties | | 3,648 | 4,065 | 5,492 |
| Advertising costs | | 9,040 | 16,781 | 13,361 |
| Warehousing and distribution costs | | 4,595 | 5,790 | 3,939 |
| Travel and transportation costs | | 1,634 | 3,197 | 2,700 |
| Other expenses | | 2,337 | 3,593 | 4,432 |
| **OPERATING EXPENSES** | | **267,120** | **267,788** | **257,320** |

Operating expenses in the year ended December 31, 2025 amounted to €267.1 million, which was a slight decrease compared to the €267.8 million in the year ended December 31, 2024. Operating expenses increased slightly by €10.5 million in the year ended December 31, 2024 from €257.3 million in the year ended December 31, 2023.

The increase in expenses for "consulting and other purchased services" in the year ended December 31, 2025 compared to 2024 comes from the increase in research and development primarily related to chikungunya Phase 4 and pediatric studies, as well for the Shigella vaccine candidate. During the comparison period of 2023, Valneva incurred higher service fees for clinical studies related to research and development of the Zika vaccine candidate and higher expenditures on the COVID-19 vaccine, VLA2001.

Expenses for "cost of services and change in inventory" increased in the year ended December 31, 2025 by €1.3 million compared to 2024, mainly driven by one-off expenses related to the transfer to the new manufacturing site Almeida in Scotland and higher inventory write-offs based on revised forecast market demand and sales expectations

Expenses for "Raw materials and consumables used" decreased in the year ended December 31, 2025 by €6.7 million, compared to 2024, mostly due to lower sales volumes across the commercial portfolio and to improvement in manufacturing performances.

"Employee benefit expenses other than share-based compensation" increased in the year ended December 31, 2025 compared to December 31, 2024 primarily related to the closure of the Nantes site in France (see Note 5.7). The increase in the year ended December 31, 2024 compared to December 31, 2023 was due to inflation-related higher salaries and social security contributions. During 2025, the Group had an average of 694 employees (in 2024: 695 employees).

"Share-based compensation expense" increased in the year ended December 31, 2025 compared to 2024 and 2023 due to the introduction of new plans. See Note 5.23 for more information on the share-based compensation plans.

The expense under "depreciation and amortization and impairment" increased in the year ended December 31, 2025 compared to 2024 by €3.1 million due to the fully deployed capacity of the Almeida facility in Livingston.

The decrease in "advertising costs" for the year ended December 31, 2025 compared to the years ended December 31, 2024 and 2023 reflects the higher advertising spend in those years, primarily related to the launch of IXCHIQ in the U.S. in early 2024.

## Principal Accountant Fees and Services

PricewaterhouseCoopers Audit and Deloitte & Associés served as independent auditors for the year ended December 31, 2025 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Valneva and consolidated subsidiaries in the years ended December 31, 2025, 2024, and 2023.

| | Year ended December 31, | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | PricewaterhouseCoopers | | | | | | Deloitte & Associés | | | | | |
| *in € thousand* | 2025 | % | 2024 | % | 2023 | % | 2025 | % | 2024 | % | 2023 | % |
| **Audit fees** | **1,182** | **74%** | **1,710** | **89%** | **2,076** | **98%** | **1,029** | **100%** | **1,311** | **89%** | **1,902** | **99%** |
| provided by the statutory auditor | 1,082 | 68% | 1,272 | 66% | 1,539 | 73% | 939 | 91% | 1,185 | 80% | 1,622 | 84% |
| provided by the statutory auditor's network | 100 | 6% | 439 | 23% | 537 | 25% | 90 | 9% | 126 | 9% | 280 | 15% |
| **Audit-related Fees** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** | **—** | **%** |
| provided by the statutory auditor | — | % | — | % | — | % | — | % | — | % | — | % |
| provided by the statutory auditor's network | — | % | — | % | — | % | — | % | — | % | — | % |
| **Tax Services** | **122** | **8%** | **45** | **2%** | **40** | **2%** | **—** | **%** | **—** | **%** | **—** | **%** |
| provided by the statutory auditor's network | 122 | 8% | 45 | 2% | 40 | 2% | — | % | — | % | — | % |
| **All Other Fees** | **292** | **18%** | **163** | **8%** | **—** | **%** | **—** | **%** | **163** | **11%** | **19** | **1%** |
| **Total** | **1,596** | **100%** | **1,918** | **100%** | **2,116** | **100%** | **1,029** | **100%** | **1,474** | **100%** | **1,921** | **100%** |

Audit-related fees comprised mainly the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees. All other fees are the aggregate fees billed for the limited assurance review of sustainability reporting and verification of disclosure requirements set out in article 8 of Regulation (EU) 2020/852.

# 5.7 Employee benefit expense

Employee benefit expenses include the following:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| Salaries | 67,801 | 63,313 | 55,793 |
| Social security contributions | 19,319 | 16,300 | 14,359 |
| Share-based compensation expense | 9,571 | 8,710 | 6,276 |
| Training and education | 597 | 1,582 | 1,292 |
| Other employee benefits | 1,669 | 1,833 | 1,553 |
| **TOTAL EMPLOYEE BENEFIT EXPENSE** | **98,957** | **91,739** | **79,273** |

For the year ended December 31, 2025 employee benefit expenses increased by €7.2 million compared to the year ended December 31, 2024. This was primarily driven by leaving indemnity payments, which rose by €4.3 million and related to social contributions which increased by €2.8 million compared to prior year. These increases mainly resulted from the closure of the Nantes site in France. The overall rise in employee benefit expenses was partially offset by reduced costs for seminars and conferences, reflecting efficiencies achieved through the Company's improvement program, which delivered process optimizations and costs savings compared to the prior year.

In the year ended December 31, 2025, the social security contributions included an expense of €1.4 million (December 31, 2024: income of €1.6 million, December 31, 2023: income of €1.6 million) resulting from the increase of the provision of employer contribution charges on share-based payment programs due to the increase in the share price.

During 2025, the Group had an average of 694 employees (2024: 695 employees, 2023: 684 employees).

# 5.8 Other income/(expenses), net

## Gain from sale of Priority Review Voucher, net

The Company sold the PRV received from the FDA for $103 million (€95 million) on February 2, 2024.

The Company was awarded a tropical disease PRV in November 2023 following the FDA's approval of IXCHIQ, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus.

The net gain from the sale of the PRV amounted to €90.8 million, after deducting expenses in the amount of €4.2 million, which included transaction fees as well as expenses in connection with contractual payment obligations related to the PRV sale.

## Other income and expenses, net

Other income and expenses, net include the following:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| Research and development tax credit | 4,942 | 10,028 | 6,797 |
| Grant income | 5,957 | 10,194 | 11,350 |
| Gain/(loss) on disposal of fixed assets and intangible assets, net | (432) | (445) | (21) |
| Gain/(loss) from revaluation of lease agreements | 1 | 711 | 45 |
| Taxes, duties, fees, charges, other than income tax | (373) | (346) | (475) |
| Miscellaneous income/(expenses), net | 305 | 564 | 3,824 |
| **OTHER INCOME AND EXPENSES, NET** | **10,400** | **20,706** | **21,520** |

Other operating income and expenses decreased by €10.3 million, or 50%, to €10.4 million for the year ended December 31, 2025, from €20.7 million for the year ended December 31, 2024, primarily due to lower grant income and lower research and development tax credit.

Income from the research and development tax credit decreased significantly due to the decrease of the R&D tax credit in Valneva Scotland (see Note 5.8.2 Research and development tax credits).

Grant income decreased considerably due to the final installment of the Scottish Enterprise grant being paid at the beginning of 2025, as well as lower grant income recognized related to the CEPI agreement (see Note 5.8.1 Grants).

The slight decrease in the "miscellaneous income/(expenses), net" for the year ended December 31, 2025 mainly reflects the discontinuation of residual income following the 2023 divestment of the Clinical Trial Manufacturing unit in Solna, with final payments received in 2024.

### 5.8.1 Grants

Grants from governmental agencies and non-governmental organizations are recognized where there is reasonable assurance that the grant will be received and the Group will comply with all conditions.

Grants received as reimbursement of approved research and development expenses are recognized as other income when the related expenses have been incurred and there is reasonable assurance that funds will be received. Advance payments received under such grants are deferred and recognized when the relevant conditions are met. Advance payments received which need to be repaid are recognized as borrowings (see Note 5.24.1 Principal loan).

Government grants received to support the purchase of property, plant and equipment are included in non-current liabilities as deferred government grants and are credited to the income statement on a straight-line basis over the expected lives of the related assets.

During the year ended December 31, 2025 €0.1 million (£0.1 million) of grant income was recognized in connection with support received from Scottish Enterprise, Scotland's national economic development agency, to support research and development as well as manufacturing development activities on the Livingston site.This represents the final amount received from the original agreement spanning over 3 years and compared to €3.7 million (£3.1 million) recognized for the year ended December 31, 2024.

In 2019, the Group signed a funding agreement with CEPI. Valneva received $24.6 million for vaccine manufacturing and late-stage clinical development of its single-dose, live attenuated vaccine against chikungunya. In line with CEPI's commitment to equitable access, the funding underwrote a partnership effort to accelerate regulatory approval of Valneva's chikungunya vaccine for use in regions where outbreaks occur and to support World Health Organization prequalification to facilitate broader access in low- and middle-income countries (LMICs). Valneva has to pay CEPI up to $7.0 million as consideration, upon achievement of certain commercial and related milestones, of which $3.0 million was paid in April 2024. The refundable consideration is accounted for as a loan and measured in accordance with IFRS 9 (see Note 5.24). The difference between the proceeds from CEPI and the carrying amount of the loan is treated under IAS 20 and presented as "Borrowings".

The partnership with CEPI was extended in July 2024 when the Group signed the second funding agreement, which was subsequently amended during 2025. CEPI now provides up to $48.9 million additional funding in the next four years to support broader access to IXCHIQ, in LMICs, as well as post-marketing trials and potential label extensions in children, adolescents, and pregnant women. The proceeds from CEPI are treated under IAS 20 and presented as Grant income. In the year ended December 31, 2025, €5.8 million (December 31, 2024 €6.5 million) of grant income related to the second agreement with CEPI was recognized.

### 5.8.2 Research and development tax credits

Research and development tax credits granted by tax authorities are accounted for as grants under IAS 20. As a consequence, the portion of the research tax credit covering operating expenses is recognized in the income statement in "Other income and expenses, net" and the portion covering capitalized development expenditures under "Intangible assets" is recorded as deduction from the assets relating to fixed assets.

In December 31, 2025, the position included research and development tax credits mainly from Austria (€3.5 million) and France (€1.1 million) whereas in December 31, 2024 Valneva recognized tax credits primarily from Austria (€3.6 million) and from Scotland (€5.2 million).

## 5.9 Finance income/(expenses), net

Interest income is recognized on a time-proportion basis using the effective interest method.

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | **2025** | **2024** | **2023** |
| **FINANCE INCOME** | | | |
| Interest income from other parties | 1,803 | 2,362 | 1,210 |
| Realized gains from cash and cash equivalents | 841 | — | — |
| **TOTAL FINANCE INCOME** | **2,644** | **2,362** | **1,210** |
| **FINANCE EXPENSES** | | | |
| Interest expense on loans | (40,903) | (22,808) | (13,681) |
| Interest expense on refund liabilities | (193) | (360) | (8,419) |
| Interest expenses on lease liabilities | (796) | (813) | (1,183) |
| Other interest expense | (6) | (3) | (42) |
| **TOTAL FINANCE EXPENSES** | **(41,898)** | **(23,984)** | **(23,325)** |
| **FOREIGN EXCHANGE GAIN/(LOSSES), NET** | **7,196** | **(3,193)** | **5,574** |
| **FINANCE INCOME/(EXPENSES), NET** | **(32,058)** | **(24,816)** | **(16,541)** |

Interest income from other parties decreased primarily due to the change in cash management in France. Realized gains from cash and cash equivalents arise from investments in money market funds classified as cash equivalents, as they are highly liquid, readily convertible to a known amount of cash, and carry an insignificant risk of value change.

The interest expense on loans increased significantly in 2025 compared to 2024 due to the repayment of the D&O Loan Agreement and consist of interest expense and related fees amounting to €12.9 million. The D&O Loan Agreement is superseded by the Pharmakon Loan Agreement during 2025. For more details on the new loan see Note 5.24.1 Principal loan. The increase from 2023 to 2024 is attributable to the additional D&O loan draw-down executed in the second half of the year 2023.

The interest expense on refund liabilities remains on a low level for the year ended December 31, 2025 after a significant decrease in 2024 due to the significant payments made to Pfizer during the second half of 2023 and the fulfillment of all payment obligations during the first half of 2024. Please refer to Note 5.29 for more information on the refund liability balances.

The foreign exchange gain/(losses), net are primarily driven by non-cash revaluation results of USD denominated liabilities as the USD depreciated against the EUR by 13% in 2025. A contrary movement of the USD/EUR rate was observed in 2024.

## 5.10 Income tax income/(expense)

The tax expense for the period comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, as the case may be. The current Income tax income/(expense) is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Group's subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions, where appropriate, based on amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred income tax is provided on temporary differences arising on investments in subsidiaries and associates, except where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not be reversed within the foreseeable future.

## 5.10.1 Current income tax

Income tax income/(expense) is comprised of current and deferred tax.

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| **CURRENT TAX** | | | |
| Current income tax charge | (502) | (2,595) | (931) |
| Adjustments in respect of current income tax of previous year | 93 | (119) | (175) |
| **DEFERRED TAX** | | | |
| Relating to origination and reversal of temporary differences | (664) | 1,953 | (1,695) |
| **INCOME TAX BENEFIT/(EXPENSE)** | **(1,073)** | **(761)** | **(2,800)** |

The individual entities' reconciliations, which are prepared on the basis of the tax rates applicable in each country while taking consolidation procedures into account, have been summarized in the reconciliation below. The estimated tax charge is reconciled to the effective tax charge disclosed.

The tax on the Group's loss before tax differs from the theoretical amount that would arise using the weighted average tax rate applicable to profits of the consolidated companies as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| **PROFIT/(LOSS) BEFORE TAX** | **(114,119)** | **(11,486)** | **(98,629)** |
| Tax calculated at domestic tax rates applicable to profits in the respective countries | 26,212 | 2,953 | 23,400 |
| Income not subject to tax (mainly R&D tax credit) | 1,517 | 3,630 | 190 |
| Expenses not deductible for tax purposes | (4,417) | (3,391) | (1,902) |
| Deferred tax asset not recognized | (24,977) | (3,896) | (23,360) |
| Utilization of previously unrecognized tax losses | 246 | 172 | (1,593) |
| Income tax credit/withholding tax/other adjustments | 258 | 168 | 553 |
| Effect of change in applicable tax rate | (12) | (34) | (160) |
| Exchange differences | 7 | (244) | (25) |
| Income tax of prior years | 93 | (119) | 98 |
| Minimum income tax | (1) | — | (2) |
| **INCOME TAX BENEFIT/(EXPENSE)** | **(1,073)** | **(761)** | **(2,800)** |
| Effective income tax rate | — | — | — |

In the year ended December 31, 2025, although the Group operated at a loss overall, there were profitable entities with revenues from the sale of commercialized travel vaccines and from the sale of third-party products.

## 5.10.2 Deferred tax

As at December 31, 2025, the deferred tax assets of €227.6 million (December 31, 2024: €201.4 million) were not recognized as there was not sufficient evidence that adequate taxable profit will be available against which the unused tax losses can be utilized in the foreseeable future. Deferred tax assets were only recognized for entities where sufficient evidence has been provided that adequate taxable profit will be available against which the unused tax losses can be utilized in the foreseeable future.

As at December 31, 2025, the Group had tax losses carried forward of €899.6 million (December 31, 2024: €843.6 million), of which €308.3 million related to Valneva SE (December 31, 2024: €307.3 million), €576.5 million related to Valneva Austria GmbH (December 31, 2024: €516.0 million), €11.6 million related to Valneva Sweden AB (December 31, 2024: €9.2 million), €0.9 million related to Vaccines Holdings Sweden AB (December 31, 2024: €0.8 million) and €2.3 million related to Valneva USA, Inc. (December 31, 2024: zero)

Tax losses carried forward in France, Austria, the United Kingdom, Sweden, and U.S. have no expiry date. The Group is assessing on a regular basis the effective capacity to use these tax losses carried forward. They may be used or maintained dependent on potential changes to the corporate footprint and future profitability.

The gross movement on the deferred income tax account was as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| **BEGINNING OF THE YEAR** | **5,443** | **2,954** | **4,943** |
| Exchange differences | (836) | 536 | (294) |
| Income statement charge / (credit) | (664) | 1,953 | (1,695) |
| **END OF THE YEAR** | **3,943** | **5,443** | **2,954** |

The deferred tax assets and liabilities are allocable to the various balance sheet items as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| in € thousand | 2025 | 2024 | 2023 |
| **DEFERRED TAX ASSET FROM** | | | |
| Tax losses carried forward | 212,876 | 200,153 | 207,858 |
| Fixed assets | 1,339 | 1,444 | 1,765 |
| Inventory | 3,567 | 7,325 | 4,388 |
| Borrowings and accrued interest | 20,824 | 9,909 | 4,722 |
| Provision | 1,793 | 1,564 | 1,501 |
| Other items | 861 | 318 | 217 |
| Non-recognition of deferred tax assets | (227,620) | (201,356) | (204,529) |
| **TOTAL DEFERRED TAX ASSETS** | **13,639** | **19,357** | **15,921** |
| **DEFERRED TAX LIABILITY FROM** | | | |
| Fixed assets | (4,522) | (6,963) | (6,364) |
| Intangible assets | (3,793) | (5,517) | (5,157) |
| Other items | (1,382) | (1,435) | (1,446) |
| **TOTAL DEFERRED TAX LIABILITY** | **(9,697)** | **(13,915)** | **(12,967)** |
| **DEFERRED TAX, NET** | **3,943** | **5,443** | **2,954** |

The corporate income tax rates remained stable across jurisdictions, with the exception of in U.S., where the corporate income tax rate decreased from 27.72% in 2024 to 27.64% in 2025. The deferred tax assets and liabilities presented above as at December 31, 2025 and December 31, 2024 have been adjusted for this change in the tax rate.

## 5.11 Earnings (Losses) per share

### Basic

Basic earnings (losses) per share are calculated by dividing the profit attributable to equity holders of the Company by the weighted average number of outstanding shares during the year, excluding shares purchased by the Company and held as treasury shares (see Notes 5.22 and 5.23).

| | Year ended December 31 | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Net profit (loss) from continuing operations attributable to equity holders of the Company *(in € thousand)* | (115,192) | (12,247) | (101,429) |
| Weighted average number of outstanding shares | 168,179,263 | 145,705,876 | 138,624,381 |
| **BASIC EARNINGS (LOSSES) FROM CONTINUING OPERATIONS PER SHARE *(€ PER SHARE)*** | **(0.68)** | **(0.08)** | **(0.73)** |

### Diluted

Diluted earnings per share are calculated by adjusting the weighted average number of ordinary outstanding shares to assume conversion of all dilutive potential ordinary shares. The Company has share options as dilutive potential ordinary shares. For the share options, a calculation is done to determine the number of shares that could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the monetary value

of the subscription rights attached to outstanding share options. The number of shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the share options.

| | Year ended December 31 | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Profit used to determine diluted earnings per share *(in € thousand)* | (115,192) | (12,247) | (101,429) |
| Weighted average number of outstanding shares for diluted earnings (losses) per share [1] | 168,179,263 | 145,705,876 | 138,624,381 |
| **DILUTED EARNINGS/(LOSSES) FROM CONTINUING OPERATIONS PER SHARE (€ PER SHARE)** | **(0.68)** | **(0.08)** | **(0.73)** |

[1] *Potentially dilutive securities (2025: 4,704,464 share options; 2024: 1,627,520 share options, 2023: 2,861,904) have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact due to the losses reported.*

## 5.12 Intangible assets

### Computer software

Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and implement the specific software. These costs are amortized on a straight-line basis over their estimated useful lives, which is generally between three to six years.

Costs associated with developing or maintaining computer software programs are recognized as expenses when they were incurred.

The costs of computer software subject to a software as a service agreement (SaaS) are recognized as expenses when they are incurred.

### Acquired research and development technology and projects

Acquired research and development technology projects are capitalized. In case of a purchase with variable payments for an intangible asset, Valneva applies the cost accumulation method. Each component of the agreement such as up-front payments, development milestone payments, and sales milestone payment are considered and assessed separately to determine if they meet the capitalization criteria. Valneva chooses to apply the cost accumulation approach for the capitalization of variable or contingent payments and does not estimate and record a liability at the acquisition date.

Amortization of the intangible asset over its useful life starts when the product has been fully developed and is ready for use. These costs are amortized on a straight-line basis over their useful lives. This useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods of 24 years, which is based on the patent life and technological replacement of a newer vaccine generation.

### Development costs

Research expenses are recognized as expenses when incurred. Development expenses incurred on clinical projects (related to the design and testing of new or significantly improved products) are recognized as intangible assets when the following criteria have been fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and to utilize or sell it;
- there is an ability to utilize or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial, and/or other resources to complete the development and to utilize or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as expenses when they are incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its useful life, generally 10 - 15 years. In 2025 and 2024, no development costs were capitalized.

### Amortization

Amortization of intangible assets is calculated using the straight-line method to allocate their cost amounts to their residual values over their estimated useful lives, as follows:

- Software 3 - 6 years
- Acquired R&D technology and projects 1 - 24 years
- Development costs 1 - 15 years

The useful life is determined on a case-by-case basis according to the nature and characteristics of the items included under this heading. The main current acquired research and development technology project is amortized over periods

of 24 years (with a remaining useful life period of 7 years) which is based on estimated period where Valneva benefits from the patent.

| *in € thousand* | Software | Acquired R&D technology and projects | Development costs | Intangible assets in the course of construction | Total |
|---|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2025** | | | | | |
| Opening net book value | 205 | 23,948 | 1,104 | — | 25,258 |
| Additions | 61 | — | — | — | 61 |
| Amortization charge | (82) | (2,685) | (137) | — | (2,904) |
| Impairment charge | (3) | — | — | — | (3) |
| Exchange rate differences | 4 | (58) | (10) | — | (64) |
| **CLOSING NET BOOK VALUE** | **186** | **21,206** | **957** | **—** | **22,349** |
| **AS AT DECEMBER 31, 2025** | | | | | |
| Cost | 5,861 | 83,012 | 7,313 | — | 96,187 |
| Accumulated amortization and impairment | (5,676) | (61,806) | (6,356) | — | (73,838) |
| **CLOSING NET BOOK VALUE** | **186** | **21,206** | **957** | **—** | **22,349** |

| *in € thousand* | Software | Acquired R&D technology and projects | Development costs | Intangible assets in the course of construction | Total |
|---|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2024** | | | | | |
| Opening net book value | 255 | 24,073 | 1,239 | — | 25,567 |
| Additions | 79 | 2,500 | — | — | 2,579 |
| Amortization charge | (126) | (2,687) | (145) | — | (2,958) |
| Impairment charge | — | — | — | — | — |
| Exchange rate differences | (2) | 62 | 11 | — | 71 |
| **CLOSING NET BOOK VALUE** | **205** | **23,948** | **1,104** | **—** | **25,258** |
| **AS AT DECEMBER 31, 2024** | | | | | |
| Cost | 5,823 | 83,349 | 7,345 | — | 96,516 |
| Accumulated amortization and impairment | (5,618) | (59,400) | (6,240) | — | (71,258) |
| **CLOSING NET BOOK VALUE** | **205** | **23,948** | **1,104** | **—** | **25,258** |

As at December 31, 2025, significant intangible assets with finite useful lives (included in acquired R&D technology and projects as well as in development costs) consist primarily of the already commercialized vaccine against Japanese encephalitis (IXIARO) with acquisition costs amounting to €78.8 million (December 31, 2024: €79.1 million) and a net book value of €19.4 million (December 31, 2024: €22.3 million).

In 2024, acquired research and development increased by €2.5 million when the Group entered into a strategic partnership with LimmaTech Biologics to accelerate the development of the world's most clinically advanced Shigella vaccine candidate.

For impairment tests, please see Note 5.15.

## 5.13 Leases (right of use assets)

The Group leases various premises, equipment, and vehicles. Rental contracts are typically made for fixed periods ranging from a few months to five years. The rental contracts for the premises in Sweden (10 and 15 years) include a significantly longer fixed period. Generally, the rental contracts do not include an option for early termination or prolongation of the rental period. The rental contracts for the premises in Sweden include options to terminate the agreements earlier. The notice periods in these contracts are between one and six years. At the commencement date, it was not reasonably certain that these early termination options were to be exercised, so they were not included in the valuation of the lease liabilities and right of use assets. Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, which is generally the case for leases in the Group, the Group uses its incremental borrowing rate. The incremental borrowing rate depends on the term, currency, and start date of the lease and is determined based on a series of inputs including: the risk-free rate

based on government bond rates, a country-specific risk adjustment, a credit risk adjustment based on bond yields, and an entity-specific adjustment when the risk profile of the entity that enters into the lease is different than that of the Group and the lease does not benefit from a guarantee from the Group. Valneva uses incremental borrowing rates between 1.046% and 7.000%, depending on the currency and the remaining term until maturity. For the rental contracts for the premises in Sweden interest rates of 2.493% and 3.401% were determined.

The Group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset. This includes also the major contracts for the premises in Sweden, which contain variable payments based on inflation rates or on published interest rates.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets (below €10,000) are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less and for which there is no option for the lessee to prolong the contract to more than 12 months or there is no reasonable certainty that such an option will be exercised. Low-value assets comprise mainly IT equipment and small items of office furniture.

The Group does not have residual value guarantees in the rental contracts.

### 5.13.1 Development of right-of-use assets

| *in € thousand* | Land, buildings and leasehold improvements | Manufacturing and laboratory equipment | Furniture, fittings and other | Total assets |
|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2025** | | | | |
| Opening net book value | 18,932 | — | 300 | 19,232 |
| Additions | 12 | 78 | 280 | 369 |
| Amortization | (1,725) | (8) | (186) | (1,919) |
| Impairment charge | — | — | — | — |
| Revaluation due to variable payments | 58 | — | (2) | 56 |
| Termination of contracts | — | (71) | (26) | (97) |
| Exchange rate differences | 916 | 2 | (2) | 916 |
| **CLOSING NET BOOK VALUE** | **18,193** | **—** | **365** | **18,558** |

| *in € thousand* | Land, buildings and leasehold improvements | Manufacturing and laboratory equipment | Furniture, fittings and other | Total assets |
|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2024** | | | | |
| Opening net book value | 20,141 | — | 251 | 20,392 |
| Additions | 38 | — | 199 | 237 |
| Amortization | (1,788) | — | (135) | (1,923) |
| Impairment charge | 980 | — | — | 980 |
| Revaluation due to variable payments | 1,404 | — | — | 1,404 |
| Termination of contracts | (1,246) | — | (12) | (1,258) |
| Exchange rate differences | (596) | — | (3) | (599) |
| **CLOSING NET BOOK VALUE** | **18,932** | **—** | **300** | **19,232** |

In the year ended December 31, 2025, right of use assets decreased from €19.2 million to €18.6 million, mainly due to amortizations.

The largest remaining active lease contract is for the building in Solna, Sweden, which has a book value of €14.8 million as at December 31, 2025 (December 31, 2024: €15.2 million).

For details on lease liabilities, see Note 5.27. For details on the impairment testing, see Note 5.15.

### 5.13.2 Other amounts recognized in the consolidated income statement

Expense relating to short-term leases and leases of low-value assets as well as expenses relating to termination of lease contracts have not been material in 2025 and 2024. There have been no substantive revaluations recognized to the income statement in 2025 and 2024.

## 5.14 Property, plant and equipment

Property, plant and equipment mainly comprise a manufacturing facility and leasehold improvements in rented office and laboratory space. All Property, plant and equipment are stated at historical cost less depreciation and less impairment losses when necessary. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or are recognized as a separate asset, only when it is probable that future economic benefits associated with the item will flow to the Group and that the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they incur.

Property, plant and equipment include machinery, for which validation is required to bring the asset to its working condition. The costs of such validation activities are capitalized together with the cost of the asset. Validation costs beyond the normal validation costs, which are usually required to bring an asset to its working condition, are expensed immediately. The usual validation costs are capitalized on the asset and depreciated over the remaining life of the asset or the shorter period until the next validation is usually required.

Depreciation of assets is calculated using the straight-line method to allocate their cost amounts to their residual values over their estimated useful lives, as follows:

- Buildings, leasehold improvements 5 - 40 years
- Machinery, laboratory equipment 1 - 15 years
- Furniture, fittings and office equipment 4 - 10 years
- Hardware 3 - 5 years

Leasehold improvements are depreciated over the shorter of their useful life or the lease term, unless the entity expects to use the assets beyond the lease term.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date.

An asset's carrying amount is immediately written down to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains and losses are included in the income statement "other income and expenses, net" (see Note 5.8).

| *in € thousand* | Land, buildings and leasehold improvements | Manufacturing and laboratory equipment | Computer hardware | Furniture, fittings and other | Assets in the course of construction | Total |
|---|---|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2025** | | | | | | |
| Opening net book value | 104,678 | 29,056 | 1,155 | 477 | 3,518 | 138,883 |
| Additions | 1,897 | 2,489 | 317 | 56 | (2,526) | 2,232 |
| Depreciation charge | (9,736) | (6,548) | (477) | (166) | — | (16,927) |
| Impairment charge/reversal | 1,904 | (629) | — | (16) | — | 1,258 |
| Disposals | (2,077) | (611) | (19) | (4) | — | (2,711) |
| Exchange rate differences | (3,296) | 22 | (10) | (19) | 41 | (3,262) |
| **CLOSING NET BOOK VALUE** | **93,369** | **23,778** | **966** | **328** | **1,032** | **119,474** |
| **AS AT DECEMBER 31, 2025** | | | | | | |
| Cost | 147,409 | 75,889 | 3,570 | 1,465 | 1,032 | 229,365 |
| Accumulated depreciation and impairment | (54,040) | (52,111) | (2,604) | (1,137) | — | (109,891) |
| **CLOSING NET BOOK VALUE** | **93,369** | **23,778** | **966** | **328** | **1,032** | **119,474** |

| *in € thousand* | Land, buildings and leasehold improvements | Manufacturing and laboratory equipment | Computer hardware | Furniture, fittings and other | Assets in the course of construction | Total |
|---|---|---|---|---|---|---|
| **YEAR ENDED DECEMBER 31, 2024** | | | | | | |
| Opening net book value | 99,100 | 31,761 | 1,053 | 560 | 3,724 | 136,198 |
| Additions | 10,356 | 3,720 | 569 | 68 | (292) | 14,421 |
| Depreciation charge | (7,828) | (6,248) | (467) | (161) | — | (14,705) |
| Impairment charge/reversal | — | 322 | — | — | — | 322 |
| Disposals | (102) | (800) | (20) | (11) | — | (932) |
| Exchange rate differences | 3,151 | 302 | 20 | 21 | 86 | 3,579 |
| **CLOSING NET BOOK VALUE** | **104,678** | **29,056** | **1,155** | **477** | **3,518** | **138,883** |
| | | | | | | |
| **AS AT DECEMBER 31, 2024** | | | | | | |
| Cost | 151,034 | 74,445 | 3,542 | 1,512 | 3,518 | 234,051 |
| Accumulated depreciation and impairment | (46,357) | (45,389) | (2,386) | (1,035) | — | (95,167) |
| **CLOSING NET BOOK VALUE** | **104,678** | **29,056** | **1,155** | **477** | **3,518** | **138,883** |

The additions in 2025 were primarily from the manufacturing and laboratory equipment, for the sites in Austria and Sweden as well as from the Almeida facility in Livingston, in 2024 the additions were primarily related to the Almeida facility in Livingston.

The depreciation charges for the fiscal year were conducted in accordance with standard practices, and present a slight increase in 2025 compared to 2024, reflecting the investment patterns of prior years.

From the total of €22.6 million (2024: €19.6 million) of depreciation, amortization and impairment expenses, €17.3 million (2024: €12.0 million) were charged to cost of goods and services, €3.9 million (2024: €6.3 million) were charged to research and development expenses, €0.5 million (2024: €0.7 million) were charged to marketing and distribution expenses and €0.4 million (2024: €0.4 million) were charged to general and administrative expenses.

### Non-current operating assets by region

Non-current operating assets for this purpose consist of intangible assets, right of use assets and property, plant and equipment. The main non-current operating assets are allocated to sites where production and research and development activities take place. Sales activities by distribution sites do not require major non-current operating assets. Revenues by region (see Note 5.5) are structured according to the location of the final customer. In some countries there are customers, but no assets.

| | Year ended December 31, | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| United Kingdom | 75,914 | 93,309 |
| Austria | 44,983 | 48,533 |
| Nordics | 35,741 | 36,264 |
| France | 3,106 | 4,350 |
| United States | 506 | 781 |
| Canada | 130 | 138 |
| **NON-CURRENT ASSETS** | **160,380** | **183,373** |

*Nordics includes Finland, Denmark, Norway and Sweden and Rest of World includes India, Israel, Australia, Peru, Japan, Brazil and New Zealand.*

## 5.15 Impairment testing

At the end of each reporting period Valneva assesses whether there is any indication that an asset may be impaired. Indicators for the necessity of an impairment test are, among others, actual or expected declines in sales or margins and significant changes in the economic environment with an adverse effect on Valneva's business. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units or CGUs). The cash-generating units correspond with the specific vaccine products and vaccine candidates. Non-financial assets, other than goodwill, that suffered impairment are reviewed for possible reversal of the impairment at each reporting date. Following the completion of the transfer of manufacturing activities for both IXIARO and IXCHIQ into the Almeida facility in Scotland, a re-assessment of Valneva's CGUs was performed, resulting in a combination of these two products into one CGU.

An assessment of impairment indicators performed for the year ended December 31, 2025 resulted in impairment indicators identified for the IXIARO / IXCHIQ CGU and no impairment indicators for DUKORAL and Shigella CGU's.

No material impairment reversal was booked in the years ended December 31, 2025 and December 31, 2024.

### IXIARO / IXCHIQ

For the first three quarters of 2025 IXIARO and IXCHIQ were considered separate CGUs. The completion of transfer activities for IXCHIQ into the new Almeida manufacturing facility in Scotland in the fourth quarter of 2025 triggered a re-assessment of the company's CGUs resulting in a combination of the previously separate CGU's into one combined CGU IXIARO / IXCHIQ.

Following the identification of impairment indicators for the combined IXIARO / IXCHIQ CGU, related to changes in the utilization of the Group's manufacturing assets as well as the termination of the drug substance supply agreement with Serum Institute of India (SII), an impairment test was performed as at December 31, 2025. Existing uncertainties were considered by assigning probabilities to different IXCHIQ revenue scenarios prepared. The impairment testing did not result in any impairment requirement as the recoverable amount for the CGU was considerably higher than the carrying value of its assets.

Further, the impairment test for the CGUs of IXIARO and IXCHIQ, which were for 2024 treated as separate CGUs, did not result in any impairment for the year ended December 31, 2024.

### DUKORAL

Following an increase in the risk-free rate that constituted an indicator of impairment, the Group conducted an impairment assessment of the DUKORAL CGU as at September 30, 2025. The analysis concluded that the CGU's recoverable amount exceeded the carrying amount of the underlying assets, and accordingly no impairment charge was recognised.

As at December 31, 2025, no further impairment indicators arose during the remainder of the reporting period; consequently, no additional impairment testing was required at year-end.

The impairment testing on DUKORAL for the year ended December 31, 2024 did not result in any impairment charges.

### Shigella

An assessment of impairment indicators was performed for the year ended December 31, 2025 resulting in no impairment indicators identified. An annual impairment test was performed, which did not result in any impairment requirements as the value in use for the CGU was considerably higher than the book value of its assets.

## Sensitivity to changes in assumptions

The net present value calculations are based upon assumptions regarding market size, expected sales volumes resulting in sales value expectations, expected royalty income or expected milestone payments. The net present value calculations are most sensitive to the following assumptions:

- discount rate
- reduction of expected revenues

The following table shows these parameters and their sensitivity to the overall result in case of described changes:

| *in € thousand (except ratios)* | IXIARO | DUKORAL | IXCHIQ | Shigella | IXIARO / IXCHIQ |
|---|---|---|---|---|---|
| **WEIGHTED AVERAGE COST OF CAPITAL (WACC)** | | | | | |
| **2025** | — % | 7.44 % | — % | 13.00 % | 8.12 % |
| **2024** | — % | — % | 8.79 % | — % | — % |
| **BREAK-EVEN WACC** | | | | | |
| **2025** | — % | 9.32 % | — % | 16.59 % | 21.14 % |
| **2024** | — % | — % | 27.04 % | — % | — % |
| **IMPAIRMENT IF WACC INCREASES BY 1%** *(in € thousand)* | | | | | |
| **2025** | — | NO | — | NO | NO |
| **2024** | — | — | NO | — | — |

As of December 31, 2025, the value in use of the DUKORAL and IXIARO/IXCHIQ CGUs would equal their carrying amount if the product revenues decrease by 1.50% and 13.00% respectively, compared to the Group's projections assuming all costs to remain unchanged..

# 5.16 Financial instruments

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value at each balance sheet date.

The valuation techniques utilized for measuring the fair values of assets and liabilities are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect management's market assumptions.

The fair value of instruments that are quoted in active markets are determined using the quoted prices where they represent those at which regularly and recently occurring transactions take place. Furthermore, the Group uses valuation techniques to establish the fair value of instruments where prices, quoted in active markets, are not available.

## 5.16.1 Financial instruments by category

The Group has materially only short-term assets and all of the financial instruments are categorized as assets at amortized costs. Financial instruments can be found in the following positions within the assets:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| **FINANCIAL INSTRUMENTS IN ASSETS** | | |
| Trade receivables | 27,813 | 35,205 |
| Other assets [1] | 356 | 1,256 |
| Cash and cash equivalents | 109,650 | 168,271 |
| **TOTAL ASSETS** | **137,819** | **204,731** |

*(1) Prepayments and tax receivables and other non-financial assets are excluded from the other assets balance, as this analysis is required only for financial instruments.*

The Group has only financial instruments which are categorized as liabilities at amortized costs. Financial instruments can be found in the following positions within the liabilities:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| **FINANCIAL INSTRUMENTS IN LIABILITIES** | | |
| Borrowings | 179,167 | 187,373 |
| Trade payables and accruals | 24,540 | 35,522 |
| Tax and employee-related liabilities [1] | 12,642 | 13,107 |
| Lease liabilities | 28,082 | 28,941 |
| Refund liabilities | 17,498 | 26,141 |
| Other liabilities [2] | 7 | 79 |
| **TOTAL LIABILITIES** | **261,936** | **291,163** |

*(1) Social security and other tax payables are excluded from the tax and employee-related liabilities balance, as this analysis is required only for financial instruments.*
*(2) Deferred income is excluded from the other liabilities balance, as this analysis is required only for financial instruments.*

## 5.16.2 Fair value measurements

As at December 31, 2025 and December 31, 2024, the Group did not have assets and liabilities measured through profit and loss. In both periods, the Group also did not subscribe to any foreign currency options nor foreign currency forwards. Due to the short-term nature of its financial instruments fair valuation has no effect on the financial position.

## 5.16.3 Foreign currency sensitivity analysis

The following table details the Group's sensitivity of financial instruments to a 10% increase and decrease in currency units against the relevant foreign currencies. 10% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management's assessment of the reasonably possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the year-end for a 10% change in foreign currency rates. The sensitivity analysis includes external loans as well as loans to foreign operations within the Group where the denomination of the loan is in a currency other than the currency of the lender or the borrower. A positive number below indicates an increase in pre-tax profit or a reduction in pre-tax loss.

With all other variables held constant, the impact from changes in exchange rates on the pre-tax result would be as follows:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| USD/EUR +10% | (15,084) | (16,973) |
| USD/EUR -10% | 18,435 | 20,745 |
| GBP/EUR +10% | 5,549 | 8,525 |
| GBP/EUR -10% | (6,782) | (10,420) |
| SEK/EUR +10% | (5,919) | (5,725) |
| SEK/EUR -10% | 7,234 | 6,998 |
| CAD/EUR +10% | 4,344 | 3,178 |
| CAD/EUR -10% | (5,309) | (3,884) |

The effect in the USD/EUR relationship is mostly due to borrowings denominated in USD while the cash and working capital is predominantly on a EUR basis. The Group has not used any hedging instruments to reduce the impact of foreign exchange rate changes.

## 5.16.4 Credit quality of financial assets

The credit quality of financial assets that are not impaired can be assessed by reference to external credit ratings (if available) or to historical information about counterparty default rates as follows:

| | Year ended December 31 | |
|---|---|---|
| **in € thousand** | **2025** | **2024** |
| **TRADE RECEIVABLES** | | |
| Receivables from governmental institutions (AAA-country) | 377 | — |
| Receivables from governmental institutions (AA-country) | 7,025 | 5,202 |
| Receivables from counterparties with credit rating A | 13,203 | 3,184 |
| Receivables from counterparties without external credit rating or rating below A | 7,128 | 26,744 |
| Contract assets from counterparties with credit rating A | — | — |
| Contract assets from counterparties without external credit rating or rating below A | 80 | 75 |
| **TRADE RECEIVABLES** | **27,813** | **35,205** |
| | | |
| **OTHER ASSETS** | | |
| Counterparties without external credit rating or rating below A | 356 | 1,256 |
| **OTHER ASSETS** | **356** | **1,256** |
| | | |
| **CASH AND CASH EQUIVALENTS** | | |
| Counterparties with external credit rating or rating AA | 5,342 | 8,921 |
| Counterparties with external credit rating or rating A | 104,308 | 156,135 |
| Counterparties without external credit rating or rating below A | — | 3,214 |
| **CASH AND CASH EQUIVALENTS** | **109,650** | **168,271** |

The rating information refers to long-term credit ratings as published by Standard & Poor's or another rating organization (equivalent to the Standard & Poor's rating).

The maximum exposure to credit risk at the reporting date is the fair value of the financial assets.

## 5.16.5 Impairment of financial assets

### Trade receivables

According to IFRS 9.5.5.15, the simplified approach (measuring the loss allowance at an amount equal to lifetime expected credit losses) has to be used for trade receivables, which do not contain a significant financing component. This is the case for the Group, as all trade receivables are short-term with a maturity lasting less than 12 months.

Loss allowances have to be established for each trade receivable based on the expected credit losses. Accordingly, at the end of each reporting period, trade receivables were adjusted through a loss allowance in accordance with the revised expected outcome.

According to IFRS 9.5.5.17, default probabilities should be determined on the basis of historical data but must be adjusted on the balance sheet date on the basis of up-to-date information and forward looking information. The analysis of the historical data and forward looking information showed as at December 31, 2025 and December 31, 2024 that losses incurred were immaterial, taking further into account the limited number of customers as well as credit checks

mentioned in Note 5.2.5. Therefore, loss allowance was considered immaterial as at December 31, 2025 and December 31, 2024.

### Other assets and cash and cash equivalents

Historically, no losses have been incurred on other assets measured at amortized costs and on cash and cash equivalents. As at December 31, 2025 and December 31, 2024, the expected credit loss was calculated using the cumulative expected default rate based on the counterparties' ratings and was immaterial.

## 5.17 Inventories

Inventories are stated at the lower of cost and net realizable value. The cost of finished goods and work in progress comprises raw materials, direct labor, other direct costs, and related production overheads (based on normal operating capacity) at standard costs. The variances between the actual costs and the standard costs are calculated monthly and allocated to the inventory, so there is no difference between actual cost of manufacture and the value of inventory. Costs arising from idle capacity or abnormally low production levels are not included in inventory and are recognized in profit or loss as cost of goods in the period incurred. Inventories exclude borrowing costs. Provisions for batches which fail to meet quality requirements and may not be sold (failed batches) are deducted from the value of inventories.

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Raw materials | 25,848 | 28,086 |
| Work in progress | 48,095 | 36,832 |
| Finished goods | 20,206 | 19,493 |
| Purchased goods (third party products) | 545 | 4,762 |
| **GROSS AMOUNT OF INVENTORIES BEFORE WRITE-DOWN** | **94,693** | **89,173** |
| Less: write-down provision | (44,462) | (35,510) |
| **INVENTORIES** | **50,232** | **53,663** |

As of December 31, 2025, the increase in gross amounts of inventories before write-down primarily related to an increase in the work in progress and finished goods, namely for, IXCHIQ and DUKORAL. The increase was partially offset by a decrease in raw materials and purchased goods from third parties. The total write-down provision on inventory amounted to €44.5 million as of December 31, 2025 (December 31, 2024: €35.5 million).

All raw materials and work in progress related to COVID-19 vaccine, VLA2001, that could not be repurposed and used for other products were written down during prior years. No change was recorded relating to the write-down provision of COVID-19 vaccine, in 2025.

Write-down provisions related to the inventory categories as follows:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Raw materials | 18,855 | 21,728 |
| Work in progress | 21,478 | 12,600 |
| Finished goods | 4,089 | 591 |
| Purchased goods (third party products) | 40 | 591 |
| **TOTAL WRITE-DOWN PROVISION** | **44,462** | **35,510** |

As at December 31, 2025, €17.2 million in write-down provisions were attributable to raw-material related to the VLA2001 COVID vaccine (December 31, 2024: €17.2 million).

As at December 31, 2025, the remaining write-down provision of €23.2 million in raw materials and work in progress is based on factors including sales volumes and market demand, related to Valneva's commercialized vaccine IXCHIQ (December 31, 2024: €17.2 million).

As at December 31, 2025, the write-down provision for finished goods for Valneva's commercialized vaccines IXIARO IXCHIQ and DUKORAL vaccines based on sales expectations and shelf life of the products amounted to €4.1 million (December 31, 2024: €0.6 million). The increase is primarily driven by the IXCHIQ write-down following the FDA license suspension, as well as the write down of IXCHIQ inventory with a remaining shelf life of less than six months.

The provision for third-party products decreased from €0.6 million at December 31, 2024 to zero at December 31, 2025, mainly due to the decrease of the quantity linked to the Company's decision to discontinue sale of these products.

### IXCHIQ

The increase in the inventory write-down as of December 31, 2025 primarily relates to IXCHIQ. The termination of the license agreement with Serum Institute of India (SII) led to a reassessment of the inventory consumption. Furthermore the suspension of the license in the United States during 2025 resulted in lower sales and reduced expected short-term demand. Accordingly, the Group recorded a write-down based on revised forecast market demand and sales

expectations, taking into account the volume of work in progress, estimated dose yield, current shelf life, potential shelf-life extension by 12 months through the freezing process, expected orders from Butantan and other partners, and forecast sales over the next five years. These forecasts incorporate a significant expected increase in annual sales volumes compared to 2025. Any further write-downs relating to IXCHIQ will depend on future forecast developments and market conditions.

| IXCHIQ related inventory only | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Raw materials | 3,392 | 3,509 |
| Work in progress | 23,351 | 11,918 |
| Finished goods | 3,558 | 1,746 |
| Purchased goods (third party products) | — | — |
| **GROSS AMOUNT OF INVENTORIES BEFORE WRITE-DOWN** | **30,301** | **17,173** |
| Less: write-down provision | (21,557) | (7,148) |
| **INVENTORIES IXCHIQ** | **8,744** | **10,024** |

## 5.18 Trade receivables

Trade receivables are initially recognized at fair value. The carrying amount of trade receivables is reduced through an allowance for doubtful account. When a trade receivable is considered uncollectible, it is written off against this allowance account. Subsequent recoveries of amounts previously written off are credited against the allowance account. Changes in the carrying amount of the allowance account are recognized in the profit or loss.

Trade receivables include the following:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Trade receivables | 27,785 | 35,182 |
| Contract assets | 80 | 75 |
| Less: loss allowance of receivables | (52) | (52) |
| **TRADE RECEIVABLES, NET** | **27,813** | **35,205** |

In 2025 and 2024, no material impairment losses were recognized. As at December 31, 2025, the amount of trade receivables and contract assets past due (which is defined as being more than 30 days late) reached €1.5 million (December 31, 2024: €2.0 million). As at December 31, 2025, trade receivables past due included €0.8 million from a distributor in Canada and an amount of €0.5 million from a distributor in France. As of December 31, 2024, an amount of €1.1 million came from a distributor in Canada and an amount of €0.3 million referred to a customer in Austria. Both were settled in the course of 2025 and led to the decrease in the outstanding amount.

As at December 31, 2025, trade receivables included €27.8 million (December 31, 2024: €35.2 million) of receivables from contracts with customers. The decrease by €7.4 million compared to December 31, 2024 is primarily due to the timing of sales and improved cash collections.

Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

## 5.19 Other assets

Other assets include the following:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| R&D tax credit receivables | 28,804 | 31,208 |
| Advance payments | 311 | 399 |
| Tax receivables | 3,417 | 3,686 |
| Prepaid expenses | 5,392 | 8,878 |
| Contract costs | 3,710 | 3,710 |
| Consumables and supplies on stock | 417 | 767 |
| Miscellaneous current assets | 28 | 11 |
| **OTHER NON-FINANCIAL ASSETS** | **42,080** | **48,659** |
| Deposits | 181 | 198 |
| Miscellaneous financial assets | 176 | 1,058 |
| **OTHER FINANCIAL ASSETS** | **356** | **1,256** |
| **OTHER ASSETS** | **42,436** | **49,915** |
| Less non-current portion | 7,590 | 8,041 |
| **CURRENT PORTION** | **34,846** | **41,874** |

Due to the short term nature of the financial instruments included in other assets, their carrying amount is considered to be the same as their fair value.

The "R&D tax credit receivables" mainly relate to the research and development tax credit in Austria, and France. The decrease is due to a €5.1 million payment received for the Scottish R&D tax credit in March 2025.

As at December 31, 2024 the miscellaneous financial assets mainly related to the grant awarded by Scottish Enterprise for which the payment was received in 2025. For more information see Note 5.8.1.

## 5.20 Cash and cash equivalents

Cash includes cash at bank, cash in hand, and deposits held at call with banks. Cash equivalents include short-term bank deposits and medium-term investments with a maximum maturity of three months that can be assigned or sold on very short notice and are subject to insignificant risk of changes in value in response to fluctuations in interest rates.

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Cash in hand | — | 1 |
| Cash at bank | 109,650 | 168,269 |
| **CASH AND CASH EQUIVALENTS** | **109,650** | **168,271** |

As at December 31, 2025, and December 31, 2024, the Group had no restricted cash. In 2025, the decrease in cash and cash equivalents was due to usage for operative activities.

## 5.21 Assets classified as held for sale

As at December 31, 2025 and December 31, 2024, no assets were classified as held for sale and no transactions involving the reclassification of assets into this category occurred during the current financial year. This status reflects the fact that all assets continue to be used in the Group's operations and that, at the date of preparation of the financial statements, no disposal is anticipated that would meet the criteria for reclassification as held for sale.

## 5.22 Equity

### 5.22.1 Share capital and share premium

The ordinary shares and convertible preferred shares are classified as equity.

| | Year ended December 31 | |
|---|---|---|
| *Number of shares* | **2025** | **2024** |
| Ordinary shares issued (€0.15 par value per share) | 173,539,745 | 162,521,524 |
| **TOTAL SHARES ISSUED** | **173,539,745** | **162,521,524** |
| Less Treasury shares | (124,322) | (124,322) |
| **OUTSTANDING SHARES** | **173,415,423** | **162,397,202** |

Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, if any, from the proceeds.

When the Company purchases its own equity share capital (treasury shares), the consideration paid, including any directly attributable incremental costs (net of income taxes, if any) is deducted from equity attributable to the Company's equity holders until the shares are cancelled, reissued or otherwise disposed of. In cases where such shares are subsequently sold or reissued, any consideration received, net of any directly attributable incremental transaction costs and related income tax effects is included in equity attributable to the Company's equity holders.

The profit or loss for the year is fully included in net result, while other comprehensive income solely affects retained earnings and other reserves.

The following table shows the development of the number of outstanding shares:

| | Year ended December 31 | |
|---|---|---|
| *Number of shares* | **2025** | **2024** |
| **OUTSTANDING AS AT JANUARY 1** | **162,397,202** | **138,787,820** |
| Share-based compensation exercises | 1,684,889 | 609,382 |
| Capital Increase | 9,333,332 | 23,000,000 |
| **OUTSTANDING AT YEAR END** | **173,415,423** | **162,397,202** |

The Company has issued stock options to employees under various employee stock option plans (ESOPs) established in the last 10 years. For details, please refer to Note 5.23.

During 2025 the Company increased its capital by a total of 9,333,332 new ordinary shares having a nominal value of €0.15 each. 7,666,666 of the new ordinary shares were issued at a price of €2.74 and an additional 1,666,666 ordinary shares at a price of €3.86. Aggregate gross proceeds of the capital increase, before deducting underwriting commissions and expenses payable by the Company, were €27.4 million. The €1.2 million transaction costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax resulting in a net proceeds of €26.2 million.

#### Conditional and authorized capital

As at December 31, 2025, the Company had 16,002,496 (December 31, 2024: 14,003,064) shares of conditional capital in connection with (see Note 5.23):

- the possible exercise of existing stock options; and
- the possible final grant of existing Free Ordinary Shares.

The Company's shareholders set limits on the maximum aggregate amount of capital increases that may be carried out pursuant to specific resolutions presented to shareholders at the Company's annual Combined General Meeting. At this meeting on June 25, 2025, shareholders approved these limits in resolution 34, which specifies that the maximum aggregate amount of capital increases that may be carried out, with immediate effect or in the future under resolutions 26, 27, 28, 29, 32 and 33 may not exceed €5,018,145, and, for capital increases authorized by resolution 25, €5,175,000. This maximum aggregate amount will be added the additional nominal amount of shares or securities to be issued in accordance with applicable legal or regulatory provisions and, if applicable, with contractual provisions providing for other forms of adjustment, in order to preserve the rights of the holders of securities or other rights giving immediate and/or future access to the capital of the Company.

### 5.22.2 Other reserves

| *in € thousand* | Other regulated reserves | Other comprehensive income | Treasury shares | Capital from Share-based compensation | Other revenue reserves | Total |
|---|---|---|---|---|---|---|
| **BALANCE AS AT JANUARY 1, 2025** | **52,820** | **(3,151)** | **(645)** | **33,696** | **(9,517)** | **73,203** |
| Currency translation differences | — | 520 | — | — | — | 520 |
| Defined benefit plan actuarial losses | — | 68 | — | — | — | 68 |
| Share-based compensation expense | — | — | — | 9,527 | — | 9,527 |
| **BALANCE AS AT DECEMBER 31, 2025** | **52,820** | **(2,563)** | **(645)** | **43,224** | **(9,517)** | **83,318** |

| *in € thousand* | Other regulated reserves | Other comprehensive income | Treasury shares | Capital from Share-based compensation | Other revenue reserves | Total |
|---|---|---|---|---|---|---|
| **BALANCE AS AT JANUARY 1, 2024** | **52,820** | **(1,871)** | **(645)** | **24,301** | **(9,517)** | **65,088** |
| Currency translation differences | — | (1,329) | — | — | — | (1,329) |
| Defined benefit plan actuarial gains | — | 49 | — | — | — | 49 |
| Share-based compensation expense | — | — | — | 9,395 | — | 9,395 |
| **BALANCE AS AT DECEMBER 31, 2024** | **52,820** | **(3,151)** | **(645)** | **33,696** | **(9,517)** | **73,203** |

As at December 31, 2025, the other regulated reserves of €52.82 million (December 31, 2024: €52.82 million) fully relate to a non-distributable mandatory legal reserve from the merger with Intercell AG.

The Company did not obtain a dividend from its subsidiaries or pay a dividend to its shareholders in 2025 and 2024.

## 5.23 Share-based compensation

The Company operates various share-based compensation plans, both equity-settled and cash-settled plans. The consolidated statement of profit or loss includes the following expenses arising from share-based payments:

| | Year ended December 31 | | |
|---|---|---|---|
| *in € thousand* | 2025 | 2024 | 2023 |
| Stock option plans | 7,054 | 7,894 | 5,152 |
| Free ordinary shares program | 2,473 | 1,501 | 1,514 |
| Phantom shares | 44 | (685) | (390) |
| **SHARE-BASED COMPENSATION EXPENSE /(INCOME)** | **9,571** | **8,710** | **6,276** |

### 5.23.1 Stock option plans

The fair value of such share-based compensation is recognized as an expense for employee services received in exchange for the grant of the options. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted, excluding the impact of any non-market vesting conditions. Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Annually, the Group revises its estimates of the number of options that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement and makes a corresponding adjustment to equity.

The proceeds received net of any directly attributable transaction costs are credited to nominal capital (nominal value) and share premium (amount exceeding nominal value) when the options are exercised.

Beginning in 2013, the Company granted stock options to employees and management pursuant to nine successive plans.

Stock options granted from 2013 to 2017 are exercisable in two equal portions after being held for two and for four years (the vesting periods), while stock options granted from 2019 onwards are exercisable in three equal portions after being held for one year, two years and three years. Stock options granted in 2019 are subject to performance conditions.

All options expire no later than ten years after being granted. Stock options are not transferable or negotiable and unvested options lapse without compensation upon termination of employment with the Group (forfeiture). Stock options granted from 2013 onwards vest with the effectiveness of the takeover of more than 50% of the outstanding voting rights of the Group. As this change of control event was considered remote, it has not been considered in the determination of the vesting period.

Changes in the number of stock options outstanding and their related weighted average exercise prices are as follows:

| | 2025 | | | 2024 | | |
|---|---|---|---|---|---|---|
| | Number of options | Number of shares available | Average exercise price (in € per share) | Number of options | Number of shares available | Average exercise price *(in € per share)* |
| **OUTSTANDING AS AT JANUARY 1** | **12,472,045** | **12,472,045** | **3.44** | **8,550,802** | **8,550,802** | **5.02** |
| Granted | 1,857,360 | 1,857,360 | 2.49 | 4,957,716 | 4,957,716 | 2.62 |
| Expired | (43,655) | (43,655) | 3.92 | — | — | N/A |
| Forfeited | (1,433,292) | (1,433,292) | 4.14 | (1,036,473) | (1,036,473) | 4.47 |
| Exercised | (1,326,252) | (1,326,252) | 2.86 | — | — | N/A |
| **OUTSTANDING AT YEAR END** | **11,526,206** | **11,526,206** | **3.92** | **12,472,045** | **12,472,045** | **3.44** |
| Exercisable at year end | 5,950,015 | 5,950,015 | 4.79 | 4,766,957 | 4,766,957 | 4.61 |

In 2025 1,326,252 employee stock options were exercised of which 2,250 were granted from ESOP 2016, 293,956 from ESOP 2017, 589,016 from ESOP 2019 and 441,030 from ESOP 2024).

No employee stock options were exercised in 2024.

Stock options outstanding at the end of the period have the following expiry dates and exercise prices:

| | | Number of options as at December 31, (presentation as number of convertible shares) | |
|---|---|---|---|
| *Expiry date* | Exercise price (in € per share) | 2025 | 2024 |
| 2025 | 3.92 | 0 | 43,655 |
| 2026 | 2.71 | 8,500 | 14,500 |
| 2027 | 2.85 | 202,375 | 551,475 |
| 2029 | 3.05 | 892,400 | 1,596,166 |
| 2032 | 6.47 | 2,040,211 | 2,339,974 |
| 2033 | 5.25 | 2,633,205 | 3,005,809 |
| 2034 | 2.62 | 3,991,655 | 4,920,466 |
| 2035 | 2.49 | 1,757,860 | — |
| **OUTSTANDING AT YEAR END** | | **11,526,206** | **12,472,045** |

During 2025, 1,857,360 stock options were granted (2024: 4,957,716). The weighted average grant date fair value of options granted during 2025 was €1.57 (2024: €1.84). The fair value of the granted options was determined using the Black Scholes valuation model.

The significant inputs into the models were:

| | As at Jul 7, 2025 |
|---|---|
| Expected volatility *(%)*, based on historical volatility | 75.65 % |
| Expected vesting period *(term in years)* | 5.50 – 6.50 |
| Risk-free interest rate *(%)* | 1.78% – 1.91% |

## 5.23.2 Free ordinary shares

In 2025, the Board of Directors approved a grant of 3,537,321 free ordinary shares to members of the Executive Committee and senior management. These awards are subject to specified performance conditions, in addition to the applicable service conditions.

In 2024, the Company granted 991,643 free ordinary shares to the Executive Committee and senior management, subject solely to service conditions, with no associated performance conditions.

These free share plans are designed to align management interests with those of shareholders and to provide a long-term incentive program for the Company's senior leadership.

The number of free ordinary shares granted was as follows:

| | Year ended December 31 | |
|---|---|---|
| *Number of free ordinary shares granted* | 2025 | 2024 |
| Executive Committee | 2,045,739 | 572,793 |
| Senior Leadership Group | 1,491,582 | 418,850 |
| **FREE ORDINARY SHARES GRANTED** | **3,537,321** | **991,643** |

In accordance with the foregoing, changes in the outstanding free ordinary shares are as follows:

| | Year ended December 31 | |
|---|---|---|
| *Number of free shares* | 2025 | 2024 |
| **OUTSTANDING AS AT JANUARY 1** | **1,485,019** | **1,368,630** |
| Granted | 3,537,321 | 991,643 |
| Forfeited | (188,663) | (265,872) |
| Exercised | (358,637) | (609,382) |
| **OUTSTANDING AT YEAR END** | **4,475,040** | **1,485,019** |
| Free ordinary shares subject to performance conditions | 3,401,001 | — |
| Free ordinary shares not subject to performance conditions | 1,074,039 | 1,485,019 |

Subject to the applicable vesting conditions — service conditions for plans prior to 2025, and both service and performance conditions for the 2025 plan — the free shares granted to a participant will vest and be definitively delivered in three tranches. Each tranche will amount to one third of the total individual allocation. If one third is not a whole number, the number of free shares will be rounded down for the first two tranches and rounded up for the third tranche.

The first tranche for the performance based free shares granted in 2025 will vest on July 7, 2027, and the second and the third tranches will vest on July 7, 2028.

Following the vesting of the free shares, no compulsory holding period will apply to the vested shares.

The expense recognized for the free ordinary share plans is measured as the number of shares expected to vest multiplied by the grant-date fair value of those shares. For all plans issued prior to 2025, the grant-date fair value is determined using the grant-date share price. For the 2025 performance free shares plan, which includes market-based performance conditions, the grant-date fair value is determined using a Monte Carlo valuation model.

The 2025 and 2024 plans further provide for accelerated vesting of the free shares in the event of a Change of Control (as defined in the applicable terms & conditions) occurring no earlier than two years after the grant date. For the 2024 plan it is October 22, 2026, and for the 2025 performance free shares plan it is July 7, 2027. As management considered the chance of a Change of Control remote at the grant date, this was not included in the determination of the vesting period.

In addition, the plans provide for the possibility to remain entitled to a prorated number of shares, for any unvested tranche, in case of retirement of a beneficiary before complete vesting. Finally, the terms and conditions applicable to the free share plans state that if a Change of Control takes place before the specified date and section III of Article L. 225-197-1 of the French Commercial Code does not apply, the plan will be canceled and the Company will indemnify the participants for the loss of unvested free shares, subject however to all required shareholder approvals where corporate officers are concerned. The gross amount of this indemnity will be calculated as though such free shares had been vested upon the Change of Control. The conditions and limitations set forth in the applicable terms and conditions of the plan will apply to this calculation, mutatis mutandis.

In accordance with the decisions of the Board of Directors of June 25, 2024 and July 7, 2025, and by application of section II (5th paragraph) of Article L. 225-197-1 of the French Commercial Code when applicable, the beneficiaries that are corporate officers, *i.e.* the CEO (*Directeur Général*) and the Associate Managing Officers (*Directeurs Généraux Délégués*), and each of the other members of the Executive Committee should keep not less than 20% of the vested free shares of each tranche until termination of both their Executive Committee membership and (as applicable) their corporate office.

## 5.23.3 Phantom shares

No new phantom shares were granted in 2025 or in 2024.

In 2017, 2019 and 2020, phantom share plans were issued for employees who are U.S. citizens, with the same conditions as the stock option and free ordinary share programs (see Note 5.23.1 and 5.23.2) but which will not be settled in equity, but in cash. Therefore, it is considered as a cash settled plan. The liability for the phantom shares is measured (initially and at the end of each reporting period until settled) at the fair value of the share options rights, by applying an option pricing model taking into account the terms and conditions on which the phantom rights were granted and the extent to which the employees have rendered services to date.

In accordance with the foregoing, changes in the outstanding phantom shares are as follows:

| | Year ended December 31 | |
|---|---|---|
| *Number of phantom shares* | 2025 | 2024 |
| **OUTSTANDING AS AT JANUARY 1** | **39,500** | **410,500** |
| Granted | — | — |
| Forfeited | — | (161,000) |
| Exercised | (29,500) | (210,000) |
| **OUTSTANDING AT YEAR END** | **10,000** | **39,500** |

The carrying amount of the liability relating to the phantom shares as at December 31, 2025 was €0.0 million (December 31, 2024: €0.0 million). The fair values of the granted options were determined on the balance sheet dates using the Black Scholes valuation model.

Phantom shares outstanding at the end of the period have the following expiry dates and exercise prices:

| *Expiry date* | Exercise price *(in € per share)* | Number of phantom shares as at December 31 2025 | 2024 |
|---|---|---|---|
| 2027 | 2.85 | — | 6,250 |
| 2029 | 3.05 | 10,000 | 33,250 |
| **OUTSTANDING AT YEAR END** | | **10,000** | **39,500** |

The significant inputs into the models were:

| | Year ended December 31 2025 | 2024 |
|---|---|---|
| Expected volatility (in %) | 41.18 % | 53.47 % |
| Expected vesting period (term in years) | — | — |
| Risk-free interest rate (in %) | 2.00 % | 2.31 % |

## 5.24 Borrowings

Borrowings are initially recognized at fair value if determinable, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date.

Borrowings of the Group at period-end include the following:

| *in € thousand* | Year ended December 31 2025 | 2024 |
|---|---|---|
| **NON-CURRENT** | | |
| Borrowings and other loans | 161,261 | 166,521 |
| **CURRENT** | | |
| Borrowings and other loans | 17,905 | 20,852 |
| **TOTAL BORROWINGS** | **179,167** | **187,373** |

As at December 31, 2025, the carrying amount of bank borrowings and other loans was €179.2 million. Of this, €173.4 million related to the Pharmakon Loan Agreement. Other borrowings related to financing of research and development expenses included the CIR (research and development tax credit in France) of €3.1 million (December 31, 2024: €3.5 million) and the CEPI grant in the amount of €2.6 million (December 31, 2024: €3.0 million), which relates to advance payments that are expected to be paid back in the future.

The maturity of the borrowings is as follows:

| *in € thousand* | Year ended December 31 2025 | 2024 |
|---|---|---|
| Between 1 and 3 years | 28,715 | 132,489 |
| Between 3 and 5 years | 131,953 | 33,349 |
| Over 5 years | 594 | 683 |
| **NON-CURRENT BORROWINGS** | **161,261** | **166,521** |
| Current borrowings | 17,905 | 20,852 |
| **TOTAL BORROWINGS** | **179,167** | **187,373** |

The carrying amounts of the Group's borrowings are denominated in the following currencies:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Borrowings denominated in EUR | 3,144 | 3,540 |
| Borrowings denominated in USD | 176,022 | 183,833 |
| **TOTAL BORROWINGS** | **179,167** | **187,373** |

## 5.24.1 Principal loan

On October 6, 2025, Valneva announced a new non-dilutive debt facility of up to $500.0 million with funds managed by Pharmakon Advisors, LP. This new loan supersedes and fully replaces the previous D&O Loan Agreement. The transaction is accounted for as a separate, new financing arrangement and does not meet the criteria for a modification of the existing agreement in accordance with IFRS. The initial $215.0 million tranche was used to fully repay Valneva Austria's existing debt with D&O including related fees and expenses, while the remaining $285.0 million may be drawn later for future business development opportunities subject to mutual agreement between the parties. The new facility extends Valneva's debt maturity from Q1 2026 to Q4 2030, lowers its interest rate, and enhances financial flexibility.

As at December 31, 2025, no further tranches have been drawn. The book value of the loan amounts to $203.8 million (€173.4 million). The interest-only period on the initial tranche lasts until the fourth quarter of 2030, and the loan will mature in October 2030. The interest rate on the initial tranche is 9.00%, translating into an effective interest rate of 10.84% as of December 31, 2025. Transaction costs amounting to $11.8 million (€10.1 million) have been deducted from the loan proceeds received in October 2025.

Similar to the D&O Loan Agreement, the loan with Pharmakon is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by Valneva SE and certain of its subsidiaries, There are no financial covenants attached to the Pharmakon Loan Agreement. The previous D&O Loan Agreement included liquidity and revenue-based covenants, which the Group complied with throughout the period. The Pharmakon Loan Agreement contains only customary affirmative and restrictive covenants.

As at December 31, 2024, a total of $200.0 million was drawn under the D&O Loan Agreement. The book value of the loan amounted to €180.8 million.

The Pharmakon Loan Agreement is included in the balance sheet item "Borrowings". The Pharmakon Loan Agreement and the previous D&O Loan Agreement, which the Pharmakon Loan superseded and fully replaced during the fourth quarter of 2025, developed as follows:

| *in € thousand* | **2025** | **2024** |
|---|---|---|
| **BALANCE AS AT JANUARY 1** | **180,841** | **167,520** |
| Proceeds of issue | 182,979 | — |
| Transaction costs | (10,130) | (944) |
| Principal repayment | (170,213) | — |
| Accrued interest | 28,403 | 22,530 |
| Payment of interest | (17,558) | (18,978) |
| Exchange rate difference | (20,916) | 10,713 |
| **BALANCE AS AT CLOSING DATE** | **173,407** | **180,841** |
| Less: non-current portion | (156,710) | (161,420) |
| **CURRENT PORTION** | **16,697** | **19,421** |

## 5.24.2 Borrowings and other loans secured

As at December 31, 2025, €176.6 million (December 31, 2024: €184.4 million) of the outstanding borrowings and other loans were guaranteed, secured, or pledged. These borrowings and other loans related to financing of research and development expenses, fixed assets and CIR (R&D tax credit in France) have various conditions (interest rates) and terms (maturities).

## 5.24.3 Fair value of borrowings and other loans

The fair value of the borrowings and other loans are calculated by discounting the contractual cash flows with interest rates derived from relevant bond yields and swap rates and adjusted for any further potential risk and liquidity risks related to the nature of each loan. The relevant bond yields were determined by an internal analysis based on Moody's RiskCalc corporate rating methodology. As at December 31, 2025, and December 31, 2024, the resulting calculations revealed no material difference between the carrying amount and the fair value.

## 5.25 Trade payables and accruals

Trade payables and accruals include the following:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Trade payables | 9,074 | 12,639 |
| Accrued expenses | 15,466 | 22,883 |
| **TOTAL** | **24,540** | **35,522** |
| Less non-current portion | — | — |
| **CURRENT PORTION** | **24,540** | **35,522** |

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature. All trade payables and accruals are current.

## 5.26 Tax and employee-related liabilities

Liabilities for tax and employee-related liabilities are generally measured at amortized costs. Liabilities related to employees comprise mainly accruals for bonuses and unconsumed vacations. The line social security and other taxes consists of amounts owed to tax authorities and social security institutions.

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Employee-related liabilities | 12,642 | 13,107 |
| Social security and other taxes | 6,913 | 6,350 |
| **BALANCE AS AT DECEMBER 31** | **19,555** | **19,458** |
| Less non-current portion | — | — |
| **CURRENT PORTION** | **19,555** | **19,458** |

## 5.27 Lease liabilities

Lease liabilities are effectively secured as the rights to the leased assets revert to the lessor in the event of default.

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| **OPENING NET BOOK VALUE** | **28,941** | **31,969** |
| Additions | 369 | 237 |
| Revaluation due to variable payments | 56 | 1,399 |
| Termination of contracts | (27) | (1,100) |
| Lease payments | (3,504) | (3,425) |
| Interest expenses | 796 | 813 |
| Exchange rate differences | 1,450 | (952) |
| **CLOSING NET BOOK VALUE** | **28,082** | **28,941** |

In 2025, lease liabilities decreased by €0.9 million, mainly due to redemption of lease liabilities in Sweden. In the fourth quarter of 2025, the Group remeasured the lease liability to reflect changes in index-linked lease payments in Sweden.

The maturity of non-current lease liabilities is as follows:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Between 1-3 years | 5,572 | 5,203 |
| Between 3-5 years | 5,414 | 5,083 |
| Over 5 years | 14,357 | 16,147 |
| **NON-CURRENT LEASE LIABILITIES** | **25,343** | **26,432** |
| Current lease liabilities | 2,739 | 2,508 |
| **TOTAL LEASE LIABILITIES** | **28,082** | **28,941** |

The carrying amounts of the Group's lease liabilities are denominated in the following currencies:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| EUR | 891 | 1,078 |
| SEK | 26,466 | 26,870 |
| Other | 725 | 992 |
| **TOTAL LEASE LIABILITIES** | **28,082** | **28,941** |

## 5.28 Contract liabilities

A contract liability has to be recognized when the customer has already provided the consideration or part of the consideration before an entity has fulfilled its performance obligation (agreed goods or services which should be delivered or provided) resulting from the "contract".

Development of contract liabilities is presented in the table below:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| **BALANCE AS AT JANUARY 1** | **3,010** | **5,697** |
| Revenue recognition | (3,320) | (462) |
| Redemption | — | (4,777) |
| Addition | 720 | 2,500 |
| Exchange rate differences | 21 | 53 |
| **BALANCE AS AT CLOSING DATE** | **432** | **3,010** |
| Less non-current portion | — | — |
| **CURRENT PORTION** | **432** | **3,010** |

As at December 31, 2025, contract liability of €0.4 million related to upfront payments for analytical support and drug substance manufacturing on ongoing contracts.

In the year ended December 31, 2025, revenue of €2.5 million was recognized in connection with the license and technology transfer performance obligation under the master collaboration and license agreement with Serum Institute of India (SII) regarding IXCHIQ.

In the year ended December 31, 2024, the redemption in the amount of €4.8 million mainly related to the DoD distribution agreement for which the obligation to replace vaccine doses was fulfilled in 2024. An upfront payment of €2.5 millionwas shown under additions and refered to the master collaboration and license agreement with Serum Institute of India (SII) regarding IXCHIQ.

## 5.29 Refund liabilities

A refund liability has to be recognized when the customer has already provided a consideration which is expected to be refunded partially or totally. It is measured at the amount the Company has an obligation to repay or amounts which did not meet the criteria for revenue recognition in the past, but there are no remaining goods and services to be provided in future.

Development of refund liabilities during the period is presented below:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| **BALANCE AS AT JANUARY 1** | **26,141** | **39,941** |
| Additions | 4,649 | 4,013 |
| Payments | — | (979) |
| Other releases | (1,117) | (18,922) |
| Revenue recognition | (9,985) | — |
| Interest expense capitalized | 193 | 360 |
| Exchange rate difference | (2,383) | 1,728 |
| **BALANCE AS AT CLOSING DATE** | **17,498** | **26,141** |
| Less non-current portion | (6,684) | (6,491) |
| **CURRENT PORTION** | **10,814** | **19,650** |

As at December 31, 2025, from the total refund liability of €17.5 million, an amount of €9.0 million - current portion only- (December 31, 2024: €18.6 million) is connected to the Collaboration and License Agreement with Pfizer. In the year ended December 31, 2025, additions of €3.5 million arose from the Pfizer Collaboration and License Agreement

(December 31, 2024: €2.6 million). In 2025, the recognized revenue of €10.0 million (December 31, 2024: nil) and other releases of €0.9 million (December 31, 2024: €18.9 million) were recorded in connection to the Collaboration and License Agreement with Pfizer as well.

Refund liabilities of €6.7 million (of which €6.7 million is non-current) (December 31, 2024: €6.5 million, of which €6.5 million was non-current) relate to the expected payment in 2027 to GlaxoSmithKline (GSK) due to the termination of the strategic alliance agreement (SAA) in 2019.

The remaining amount of €1.8 million is mainly due to statistical return provision and rebates as at December 31, 2025 (December 31, 2024: €1.1 million).

# 5.30 Provisions

## 5.30.1 Provisions for employee commitments

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Employer contribution costs on share-based compensation plans | 1,497 | 81 |
| Phantom shares | 7 | 1 |
| Retirement termination benefits | 171 | 515 |
| Leaving indemnities and restructurings | 4,671 | 964 |
| **BALANCE AS AT CLOSING DATE** | **6,346** | **1,561** |
| Less non-current portion | 697 | 546 |
| **CURRENT PORTION** | **5,649** | **1,015** |

On September 16, 2025, Valneva's employee representatives and Valneva's teams based in Nantes were informed of the proposed closure of the Nantes site. In accordance with its legal obligations, Valneva initiated an information and consultation process with the Company's local work council to reorganize its activities. In the year ended December 31, 2025 the provision for leaving indemnities and restructuring mainly relates to the proposed closure of the Nantes site.

### Share-based provisions

Employer contribution costs on share-based compensation plans and phantom shares are calculated at the balance sheet date using the share price of Valneva as at December 31, 2025: €3.72 (December 31, 2024: €2.16). The increase in these provisions as at December 31, 2025 is mainly due to the share price movement.

### Retirement termination benefits

Some Group companies provide retirement termination benefits to their retirees.

For defined benefit plans, retirement costs are determined once a year:

- From December 31, 2021 onward, under the new calculation method proposed by the IFRS IC and according to the updated recommendation of the ANC n 2013-02 as at December 31, 2021: under this method, when the plan provides for the payment of an indemnity to the employee, if he or she is present at the date of retirement, the amount of which depends on seniority and is capped at a certain years of service, the commitment must be calculated solely on the basis of the years of service prior to the retirement date.

The final obligation is then discounted. These calculations mainly use the following assumptions:

- a discount rate;
- a salary increase rate;
- an employee turnover rate.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise.

For basic schemes and defined contribution plans, the Group recognizes the contributions as expenses when payable, as it has no obligations over and above the amount of contributions paid.

### Assumptions used

| | Year ended December 31 | |
|---|---|---|
| | 2025 | 2024 |
| Discount rate | 3.90 % | 3.40 % |
| Salary increase rate | 2.00 % | 2.50 % |
| Turnover rate | 0%-21.35% | 0%-21.35% |
| Social security rate | 46.00 % | 43.00%-47.00% |
| Average remaining lifespan of employees (in years) | 17 | 20 |

### Changes in defined benefit obligation

Present value of obligation development:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| **BALANCE AS AT JANUARY 1** | **515** | **459** |
| Current service cost | 128 | 105 |
| Past service cost due to curtailment | (404) | — |
| Actuarial losses/(gains) | (68) | (49) |
| **BALANCE AS AT CLOSING DATE** | **171** | **515** |

The proposed closure of the Nantes site leads to a significant reduction of the defined benefit obligation.

## 5.30.2 Other provisions

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| Non-current | 694 | — |
| Current | 6,010 | 5,671 |
| **PROVISIONS** | **6,705** | **5,671** |

The position mostly comprises €5.2 million from a provision for expected legal and settlement costs under a court proceeding related to the Intercell AG/Vivalis SA merger (December 31, 2024: €5.2 million) For further information on this court proceeding, please see Note 5.33.

Additionally to cover employee non-related cost related to the closure of the Nantes side, a restructuring provision of €0.4 million (December 31, 2024: nil) was recorded in 2025.

In the year ended December 31, 2025 the non-current provision relates to an onerous lease agreement.

## 5.31 Other liabilities

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | 2025 | 2024 |
| Deferred income | 5,794 | 5,028 |
| Other financial liabilities | 7 | 79 |
| Miscellaneous liabilities | 134 | 91 |
| **OTHER LIABILITIES** | **5,935** | **5,198** |
| Less non-current portion | (246) | (46) |
| **CURRENT PORTION** | **5,689** | **5,152** |

As at December 31, 2025 the other liabilities increased due to a received resilience grant of €0.9 million from the European Union. In both 2025 and 2024 other liabilities mainly comprised deferred income related to the second agreement signed with CEPI.

# 5.32 Cash flow information

## 5.32.1 Cash generated from operations

The following table shows the adjustments to reconcile net loss to net cash generated from operations:

| | Year ended December 31, | | |
|---|---|---|---|
| *in € thousand* | **2025** | **2024** | **2023** |
| **PROFIT/(LOSS) FOR THE PERIOD** | **(115,192)** | **(12,247)** | **(101,429)** |
| | | | |
| **Gain from sale of Priority Review Voucher, net** | **—** | **(90,833)** | **—** |
| **Adjustments to reconcile profit/(loss) for the period to cash generated from/(used in) operations:** | | | |
| Depreciation and amortization | 21,750 | 19,586 | 17,584 |
| Write-off / impairment fixed assets/intangibles | 895 | — | (731) |
| Share-based compensation expense | 9,533 | 7,975 | 5,111 |
| Income tax expense/(income) | 1,073 | 761 | 2,800 |
| (Profit)/loss from disposal of property, plant, equipment and intangible assets | 432 | (266) | (12) |
| (Profit)/loss from disposal held for sale | — | — | 580 |
| (Gain)/loss from MMF investments | (841) | — | — |
| Provision for employer contribution costs on share-based compensation plans | 1,408 | (1,594) | (1,659) |
| Other non-cash (income)/expense | (9,697) | 895 | (804) |
| Interest income | (1,803) | (2,362) | (1,210) |
| Interest expense | 41,898 | 23,984 | 23,325 |
| **Total adjustments to reconcile profit/(loss) for the period to cash generated from/(used in) operations** | **64,649** | **48,979** | **44,984** |
| **CHANGES IN NON-CURRENT OPERATING ASSETS AND LIABILITIES (EXCLUDING THE EFFECTS OF ACQUISITION AND CONSOLIDATION):** | | | |
| Other non-current assets | 446 | 449 | (192) |
| Long term refund liabilities | — | — | 1,136 |
| Other non-current liabilities and provisions | 877 | (629) | (430) |
| **TOTAL CHANGES IN NON-CURRENT OPERATING ASSETS AND LIABILITIES** | **1,323** | **(180)** | **514** |
| **CHANGES IN WORKING CAPITAL (EXCLUDING THE EFFECTS OF ACQUISITION AND EXCHANGE RATE DIFFERENCES ON CONSOLIDATION):** | | | |
| Inventory | 1,032 | (6,803) | (9,165) |
| Trade and other receivables | 13,326 | 15,707 | (2,855) |
| Contract liabilities | (2,600) | (2,793) | (3,471) |
| Refund liabilities | (8,774) | (14,183) | (112,689) |
| Trade and other payables and provisions | (4,455) | (3,321) | (17,398) |
| **Total changes in working capital** | **(1,471)** | **(11,394)** | **(145,578)** |
| **CASH GENERATED/(USED) IN OPERATIONS** | **(50,691)** | **(65,674)** | **(201,509)** |

### 5.32.2 Reconciliation of liabilities arising from financing activities

Liabilities arising from financing activities are those for which cash flows were (or future cash flows will be) classified in the Group's consolidated statement of cash flows as cash flows from financing activities. The below table illustrates the development of borrowings. For development of lease liabilities see Note 5.27.

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| **BALANCE AS AT JANUARY 1** | **187,373** | **176,847** |
| Proceeds of issue | 184,015 | 910 |
| Transaction costs | (10,130) | (944) |
| Repayments | (171,632) | (3,734) |
| Revaluations | (209) | (385) |
| Accrued interest | 28,695 | 22,862 |
| Payment of interest | (17,682) | (19,156) |
| Exchange rate difference | (21,265) | 10,974 |
| **BALANCE AS AT DECEMBER 31** | **179,167** | **187,373** |

## 5.33 Commitments and contingencies

As at December 31, 2025, there were €1.0 million of capital expenditure contracted, mainly related to manufacturing site in Sweden for equipments (December 31, 2024: €3.5 million). The contracts in 2024 were all related to the finalization of the Almeida building in Scotland, the new manufacturing facility and production site for IXIARO and IXCHIQ, and to manufacturing equipment in Sweden for DUKORAL production site.

As at December 31, 2025, there were €33.2 million (December 31, 2024: €39.3 million) related to R&D collaboration agreements. These commitments include milestone payments depending on successful clinical development or meeting specific revenue targets. The amount disclosed represents the maximum that would be paid if all milestones achieved.

### 5.33.1 Other commitments, pledges and guarantees

The other commitments mainly relate to royalty payments and consist of:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Royalties | 4,255 | 6,025 |
| **OTHER COMMITMENTS** | **4,255** | **6,025** |

The pledges consist of:

| | Year ended December 31 | |
|---|---|---|
| *in € thousand* | **2025** | **2024** |
| Pledges on bank accounts | 105,758 | 164,546 |
| **GUARANTEES AND PLEDGES** | **105,758** | **164,546** |

As at December 31, 2025, the stated pledges on cash at banks originate from the requirements of the Pharmakon Loan Agreement, whereas at December 31, 2024, they stem from the requirements of the D&O Loan Agreement. Similar to the D&O loan, the Pharmakon loan is secured by substantially all of Valneva's assets, including its intellectual property, and is guaranteed by the Company and certain of its subsidiaries. For more information about this loan agreement, please refer to Note 5.24.

### 5.33.2 Contingencies and litigations

Following the merger between the companies Vivalis SA and Intercell AG in 2013, certain former Intercell shareholders initiated legal proceedings before the Commercial Court of Vienna to request a revision of either the cash compensation paid to departing shareholders or the exchange ratio between Intercell and Valneva shares used in the merger.

In October 2021, Valneva received an opinion from a court-appointed expert regarding the exchange ratio. The expert confirmed the calculation used previously, but also recommended the calculation of safety margins. Additionally, the expert addressed the cash compensation paid to departing shareholders and recommended an increase in such compensation. The expert provided a supplemental opinion in April 2022, and the judicial committee in charge of the proceedings gave its opinion to the Commercial Court of Vienna in April 2023.

On December 1, 2025, Valneva was informed that the Vienna Commercial Court had confirmed that 1) the exchange ratio was adequate, meaning no additional compensation is required in connection with the conversion of Intercell shares, 2) shareholders are entitled to an additional cash compensation of EUR3.52 plus interest per share (in line with the

Company's expectations) and 3) the Court's decision on costs is reserved until final conclusion of the proceedings. On January 16, 2026, the Commercial Court informed the Company of two appeals of this initial decision. The first appeal was filed by the common representative of the plaintiffs and challenges the exchange ratio. The second appeal was filed by two shareholders and challenges both the exchange ratio and the amount of cash compensation. The Company has submitted a response to these appeals and is now awaiting further information from the Commercial Court. Valneva is not obligated to make any payments to litigants until a final judgment is available.

The final outcome will depend on the court's position on specific legal points and the Court has not made a final decision yet. The Company therefore has decided to retain the original provision of €5.2 million, which assessed the probability of several scenarios, to cover the potential amounts due and legal costs (December 31, 2024: €5.2 million).

## 5.34 Related-party transactions

In the year ended December 31, 2025, there were no changes to related parties, whereas some changes occurred in 2024. As the business evolved, management reassessed the contract with Groupe Grimaud La Corbière SAS in the previous year, Sevremoine (France) and its affiliate Vital Meat SAS. It was determined that they are no longer considered as related parties. Bpifrance, Maisons-Alfort (France) continues to be considered as related party due to its significant influence through material transactions and through a membership in the Company's Board of Directors until June 25, 2025.

Additionally, there have been some changes in the key management personnel during the year. Since the transition to a one-tier governance model, in December 2023, the key management consists of the Board of Directors as well as the Executive Committee while until December 2023, it included the Management Board and the Supervisory Board.

### 5.34.1 Rendering of services

Transactions with related parties are carried out similar to those of the market:

| | Year ended December 31 | | |
|---|---|---|---|
| *In € thousand* | 2025 | 2024 | 2023 |
| **Provision of services:** | | | |
| Operating activities | — | 391 | 260 |
| Financing activities | 141 | 194 | 76 |
| **PROVISION OF SERVICES** | **141** | **585** | **335** |

Services provided by Valneva to Groupe Grimaud La Corbière SAS, a shareholder of Valneva, were considered related party transactions until December 31, 2024 and consist of services within a collaboration and research license agreement and of the provision of premises and equipment and sale of patents and cells shown in the operating activity line.

From June 2022 onward, Bpifrance qualifies as a related party since it is a shareholder of Valneva with significant influence through its membership of the Company's Board of Directors. Valneva has borrowed amounts amounting to 80% of French Tax Authorities receivables relating to Research Tax Credits for 2022 and 2023 and 2024 from Bpifrance. The total amount borrowed from Bpifrance is €3.1 million. A commitment fee of 0.5% as well as interest at the EURIBOR one-month average rate of the previous month (the rate mentioned is a variable rate deducted at nil percent if it were to be negative) plus 1.7% p.a. is applicable to these borrowed amounts (see table above).

The borrowings related to the Research Tax Credits outstanding:

| *In € thousand* | Amount | Grant date |
|---|---|---|
| BPI payable relating to Research tax credit 2022 | 1,198 | December 2023 |
| BPI payable relating to Research tax credit 2023 | 910 | November 2024 |
| BPI payable relating to Research tax credit 2024 | 1,036 | December 2025 |

### 5.34.2 Key management compensation

The aggregate compensation of the key management (including Executive Committee and Board of Directors) was as follows:

| | Year ended December 31 | | |
|---|---|---|---|
| *In € thousand* | 2025 | 2024 | 2023 |
| Salaries and other short-term employee benefits | 5,359 | 4,624 | 3,439 |
| Other long-term benefits | 90 | 83 | 52 |
| Share-based payments (expense of the year) | 3,765 | 3,128 | 2,145 |
| **KEY MANAGEMENT COMPENSATION** | **9,213** | **7,835** | **5,636** |

In the year ended December 31, 2025, the aggregate compensation of the members of the Company's Executive Committee (former Management Board) amounted to €8.7 million (2024: €7.4 million, 2023: €5.2 million) and represents primarily salaries and share-based payments. The increase in 'Salaries and other short-term employee benefits' relates to additional two Executive Committee members. 'Share-based payments' increased due to the new free ordinary shares granted during 2025.

The presented key management compensation includes that of the Board of Directors in the amount of €0.5 million for the year ended December 31, 2025 (2024: €0.5 million; 2023: €0.5 million).

## 5.35 Events after the reporting period

### *Valneva Provides Update on Chikungunya Vaccine IXCHIQ*

On January 19, 2026, Valneva SE announced its decision to voluntarily withdraw the Biologics License Application (BLA) and Investigational New Drug (IND) application for its chikungunya vaccine, IXCHIQ, in the United States. This decision followed the suspension of the vaccine license by the U.S. Food and Drug Administration (FDA) in August 2025 and the FDA's subsequent decision to place the IND on clinical hold pending an investigation into a newly reported foreign serious adverse event.

### *Lyme VALOR study - Phase 3 data-readout expected in the first half of 2026*

Valneva is awaiting results from the pivotal, placebo-controlled efficacy clinical study, "Vaccine Against Lyme for Outdoor Recreationists (VALOR)" in the first half of 2026, conducted by our partner Pfizer. A positive outcome of the study may lead to potential regulatory approvals and commercialization of VLA15, upon which the Company will be eligible to receive milestone and royalty payments. This increased revenue will allow investments in future R&D projects and may position the Company to become financially self-sustainable. If the primary endpoint of the Phase 3 trial is not met, the Group will be required to undergo restructuring and implement cost-containment measures that would allow the Group to meet its financial obligations for the foreseeable future but would significantly impact its operations and prospects. These restructuring measures would require alignment with Pharmakon to avoid an event of default. The Company cannot guarantee such measures would be sufficient in the long term, and renegotiation of existing debt terms or alternative measures to refinance or repay the debt may be required.

### *FDA audit of the Livingston manufacturing site*

Following an inspection of our Livingston manufacturing site in February 2026, the FDA informed the Company that it is unable to grant approval of the BLA supplement related to manufacture of IXIARO at the Almeida facility due to outstanding compliance issues associated with the inspection. As a result, Valneva is currently unable to use the Almeida facility to produce doses of IXIARO intended for distribution in the United States. The Almeida facility is approved by EMA and Health Canada. Therefore, IXIARO doses produced at this facility will be sold in these regions while products manufactured at the Manson site will be distributed in the United States. The Company currently does not anticipate material supply constraints in the US market and expects to remediate the observations identified by the FDA in 2026 and potentially restart manufacturing at Manson. Valneva does not expect this event to have a material impact on its cash projection in the foreseeable future.