

**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, 2022
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
- For the transition period from \_\_\_\_\_ to \_\_\_\_\_
- 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 001-38281

**ERYTECH Pharma S.A.**

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

France

(Jurisdiction of incorporation or organization)

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(Address of principal executive offices)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value €0.10 per share	ERYP	The Nasdaq Global Select Market
Ordinary shares, nominal value €0.10 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, nominal value €0.10 per share: 31,018,553 as of December 31, 2022

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.

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.  Yes  No

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 required 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, “ERYTECH,” “the company,” “our company,” “we,” “us” and “our” refer to ERYTECH Pharma S.A. and its consolidated subsidiary.

“ERYTECH Pharma,” “ERYCAPS®” “GRASPA®” the ERYTECH logo and other trademarks or service marks of ERYTECH Pharma S.A. appearing in this Annual Report on Form 20-F for the year ended December 31, 2022, or the Annual Report, are the property of ERYTECH Pharma S.A. or its subsidiary, ERYTECH Pharma, Inc. 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 U.S. 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 positions, 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:

- our exploration of strategic alternatives for our business;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials;
- our ability to successfully develop our ERYCAPS<sup>®</sup> platform and develop our pipeline of product candidates;
- the size and growth potential of the markets for our product candidates, if approved, and the rate and degree of market acceptance of our product candidates, including reimbursement that may be received from payors;
- the timing of our regulatory filings for our product candidates, along with regulatory developments in the United States, European Union and other foreign countries;
- our ability to maintain and enter into and successfully complete collaborations and licensing arrangements or to in-license or acquire rights to other products, product candidates or technologies;
- our reliance on third parties to manufacture and conduct the clinical trials of our ERYCAPS<sup>®</sup> product candidates, which could limit our commercialization efforts or delay or limit their future development or regulatory approval;
- our ability to enter into partnership agreements to effectively commercialize the sale, commercialization, marketing and manufacturing of the products we develop;
- our ability to produce adequate supplies of our product candidates for preclinical and clinical testing and to fulfill our contractual obligations to third-party distributors;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to obtain funding for our operations and working capital requirements;
- our ability to maintain, protect and enhance our intellectual property rights and proprietary technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- regulatory developments in the United States, the European Union and other foreign countries;
- our ability to attract and retain qualified employees and key personnel;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our planned level of capital expenditures, our cash preservation measures and the sufficiency of our existing cash, cash equivalents and short-term investments and other transactions in the future to fund our operating expenses and capital expenditure requirements;
- the uncertainty of economic conditions in certain countries in the European Union and Asia, such as those related to the COVID-19 pandemic, the armed conflict between Russia and Ukraine and general economic conditions;
- the ability of our ordinary shares represented by American Depositary Shares to regain compliance with the continued listing standards of the Nasdaq Global Select Market and remain listed;
- whether or not we are classified as a passive foreign investment company, or PFIC, for current and future periods; 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.

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.

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. 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.

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

Investing in our shares involves numerous risks, including the risks described in “Item 3.D—Risk Factors” of this Annual Report on Form 20-F. Below are some of our principal risks, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects:

- Following the halt of our principal product candidate, we have announced a proposed strategic combination with Pherecydes, that could be delayed or could not occur.
- We will need to raise substantial additional funding to pursue our business objectives, which may not be available on acceptable terms, or at all, and failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts, potential commercialization efforts or other operations.
- We have incurred significant losses since our inception and expect that we will continue to incur significant losses for the foreseeable future and we may never achieve profitability.
- Changes in European Union regulations may limit our ability to attract and obtain additional financing sources outside France.
- We have no approved products, which makes it difficult to assess our future prospects.
- We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us.
- Due to our limited resources and access to capital, our decisions to prioritize development of certain product candidates may adversely affect our business prospects.
- If our product candidates are not approved for marketing by applicable government authorities, we will be unable to commercialize them.
- Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the European Commission, the EMA, FDA and other regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.
- In the United States, our product candidates will be regulated as biological products, or biologics, which may subject them to competition sooner than we currently anticipate.
- We rely on third parties to assist in our discovery and development activities, and the loss of any of our relationships with research institutions could hinder our product development prospects.
- We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.
- Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we market our products, which could materially impair our ability to generate revenues.
- Our production capacity could prove insufficient for our needs.
- Our production costs may be higher than we currently estimate.
- Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may adversely affect our results of operations, our cash flows and our financial condition.
- Our ability to compete may decline if we do not adequately protect our proprietary rights.
- The market price of our equity securities may be volatile or may decline regardless of our operating performance.
- The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of our ordinary shares and ADSs.
- 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.

## 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.

#### 3.A. Selected Financial Data

Not applicable.

#### 3.B. Capitalization and Indebtedness

Not applicable.

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

Not applicable.

#### 3.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.*

##### 3.D.1. Risks Related to our Financial Position and Capital Needs

*We will need to raise substantial additional funding to pursue our business objectives, which may not be available on acceptable terms, or at all, and failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts.*

We have structurally recorded net losses since our inception. Our net cash flows used in operating activities were €51.7 million, €56.8 million and €31.8 million for the years ended December 31, 2020, 2021 and 2022, respectively. As of December 31, 2022, our cash and cash equivalents were €38.8 million (\$41.5 million) compared to €33.7 million as of December 31, 2021 which represents an annual cash and cash equivalents net increase of €5.1 million.

In October 2021, we announced that our Phase 3 clinical trial of eryaspase (also referred to as GRASPA<sup>®</sup>), our lead product candidate at that time, for the treatment of second-line advanced pancreatic cancer did not meet its primary endpoint of overall survival. Following announcement, we conducted a specific review of our liquidity risk and put in place cash preservation measures. In April 2022, we sold the lease for our manufacturing facility in Princeton, New Jersey (the "Princeton Facility"), which began producing eryaspase for use in our US clinical trials in the fourth quarter of 2019, and certain assets and inventory of materials located thereat to Catalent Princeton, LLC ("Catalent") pursuant to an asset purchase agreement, for aggregate gross proceeds of approximately \$44.5 million (€40.7 million). In November 2022, following the FDA's feedback on a potential Biologics License Application ("BLA") submission in hypersensitive acute lymphoblastic leukemia ("ALL"), we announced our strategic decision to halt further development of GRASPA<sup>®</sup> and to focus on leveraging our platforms and expertise, including drug-delivery by encapsulation with red blood cells (ERYCAPS<sup>®</sup>) or red blood cell-derived vesicles (ERYCEV<sup>™</sup>).

Please see the sections titled "Item 4.B.1. Overview" and "Item 4.B.2 Our Strategy" of this Annual Report for further information on recent developments of our business and strategic alternatives and development opportunities.

We believe, based on our current development plan, that our cash and cash equivalents of €38.8 million as of December 31, 2022, taking into account the sale of the Princeton Facility to Catalent and the associated cost reductions, will enable us to cover our cash requirements until mid-2024.

Combined company (including Pherecydes) cash runway would extend into Q3 2024, with a consolidated cash position of approximately €41 million as of December 31, 2022, and would enable funding of existing and new programs through multiple clinical milestones.

However, we will need to obtain substantial additional funding to support our continuing operations beyond mid-2024. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we or any current or future collaborators may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, any of our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from the sale of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Our ability to raise additional funds in the short-term will depend on financial, economic and market conditions and the willingness of potential investors or lenders to provide funding, all of which are outside of our control, and we may be unable to raise financing in the short-term, or on terms favorable to us, or at all. Furthermore, high volatility in the capital markets has had, and could continue to have, a negative impact on the price of our ordinary shares, including ordinary shares represented by American Depositary Shares (“ADSs”), and could adversely impact our ability to raise additional funds. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or cease all operations, and our shareholders could lose all or part of their investment in our company.

### ***Risks related to the proposed merger with Pherecydes Pharma***

In February 2023, we announced a proposed strategic combination with Pherecydes intending to create a global player in phage therapy and accelerating the development of a portfolio of drug candidates, targeting pathogenic bacteria and other potential indications with significant unmet medical needs. The Proposed Merger is expected to close at the end of the first half of 2023 (or the beginning of the second half of 2023).

The obligation of the Company and Pherecydes to complete the Proposed Merger is subject to a number of conditions precedent, some of which could prevent, delay or materially and adversely affect the completion of the Proposed Merger. We cannot guarantee as to when these conditions will be satisfied or that other events that could delay or prevent the completion of the Proposed Merger will not occur.

If for any reason the Proposed Merger is not completed, our Board of Directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our remaining assets, or seek to continue to operate our business. Any of these alternatives would be costly and time-consuming and would require that we obtain additional funding. We expect that it would be difficult to secure such funding in a timely manner, on favorable terms or at all.

Any delay in completing the Proposed Merger could prevent or delay the realization by the combined group of some or all of the cost savings, synergies, growth opportunities and other benefits that the Company expects to achieve through a timely completion of the merger. If the Proposed Merger is not completed for any reason, including because the Company's shareholders or Pherecydes' shareholders do not approve the Proposed Merger, the Company's business, cash flows, financial condition or results of operations could be materially adversely affected. If the Company fails to realize the expected benefits of the Proposed Merger, it would be exposed to a number of risks, including

- we could be confronted with negative reactions from the financial markets, including a decrease in the market price of our shares ;
- we could be adversely affected by the significant deployment of time and resources by our management team in connection with the Proposed Merger, which would have otherwise been devoted to day-to-day operations and other potentially beneficial opportunities for the Company had the Proposed Merger not been contemplated.

In addition, the combined group may not realize some or all of the expected benefits of the Proposed Merger. The realization of the expected benefits of the Proposed Merger is subject to a number of uncertainties, and depends in particular on our ability to integrate the business of Pherecydes in an efficient and timely manner. Indeed, the group thus formed may not have, or may not have sufficiently, assessed, developed and worked on the compatibility of the organizations, the degree of transformation they can support and the conduct of this process. It could be difficult to reconcile the operational requirements and the strategic vision of the new entity. If the expected benefits are not achieved, this could result in increased costs, reduced results for the combined company and a detour

of management's time and energy, which could have a material adverse effect on the combined group's business, cash flows, financial condition or results.

All of these factors could limit or delay the expected beneficial effect of the Proposed Merger.

***We cannot assure you that our exploration of strategic alternatives for our business will result in us successfully pursuing a transaction or that any such transaction would be successfully completed; there may also be negative impacts on our business and share price as a result of the process of exploring strategic alternatives for our business.***

Following the sale of the Princeton Facility to Catalent in April 2022, we engaged a financial advisor to assist in the process of exploring strategic alternatives for our business, intended to maximize shareholder value.

On February 15, 2023, we and PHERECYDES Pharma S.A. ("PHERECYDES") jointly issued a press release announcing a proposed combination (the "Proposed Merger") of the two companies, intended to create a global leader in extended phase therapy. On that date, we entered into a memorandum of understanding with PHERECYDES, setting forth the key transaction terms. While we expect to enter into a definitive merger agreement with PHERECYDES for the Proposed Merger, subject to consultation with our works council, the signing of such definitive merger agreement and the closing of the Proposed Merger may be delayed or may not occur at all. In addition, there can be no assurance that the Proposed Merger, if completed, will deliver the anticipated benefits the parties expect or enhance shareholder value.

Further, in each of the foregoing scenarios, the failure to complete the Proposed Merger may result in negative publicity and a negative impression of our company in the investment community, could significantly harm the market price of our ordinary shares (including shares represented by ADSs), may affect our relationship with employees, service providers and other partners in the business community, and may further impede the ability to raise additional financing.

If for any reason the Proposed Merger is not completed, there is no guarantee that we will be able to obtain additional financing or to find a new strategic partner. If a new strategic partner were identified, we can provide no assurance that it would be able to close an alternative transaction on terms that are at least as favorable as the terms contemplated by the Proposed Merger. Accordingly, there is significant risk that such alternatives, if any, may not be successfully consummated, if pursued. In such case, our Board of Directors may decide that it is in the best interests of our shareholders to dissolve the company and liquidate its assets.

The price of our ordinary shares or ADSs may be adversely affected if the process does not result in a transaction or if a transaction is consummated on terms that investors view as unfavorable to us. Even if a transaction is completed, there can be no assurance that it will be successful or have a positive effect on shareholder value. Our Board of Directors may also determine that no transaction is in the best interest of our shareholders.

In addition, our financial results and operations could be adversely affected by the Proposed Merger process and by the uncertainty regarding its outcome. The attention of management, including management of our business and of our Board of Directors, could be diverted from our core business operations, and we have diverted capital and other resources to the process that otherwise could have been used in our business operations, and we will continue to do so until the process is completed. We could incur substantial expenses related to employee retention payments, equity compensation, severance pay and legal, accounting and financial advisor fees. In addition, the process could lead us to lose or fail to attract, retain and motivate key employees, and to lose or fail to attract business partners, and could expose us to litigation.

See also the risk factor titled "*We may not realize the benefits of our proposed acquisition of PHERECYDES*" below.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our product candidates.***

To date, we have financed our operations primarily through a combination of sale of equity securities, debt financings, including, but not limited to, an at-the-market ("ATM") offering program and registered direct offerings in the United States, the convertible bond financing pursuant to the OCABSA Agreement (as defined below), state-guaranteed loans in France (Prêt Garanti par l'Etat, or PGE, loans), and public assistance programs in support of innovation, such as the conditional advances and subsidies from the *Banque Publique d'Investissement* ("Bpifrance") and research tax credits. Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if

available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Under French laws, the total number of new shares that may be issued pursuant to the US ATM offering program is capped at 20% of the number of shares admitted to trading on Euronext Paris, including shares admitted without a prospectus during the twelve months prior to their issuance. Please refer to “Item 10.B. Liquidity and capital resources” and “Item 10.C Material Contracts” for further information on the convertible bond financing and the ATM program.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We have incurred significant losses since our inception and expect that we will continue to incur significant losses for the foreseeable future and we may never achieve profitability.***

We have not yet generated significant revenues and have incurred significant operating losses since our inception. We incurred net losses of €73.3 million, €53.8 million and €0.2 million for the years ended December 31, 2020, 2021 and 2022, respectively; these losses have adversely impacted, and will continue to adversely impact, our equity attributable to shareholders and net assets. These losses are principally the result of our research expenditures and development costs for conducting preclinical studies and clinical trials, as well as general and administrative expenses associated with our operations. We anticipate that our operating losses will continue until we generate substantial revenues from any approved product candidates. As of December 31, 2022, we had a total shareholders' equity of €23.5 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. The amount of our future net losses will depend, in part, on the pace and amount of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or tax credits until such time, if ever, as we can generate substantial product revenue. We have not yet received marketing approval for any of our product candidates. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We anticipate that our expenses will increase substantially as we:

- continue the preclinical development of our product candidates;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract new and retain existing skilled personnel; and
- create additional infrastructure or improve existing ones to support our operations.
- incur additional transaction and reorganization costs in connection with the Proposed Merger with Pherecydes.

Our operating results may fluctuate significantly from year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular period or periods, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ordinary shares and ADSs to decline.

***We have entered into a note and warrant transaction consisting of tranches of convertible bonds with warrants attached (OCABSA) and may encounter adverse effects as a result thereof.***

On June 24, 2020, we entered into an agreement with Luxembourg-based European High Growth Opportunities Securitization Fund, represented by its asset manager European High Growth Opportunities Manco SA, which we refer to as the OCABSA Agreement, pursuant to which we may issue 1,200 convertible notes (bons d'émission, or BEOCABSA) that give the holder the right to receive new and/or existing ordinary shares with warrants attached (“OCABSA”). The share warrants attached to the notes represent 10% of

the nominal amount of the issued notes and have an exercise price of €8.91 per share. This exercise price represents a 20% premium over the lowest volume-weighted average daily price of the share over the reference period preceding the issue of the first tranche.

As of December 31, 2022, we issued nine tranches of €3.0 million (on July 6, 2020, August 24, 2020, November 17, 2020, December 7, 2020, December 22, 2020, March 2, 2021, May 19, 2021, July 22, 2021 and August 24, 2021), for a total amount of €27.0 million, all of which convertible notes have been converted into ordinary shares and no warrants have been exercised. Pursuant to the OCABSA Agreement, the provision for issuance of additional tranches expired on June 25, 2022.

By using this financing program, we may encounter the following adverse effects:

- the rapid and frequent sale of the new shares resulting from the exercise of the share warrants by the investor may adversely impact our share price;
- as our share price has an impact on the number of shares issued upon the exercise of the share warrants, the number of shares issued upon the exercise of the share warrants is uncertain and may significantly fluctuate during the lifetime of the financing program; and
- the exercise of all or part of the share warrants could have a potentially significant dilutive effect for our shareholders.

### **3.D.2. Risks Related to Development of our existing Product Candidates**

***We have no approved products, which makes it difficult to assess our future prospects.***

A key element of our strategy is to use and expand our proprietary ERYCAPS® platform to build a pipeline of innovative product candidates and to progress these drug candidates through clinical development for the treatment of severe forms of cancer and orphan diseases. The discovery of therapeutic drugs based on encapsulating molecules inside red blood cells is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop drug candidates are relatively new. The scientific evidence to support the feasibility of developing drug candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of product candidates, we have not obtained approval for any products, we have not yet generated any revenues from the sale of approved products and we may not be able to develop product candidates that are considered to be safe and effective. Our operations to date have been limited to developing our ERYCAPS® platform technology and undertaking preclinical studies and clinical trials of our product candidates. However, we have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. Consequently, the ability to predict our future operating results or business prospects is more limited than if we had a longer operating history or approved products on the market.

***We may not be successful in our efforts to use and expand our ERYCAPS® platform to develop marketable products.***

We believe that our ERYCAPS® platform has broad potential application and can be used to encapsulate a wide range of therapeutic agents within red blood cells for which long-circulating therapeutic activity and rapid and specific targeting is desired. However, we are at an early stage of development and our platform has not yet, and may never, lead to approved or marketable products. Even if we are successful in continuing to build our product pipeline, the potential product candidates that we identify may not be suitable for clinical development, including for reasons related to their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Use of red blood cells as the basis for our ERYCAPS® platform may result in similar risks that affect the ability of our products to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not be able to obtain product or collaboration revenues in future periods, which would harm our business and our prospects.

***We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us.***

The biopharmaceuticals industry is highly competitive. Numerous biopharmaceutical laboratories, biotechnology companies, institutions, universities and other research entities are actively involved in the discovery, research, development and marketing of therapeutics to treat severe forms of cancer and orphan diseases, making it a highly competitive field. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. Any of our product candidates that are approved in the future will also face other competitive factors, including generic competition, which could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our product candidates. If we are not able

to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

### **3.D.3. Risks Related to the Discovery and Development of and Obtaining Regulatory Approval for our Product Candidates**

***Due to our limited resources and access to capital, our decisions to prioritize development of certain product candidates may adversely affect our business prospects.***

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from more promising opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to some of our product development programs may also prove not to be optimal and could cause us to miss valuable 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 arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, our business prospects could be harmed.

***If our product candidates are not approved for marketing by applicable government authorities, we will be unable to commercialize them.***

The European Commission (following review and an opinion by the European Medicines Agency, or EMA) in the European Union, the U.S. Food and Drug Administration, or FDA, in the United States and comparable regulatory authorities in other jurisdictions must approve new drug or biologic candidates before they can be commercialized, marketed, promoted or sold in those territories. We must provide these regulatory authorities with data from preclinical studies and clinical trials that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to the outcome. We must provide data to ensure the identity, strength, quality and purity of the drug substance and drug product. Also, we must assure the regulatory authorities that the characteristics and performance of the clinical batches will be replicated consistently in the commercial batches. We have focused our development and planned commercialization efforts in the European Union and the United States.

The processes by which regulatory approvals are obtained from the European Commission and FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. We cannot assure you that any of our future product candidates will receive European Commission or FDA approval. For example, in September 2015, we submitted a Marketing Authorization Application, or MAA, to the EMA for the approval of GRASPA<sup>®</sup> as a treatment for ALL. However, in November 2016, we announced our withdrawal of the MAA for GRASPA<sup>®</sup>. In October 2017, we resubmitted to the EMA our MAA for GRASPA<sup>®</sup> for relapsed or refractory ALL and subsequently announced our withdrawal of the MAA for GRASPA<sup>®</sup> in June 2018. In August 2022, we halted further plans to pursue a BLA submission seeking an approval for GRASPA<sup>®</sup> in hypersensitive ALL. Even if we obtain marketing approval of any of our product candidates in a major pharmaceutical market such as the United States or the European Union, we may never obtain approval or commercialize our products in other major markets, due to varying approval procedures or otherwise, which would limit our ability to realize their full market potential.

***Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the European Commission, the EMA, FDA and other regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.***

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a product candidate, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. 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. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business and financial condition and on the value of our securities.

In connection with clinical testing and trials, we face a number of risks, including risks that:

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- extension studies on long-term tolerance could invalidate the use of our product;
- the results may not confirm the positive results of earlier testing or trials; and
- the results may not meet the level of statistical significance required by the European Commission, the EMA, FDA or other regulatory agencies to establish the safety and efficacy of our product candidates.

The results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. Differences in enrollment criteria and different combinations with other treatment modalities may also lead to different outcomes in our future clinical trials. As a result, we may not observe a similarly favorable safety or efficacy profile as in our prior clinical trials. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or European Commission approval. In addition, we cannot assure you that in the course of potential widespread use in the future, we will not suffer setbacks in maintaining production quality or stability.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before marketing applications may be submitted to the EMA or FDA, as applicable. For instance, despite having observed favorable results and safety profile in multiple clinical trials of eryaspase in patients with ALL, based on feedback from the regulatory agencies requiring additional investment, increasingly competitive landscape and the limited market opportunity for eryaspase with ALL, we decided in June 2018 to cease further clinical developments efforts in ALL. In addition, our research and development costs amounted to €57.6 million, €45.1 million and €19.9 million during the years ended December 31, 2020, 2021 and 2022, respectively. Although there are a large number of drugs and biologics in development in Europe, the United States and other countries, only a small percentage result in the submission of a marketing application, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed.

***Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay or prevent our ability to generate revenues.***

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. The completion of trials for our other product candidates may be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;
- obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials;
- manufacturing sufficient quantities of a product candidate;
- obtaining approval of applications from regulatory authorities for the commencement of a clinical trial;
- obtaining institutional review board, or IRB, and Ethics Committee, or EC, approval to conduct a clinical trial at a prospective clinical trial site;
- determining dosing and clinical trial design; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

For example, in our Phase 1 clinical trial in the United States in adult ALL patients, patient enrollment took longer than expected.

The commencement and completion of clinical trials for our product candidates may be delayed, suspended or terminated due to a number of factors, including:

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;
- our inability to maintain or enter into collaborations relating to the development and commercialization of our product candidates;
- our failure to conduct clinical trials in accordance with regulatory requirements;
- our inability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- varying interpretations of our data, and regulatory commitments and requirements by the European Commission, the EMA, FDA and similar regulatory authorities;
- continuing impacts of the COVID-19 pandemic; and
- impacts of geopolitical tensions.

If we experience delay, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed or such revenues could be reduced or fail to materialize.

***We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.***

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit patients to participate, as well as completion of required follow-up periods. If patients are unwilling to enroll in our clinical trials because of competitive clinical trials for similar patient populations or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of clinical trials altogether.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA, EMA or other regulatory authorities. Also, we may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment can be affected by many factors, including:

- size of the patient population and process for identifying patients;
- eligibility and exclusion criteria for our clinical trials;
- perceived risks and benefits of our product candidates;
- severity of the disease under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patient consent;
- patient drop-outs prior to completion of clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients or finding additional clinical trial sites to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have an adverse effect on our business, financial condition, results of operations and prospects.

***Changes in regulatory requirements, guidance from regulatory authorities or unanticipated events during the clinical trials of our product candidates could necessitate changes to clinical trial protocols or additional clinical trial requirements, which would result in increased costs to us and could delay our development timeline.***

Changes in regulatory requirements, FDA guidance or guidance from the EMA or other European Union regulatory authorities, or unanticipated events during our clinical trials, may force us to amend clinical trial protocols. The regulatory authorities could also impose additional clinical trial requirements. Amendments to our clinical trial protocols would require resubmission to the FDA, national clinical trial regulators, IRBs and ECs for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed.

***We rely on third parties to assist in our discovery and development activities, and the loss of any of our relationships with research institutions could hinder our product development prospects.***

We currently have and expect to continue to depend on collaborations with public and private research institutions to conduct some of our early-stage drug discovery activities. If we are unable to enter into research collaborations with these institutions, or if any one of these institutions fails to work efficiently with us, the research, development or marketing of our product candidates planned as part of the research collaboration could be delayed or canceled. In the event a research agreement is terminated or we become no longer in a position to renew the arrangement under acceptable conditions, our drug discovery and development activities may also be delayed.

***We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.***

We rely, and will rely in the future, on medical institutions, clinical investigators, CROs, contract laboratories and collaborators to perform data collection and analysis and to carry out our clinical trials.

Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not devote a sufficient amount of time or effort to our activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

We generally would not have the ability to control the performance of third parties in their conduct of development activities. In the event of a default, bankruptcy or shutdown of, or a dispute with, a third party, we may be unable to enter into a new agreement with another third party on commercially acceptable terms. Further, third-party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. In addition, our third-party agreements usually contain a clause limiting such third party's liability, such that we may not be able to obtain full compensation for any losses we may incur in connection with the third party's performance failures. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

***We may enter into collaboration agreements with third parties for the development and commercialization of our product candidates, which may affect our ability to generate revenues.***

We have limited capabilities for product development and may seek to enter into collaborations with third parties for the development and potential commercialization of our product candidates. For example, in June 2019, we entered into a collaboration with SQZ Biotechnologies to focus on the development of novel red blood-cell based therapeutics for the treatment of immuno-oncology and tolerance induction. Should we seek to collaborate with any additional third parties with respect to a prospective development program, we may not be able to locate a suitable collaborator and may not be able to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing collaborators for the development and commercialization of our product candidates, we will have limited control over the amount and timing that our collaborators may dedicate to the development or commercialization of our product candidates. These collaborations pose a number of risks, including the following:

- collaborators may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Some collaboration agreements are terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

#### ***3.D.4. Risks Related to the Commercialization of Our Product Candidates***

***Even if we successfully complete clinical trials of our product candidates, those candidates may not be commercialized successfully for other reasons.***

Even if we successfully complete clinical trials for one or more of our product candidates and obtain relevant regulatory approvals, those candidates may not be commercialized for other reasons, including:

- failing to receive regulatory clearances required to market them as drugs;
- being subject to proprietary rights held by others;
- failing to obtain clearance from regulatory authorities on the manufacturing of our products;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable;
- failing to compete effectively with products or treatments commercialized by competitors; or
- failing to show that the long-term benefits of our products exceed their risks.

***Even if any of our product candidates are commercialized, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or the medical community in general necessary for commercial success.***

Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we are unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives marketing approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our ability to educate the medical community about the safety and effectiveness of the product;

- the experience of clinicians with other potential treatments that use red blood cells to deliver therapeutics;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the product; and
- the market price of our product relative to competing treatments.

***If we are unable to establish sales, marketing and distribution capabilities for our product candidates, through partnership with a third party, we may not be successful in commercializing those product candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical drugs. To achieve commercial success for our product candidates, we will need to establish a sales and marketing partnership to co-promote those products. We currently do not have sufficient marketing and sales capacities, and we have shifted our focus to finding one or more marketing partnerships. Our development and our ability to generate revenues may therefore depend on our capacity to enter into partnerships and commercialize our products on suitable terms.

The conclusion of a collaboration agreement include the following risks :

- the partnership: we may not be able to enter into an agreement on commercially reasonable terms (for example, we could be required to continue the development of a product candidate, even if the counterpart received under the partnership agreement is not sufficient to cover our costs);
- the partner: risks relating to our intellectual property rights being challenged, risk related to the partner in obtaining regulatory authorizations, risk related to the partner in the partner encountering difficulties or not putting in place all the resources necessary for the commercial success of our products, or conflicts arising between us and some partners. In particular, we cannot guarantee that none of our partners will design or seek to implement a commercial activity using products that compete with our products.

If we are unable to find industrial partners in order to obtain financing and to benefit from their expertise and commercial structures already in place, the commercialization of our product candidates could be difficult or compromised, despite the potential approval. We will therefore need to incur additional expenses, mobilize management resources, recruit specific personnel, call upon new skills and take the time necessary to put in place the appropriate organization and structure to support the development of the product in accordance with applicable legislation and, more generally, to optimize its marketing efforts. There can be no assurance that we will be able to establish or maintain relationships with third parties to market its products. Such events could have a material adverse effect on the Company's business, prospects, results, financial condition and development.

***Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we market our products, which could materially impair our ability to generate revenues.***

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize the product or may be required to carry a warning in its labeling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance.

***Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues even if we obtain regulatory approval to market a product.***

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are

requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may negatively affect our commercialization prospects, including:

- our ability to set a price we believe is fair for our products, if approved;
- our ability to obtain and maintain market acceptance by the medical community and patients;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

We cannot be sure that coverage and reimbursement will be available for any potential product candidate that we may commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the United States, the ACA is significantly impacting the provision of, and payment for, healthcare. Various provisions of the ACA are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide healthcare benefits, prohibit denials of coverage due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, since January 2017, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such challenges and healthcare reform measures of the Biden administration will impact ACA and our business.

In addition, both the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 have instituted, among other things, mandatory reductions in Medicare payments to certain providers. The Budget Control Act of 2011, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid

drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce reimbursement and/or coverage of our product candidates, if approved.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. 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.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product candidate. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in some foreign markets, the pricing of prescription drugs 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. A member state may approve a specific price for the medicinal product, may refuse to reimburse a product at the price set by the manufacturer or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 other product candidates that may be approved. 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.

Moreover, in the EU some countries may 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 entered into force on 11 January 2022. It will apply from 2025. We believe that pricing pressures at the federal and state levels in the United States, at national level in the European Union, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential product candidates that may be approved in the future at a price acceptable to us or any third parties with whom we may choose to collaborate. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

***Any of our product candidates for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products following approval.***

Any of our product candidates for which we obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the European Commission, the EMA, FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a REMS to ensure that the benefits of a drug or biological product outweigh its risks.

The European Commission and FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long-term observational studies on natural exposure. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The European Commission and FDA impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market any of our product candidates for which we receive marketing approval for only their approved indications, we may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug and Cosmetic Act, or FDCA, and other statutes, including the civil False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws. Post marketing regulations in the EU and in EU Member States also require specifications regarding promotion and advertising of prescription drugs.

***The FDA, and national authorities in the individual EU Member States and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of drugs for off-label uses. If we are found to have improperly promoted off-label use, we may become subject to significant liability.***

The FDA, the national authorities in the individual EU Member States, and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the European Commission, FDA or such other regulatory agencies as reflected in the product's approved labeling. However, we may share truthful and not misleading information that is otherwise consistent with the product's approved labeling. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products, if approved, we could become subject to significant liability, which would harm our reputation and negatively impact our financial condition. In addition to European legislation, each EU Member State also enforces specific national laws regarding the regulation of promotional claims which may change depending of the country marketing.

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

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets within and without the United States and the European Union. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;

- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

***Adverse market and economic conditions may exacerbate certain risks associated with commercializing our product candidates.***

Future sales of our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for any of our product candidates that are approved for commercialization in the future. In addition, there have been concerns for the overall stability and suitability of the euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the euro as a common European Union currency or an otherwise diminished value of the euro could materially and adversely affect our future product revenue from European Union sales of our products.

***3.D.5. Risks Related to the Production and Manufacturing of our Product Candidates and Future Products, if Any***

***Our production capacity could prove insufficient for our needs.***

Our production capacity may prove insufficient in the future to meet the growth of our business, including producing sufficient quantities of product candidates for preclinical studies, clinical trials and, ultimately, our customers and distributors and there is no guarantee that we will or have properly estimated our required manufacturing capacities or that the third parties we rely on to provide required machinery and materials for the manufacturing process will be able to perform on our proposed timelines or meet our manufacturing demands, if at all. Also, if we must increase production capacity for any reason, we may need to make considerable investments that could lead to significant financing needs or require us to enter into subcontracting agreements in order to outsource part of the production.

***Our manufacturing facilities are subject to significant government regulations and approvals. If we or our third-party manufacturers fail to comply with these regulations or maintain these approvals, our business will be materially harmed.***

We and our third-party manufacturers are subject to ongoing regulation and periodic inspection by the EMA, FDA and other regulatory bodies to ensure compliance with current Good Manufacturing Practices, or cGMP, as part of our clinical trials. Any failure to follow and document our or their adherence to such cGMP 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, or may delay or prevent filing or approval of marketing applications for our product candidates.

Failure to comply with applicable regulations could also result in the European Commission, FDA, the national authorities in the individual EU Member States, 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;
- 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, our key suppliers 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. In addition, before any additional products would be considered for marketing approval in the United States, the European Union or elsewhere, our suppliers will have to pass an audit by the applicable regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits, and the audits and any audit remediation may be costly. Failure to pass such audits by us or any of our suppliers would affect our ability to commercialize our product candidates in the United States, the European Union or elsewhere.

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

We manufacture our product candidates 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 are 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 to patients 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;
- logistical error; and
- rupture in the cold chain, which is a system for storing and transporting blood and blood products within the correct temperature range and conditions.

In addition, a rise in direct or indirect energy rates may increase product manufacturing and logistical costs. Any of these risks, should they occur, could disrupt our activities and compromise our financial position, results, reputation or growth.

**3.D.6. Risks Related to Our Employees and Business**

***We depend on qualified management personnel and our business could be harmed if we lose key personnel and cannot attract new personnel.***

Our success depends to a significant degree upon the technical and management skills of our senior management team. The loss of the services of any of these individuals could have a material adverse effect on our ability to achieve our corporate objectives and successfully execute our business plan. Although we have implemented an executive compensation policy that includes variable compensation based on performance as well as share-based compensation plans for the benefit of our key employees, we cannot guarantee that this policy will be sufficient to retain these key employees. Our success also will depend upon our ability to attract and retain additional qualified management, marketing, technical, and sales executives and personnel. We compete for key personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so, could harm our operations and our growth prospects.

***Our workforce reduction initiated in June 2022 could result in disruption of our business.***

In June 2022, we initiated a redundancy procedure (PSE) in France involving the termination of approximately 25% of our employees compared to the start of 2022. We completed the terminations during the fourth quarter of 2022. This redundancy procedure will decrease our full year 2023 operating expenses. The workforce reduction may be disruptive to our operations and could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the workforce reduction seek alternative employment, this could result in our seeking contractor support at unplanned additional expense or harm the Company's productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific and/or clinical personnel. Any failure to attract or retain qualified personnel could prevent us from successfully developing potential product candidates or supporting our existing operations.

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

As of December 31, 2022, we had 49 employees. To manage our development and expansion, including the potential commercialization of our product candidates in the European Union and the United States, we will need to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Also, 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 these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

***Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may adversely affect our results of operations, our cash flows and our financial condition.***

As a French biopharmaceutical company, we have benefited from certain tax advantages, including, for example, the CIR, which is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess, if any, may be refunded. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and amounted to €3.4 million, €3.7 million and €1.5 million for the years ended December 31, 2020, 2021 and 2022, respectively. The French tax authorities, with the assistance of the Research and Higher Education Ministry, may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR 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. Should the French tax authorities be successful, the CIR representing the majority of the our operating revenues (88% of revenues for the year ended December 31, 2021 and more than 90% for the years ended December 31, 2020 and December 31, 2022), our credits may be reduced, which would have a negative impact on our results of operations and future cash flows. We believe, due to the nature of our business operations, that we will continue to be eligible to receive the CIR tax credit. However, if the French Parliament decides to eliminate, or to reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations.***

We are a company based in France with international operations, including in the United States. A significant portion of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the withdrawal of the United Kingdom from the EU;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires, or public health emergencies, such as the COVID-19 pandemic.

In late February 2022, Russian military forces invaded Ukraine, resulting in sustained conflict and disruption in the region. The impact to Ukraine, as well as actions taken by other countries, including sanctions by Canada, the United Kingdom, the European Union, the United States and other countries and organizations against officials, individuals, regions, and industries in Russia, Ukraine and

Belarus, and each country's potential response to such sanctions, tensions, and military actions could damage or disrupt international commerce and the global economy, and could have a material adverse effect on our business and results of operations.

While our business and operations are currently not impacted, it is not possible to predict the broader or longer-term consequences of the Russia-Ukraine crisis or other geopolitical conflicts. Consequences could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. There can be no assurance that these events, including any resulting sanctions, export controls or other restrictive actions, will not have a material adverse impact on our future operations and results.

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

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the euro and the U.S. dollar, may adversely affect us. Although we are based in the France, we source research and development, manufacturing, consulting and other services from the United States as well as other countries outside the European Union. We incur some of our expenses, and may in the future derive revenues, in currencies other than the euro.

We use the euro as our functional currency for our financial communications. However, a significant portion of our expenses, financial assets and liabilities are denominated in U.S. dollars and are exposed to changes in foreign currency exchange rates. We also entered into a license agreement with SQZ Biotechnologies in 2019 and any potential revenues pursuant to this agreement will be made in U.S. dollars. We do not currently engage in hedging transactions or the use of forward contracts but may in the future in order to minimize the impact of uncertainty in future exchange rates on cash flows. A deterioration of the U.S. dollar of the Euro could reduce our cash and cash equivalents. Refer to "Item 11. Quantitative and Qualitative Disclosures About Market Risk" for more information.

As we advance our clinical development in the United States and potentially commercialize our product candidates in that market, we expect to face greater exposure to exchange rate risk. 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. 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 may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time-consuming and costly.***

Our research and development 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 may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. French and U.S. federal, state, local or foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

***Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.***

Although we comply with cGMP, and Good Clinical Practices, or GCPs, the risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical products. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient's condition, injury or even death. Our liability could be sought after by patients participating in the clinical trials in the context of the development of the therapeutic products 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 patients, 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 and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products.

We maintain product liability insurance coverage for our clinical trials at levels which we believe are appropriate for our clinical trials. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against

potential product or other legal or administrative liability claims by us or our collaborators, licensees or subcontractors, which could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval. Product liability claims could also harm our reputation, which may adversely affect our ability to commercialize our products successfully.

***Our internal computer systems, or those of our third-party contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure, accident or security breach to date, including cybersecurity incidents, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. As these threats continue to evolve, particularly around cybersecurity, we may be required to expend significant resources to enhance our control environment, processes, practices and other protective measures. Despite these efforts, such events could materially adversely affect our business, financial condition or results of operations.

***We may not realize the benefits of our proposed acquisition of PHERECYDES.***

As a result of the failure of the Phase 3 study in pancreatic cancer and the non-conclusive early readout of first patients in the Phase 2 study in triple-negative breast cancer (TNBC), both conducted with the same product candidate, we have taken the decision to halt the development of GRASPA<sup>®</sup>, which was previously our lead product candidate. In this context, we have begun in November 2021 evaluating valuable strategic options and announced in February 2023 a proposed strategic combination with Pherecydes Pharma ("Pherecydes") to create a global player in extended phage therapy and accelerate the development of a portfolio of drug candidates targeting pathogenic bacteria and potential other indications of high unmet medical needs. Closing of the Proposed Merger is expected at the end of the first half of 2023 (or early second half of 2023). There is no guarantee that we will be able to successfully complete the Proposed Merger.

In case of our failure to complete the Proposed Merger, including the risk that the conditions to the closing and related transactions are not satisfied and the failure to timely obtain shareholder approval for such transactions, we may not be able to find and successfully conclude another strategic transaction. Partnerships are complex and require significant resources and time to negotiate, conclude and implement. See also the risk factor titled "*We cannot assure you that our exploration of strategic alternatives for our business will result in us successfully pursuing a transaction or that any such transaction would be successfully completed; there may also be negative impacts on our business and share price as a result of the process of exploring strategic alternatives for our business*" above.

As part of this strategy, we may acquire companies or technologies facilitating or enabling us to access to new medicines, new research projects, or new geographical areas, or enabling us to express synergies with our existing operations. The success of this strategy would depend, in part, on our ability to select relevant new products or areas of development, identify attractive targets and make these acquisitions on satisfactory terms and successfully integrate them into our operations or technology, while achieving the expected cost savings or synergies. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

In addition, if such acquisitions take place in the future, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. We may not be able to conclude partnerships on economically reasonable terms, which could have a material adverse effect on our business, prospects, financial situation, results and development.

The Company's external growth will also depend on its ability to identify, develop and conclude new partnerships in order to be able to acquire, develop and market, in the long term, new therapeutic products. To identify new product candidates, we may need substantial additional technical, human and financial resources, as partnerships are complex and require significant resources and time for their negotiation, conclusion and implementation.

Any difficulty encountered by us in integrating other companies, activities or technologies or in developing new product candidates and, more generally, in implementing its external growth policy, could have a significant adverse effect on our business, prospects, financial situation, results and development.

***European Union and UK data processing is governed by restrictive regulations governing the collection, processing, and cross-border transfer of personal data.***

The collection and use of personal data in the European Union is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or GDPR. This legislation imposes requirements relating to having legal bases for processing personal data relating to identifiable individuals and securing transfers of such data outside the European Economic Area including to the United States, providing information to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, conducting record-keeping and, where applicable, appointing data protection officers and conducting data protection impact assessments. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. The GDPR applies across the EEA. However, the GDPR provides that EEA countries can make their own further laws and regulations to introduce specific additional requirements related to the processing of personal data related to health, biometric and genetic information. Given the breadth and depth of data protection obligations, maintaining compliance with the GDPR requires significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the data protection rules. This may be onerous and adversely affect our business, financial condition and results of operations.

The GDPR and accompanying laws are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal data, including health data. We may also need to collect more extensive health-related information from our employees to manage our workforce.

In addition, following the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the "UK GDPR"). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the European Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

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. Certain jurisdictions have enacted data localization and cross-border data transfer laws, which could make it more difficult to transfer information across jurisdictions. Existing mechanisms that may facilitate cross-border transfers of personal data may change or be invalidated. A decision by the Court of Justice of the EU, or CJEU, (the Schrems II ruling) has invalidated the E.U.-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe. Similarly, the Swiss Federal Data Protection and Information Commissioner opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. On June 4, 2021, the European Commission adopted new Standard Contractual Clauses ("SCCs") that are designed to be a mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, the SCCs are a valid mechanism to transfer personal information outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. Moreover, due to potential legal challenges, uncertainty exists regarding whether the SCCs will remain a valid mechanism. The new SCCs may increase the legal risks and liabilities under European privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs, any transfers by us or our vendors of personal information from the EEA may not comply with EU data protection laws, which may increase our exposure to EU data protection laws' heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of personal information outside of the EEA (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products. The U.K. is not subject to the European Commission's revised SCCs but has published its own transfer mechanism, the International Data Transfer Agreement ("IDTA"), which enables transfers from the U.K. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and the U.K. GDPR and doing so will

require significant effort and cost. In addition, additional measures may be required even when relying on SSCs or the IDTA, where the laws of the importer's country do not offer an adequate level of protection, such as the U.S. Use of SCCs and IDTA must consequently be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals.

On 25 March 2022, the European Commission and the United States announced that they had agreed, in principle, on a successor of the previously invalidated Privacy Shield Framework, the Trans-Atlantic Data Privacy Framework. On 7 October President Biden signed an Executive Order on "Enhancing Safeguards for United States Signals Intelligence Activities" and on 13 December 2022, the European Commission published a draft adequacy decision for adoption that takes into account the Executive Order. However, a related adoption is not expected before spring 2023 and it is remained to be seen whether the new adequacy decision would withstand scrutiny by the CJEU if the adequacy decision's validity was to be challenged.

Furthermore, the risk of GDPR litigation may increase because of a recent decision of the CJEU. The CJEU ruled that a consumer protection association may bring representative actions alleging breaches of the GDPR even when the consumer protection association does not have a mandate to take action from any specific individuals and a specific breach of any individual's data protection rights was not demonstrated.

Failure, by us or our third party partners, to comply with the requirements of the GDPR and related national data protection laws of EEA countries may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, results of operations and financial condition. Moreover, in some EEA countries, including France, the hosting of personal health data must be carried out by specifically certified hosting service providers. The absence or suspension of the appropriate certification of such hosting service provider may adversely affect our business, or even lead to penalties related to breach of security of personal data.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

### ***3.D.7. Risks Related to Other Legal Compliance Matters***

***We are subject to anti-bribery, anti-kickback, fraud and abuse and other healthcare laws and regulations which may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.***

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our products, if approved. Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third party payors and patients may expose us to broadly applicable federal and state anti-bribery fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, proposed sales, marketing and education programs of our product candidates that obtain marketing approval. 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 remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal, civil and criminal statutes that impose criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as “covered entities,” and persons or entities that perform functions or activities that involve individually identifiable health information on behalf of a covered entity, known as “business associates,” including mandatory contractual terms as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- U.S. federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to track and annually report to the CMS payments and other transfers of value provided 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 certain ownership and investment interests held by physicians or their immediate family members;
- analogous state or foreign laws and regulations, such as state anti-kickback and false claims laws, 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 that may be broader in scope than the federal requirements, 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 drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug 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;
- GDPR, the local EU data protection laws, UK GDPR and other ex-U.S. protections;
- the French “transparency” provisions, or “French Sunshine Act” (Articles L. 1453-1 and D. 1453-1 and seq. PHC), which contains provisions regarding transparency of fees received by some healthcare professionals or social media influencers from industries, such as companies manufacturing or marketing healthcare products (medicinal products, medical devices, etc.) or services related to these products in France. According to the provisions, these companies shall publicly disclose (on a specific public website available at [www.entreprises-transparence.sante.gouv.fr](http://www.entreprises-transparence.sante.gouv.fr)) the advantages and fees paid to healthcare professionals or social media influencers amounting to €10 or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional or social media influencers, etc.); and
- the French “anti-gift” provisions (Articles L.1453-3 to L.1453-12 PHC), setting out a general prohibition of payments and rewards from industries, i.e. companies manufacturing or marketing health products, to, but not only, healthcare professionals, with limited exceptions and strictly defines the conditions under which such payments or awards are lawful, notably the authorization of the *Conseil National de l’Ordre des Médecins* (CNOM) if the financial counterpart is higher than a certain amount, this limit being different according to the nature of the benefit concerned.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do 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 were 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, damages, fines, disgorgement, imprisonment, possible exclusion from 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 non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could substantially disrupt our operations. 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 criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain professional liability insurance which cover for costs and expenses we may incur due to environmental liability that may be asserted against us or due to injuries to our employees resulting from the use of hazardous materials, may not provide adequate coverage against potential liabilities.

***Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with legal requirements or the requirements of CMS, European Commission, EMA, FDA and other government regulators, provide accurate information to applicable government authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. 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. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from 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 non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

***Changes in European Union regulations may limit our ability to attract and obtain additional financing sources outside France.***

As a result of the implementation of Regulation (EU) 2019/452 of the European Parliament and of the Council of March 19, 2019 establishing a framework for the screening of foreign direct investments into the European Union, the list of sectors of activity which are subject to a control by the French authorities has been extended to cover foreign investments in additional economic sectors. Prior authorization of the Minister of Economy is required for investments in: (i) businesses participating, even occasionally, under the exercise of French public authority, (ii) businesses that would be liable to negatively impact public order, public security or the national defense interest, as well as (iii) business focused on research, production or trade of arms, ammunition, gunpowder and explosive substances.

A foreign direct investment will be subject to authorization where there is an (i) acquisition of control, under article L.233-3 of the French Commercial Code, of an entity subject to French law, (ii) where a party acquires all or part of a branch of activity of an entity subject to French law, (iii) or where a party crosses directly or indirectly, and acting alone or in concert, the 25% voting rights threshold of an entity subject to French law.

The French government has adapted the foreign investment control procedure in France within the context of the ongoing COVID-19 pandemic in two ways: (i) the inclusion, by a Ministerial order (arrêté) of April 27, 2020, of biotechnologies in the list of critical technologies and (ii) the addition, by a Decree (décret) of July 22, 2020 as amended by Decree n°2020-1729 of December 28, 2020, of the threshold of 10% of voting rights of a company subject to French law whose securities are listed on a stock exchange as triggering the control procedure. The Decree of July 22, 2020, as extended by the decree n° 2022-1622 of December 23, 2022, currently provides that this new 10% threshold will be effective until December 31, 2023 and a fast-track review procedure for foreign investments exceeding this threshold.

If an investment in the company subject to prior authorization is realized without this authorization having been granted, the Minister will be able to order the investor, subject to a fine for non-performance, to: (i) file an authorization application, (ii) restore the previous situation, or (iii) amend the investment and, if he considers that the conditions for the authorization have not been met, the Minister may also revoke the authorization or order the investor, subject to a fine for non-performance, to comply with the authorization. In both cases, he may also take provisional measures. Furthermore, an investor who has carried out a transaction without prior authorization or has not complied with the orders or measures set by the French Minister of Economy will be liable to a fine of up to the greater of the following amounts: (i) double the amount of the irregular investment, (ii) 10% of the turnover (excluding taxes) of the company, (iii) five million euros for legal entities, and (iv) one million euros for individuals.

Inclusion of biotechnologies in the list of critical technologies subject to foreign investment control procedure could discourage foreign investment in the Company's securities, thereby limiting access to foreign sources of financing. If interested investors do not or cannot obtain such authorization, their investment could be cancelled and be subject to additional fees and/or monetary penalties.

***Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.***

Our tax treatment is subject to the enactment of, or changes in, tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related, the Organization for Economic Co-Operation and Development's Base Erosion and Profit Shifting Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) changes in corporate tax rates, the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid, including foreign earnings, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses. For instance, the recently enacted Inflation Reduction Act imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax laws, regulations, policies or practices, could affect our financial position, including the value of our deferred tax assets, and overall or effective tax rates in the future in countries where we have operations, result in significant one-time charges, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

***Tax authorities may disagree with our positions and conclusions regarding certain tax positions, 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 U.S. 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, in which case, we expect that we might contest such assessment. 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.

***For U.S. tax purposes, our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.***

Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, U.S. federal net operating losses, or NOLs, generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOLs may be limited. In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its stock ownership over a three-year period) is subject to limitations on its ability to utilize its pre-change U.S. federal NOLs to offset future taxable income. If we undergo an ownership change, or if future changes in our stock ownership, some of which are outside of our control, results in an ownership change, our ability to utilize our U.S. federal NOLs may be limited by Section 382 of the Code. As a result, even if we earn net taxable income, our ability to use our NOLs to offset such income may be limited, which could increase our tax

liability and decrease our cash flow. It is uncertain if and to what extent states will conform to U.S. federal income tax law with respect to the treatment of NOLs.

### **3.D.8. Risks Related to Intellectual Property**

#### ***Our ability to compete may decline if we do not adequately protect our proprietary rights.***

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and defending these rights against third-party challenges. We will only be able to protect our product candidates and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our product candidates is uncertain due to a number of factors, including:

- we or our licensors may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we or our licensors may not have been the first to file patent applications for our product candidates or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our or our licensors' disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our or our licensors' pending patent applications may not result in issued patents;
- we or our licensors may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us or our licensors may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our or our licensors' compositions and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
- or others may identify prior art or other bases which could invalidate our or our licensors' patents.

Even if we have or obtain patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future, may file, patent applications covering compositions or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the cancer treatment field in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

#### ***Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.***

If we initiate legal proceedings against a third party to enforce a patent covering our product candidate or technology, the defendant could counterclaim that the patent covering our product candidate or technology is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement.

Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review and/or inter partes review and equivalent proceedings in foreign jurisdictions, and opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

***Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.***

The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the U.S. Patent and Trademark Office, or USPTO, are evolving and could change in the future. Consequently, we cannot predict the issuance and scope of patents with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our or our licensors' discoveries or to develop and commercialize our technology and products without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection for our product candidates, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

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

From time to time, the U.S. Supreme Court, other federal courts, 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 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. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. 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 on March 16, 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.

***If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will

be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

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

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We have entered into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

***We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the federal and state laws in the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent 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. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Third parties may assert ownership to inventions we develop.***

Collaborators or third party partners may in the future make claims challenging the inventorship or ownership of our intellectual property developed in the context of their collaboration with us. We have written agreements with collaborators and third party partners that provide us the ownership of intellectual property or provide that we must negotiate certain intellectual property rights with collaborators and third party partners with respect to joint inventions or inventions made by them that arise from the results of the collaboration. In some instances, written provisions or conditions may be challenged or may not be adequate to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate ownership of intellectual property to the inventions that result from our use of a third-party partner or collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a third-party partner or collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

***If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business.***

We license intellectual property that is critical to our business, including licenses underlying the technology in our diagnostic tests, and in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from distributing our current tests, or inhibit our ability to commercialize future test candidates. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who 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 and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. 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 and other employees.

***A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.***

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a negative impact on our cash position. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

- us or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

Any of these outcomes could hurt our cash position and financial condition and our ability to develop and commercialize our product candidates.

***If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively.

***3.D.9. Risks Related to Ownership of our Securities and our Status as a Non-U.S. Company with Foreign Private Issuer Status***

***The market price of our equity securities may be volatile or may decline regardless of our operating performance.***

The market price for our ADSs and ordinary shares has fluctuated and is likely to continue to fluctuate, substantially. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that in some instances is unrelated to the operating performance of particular companies. For example, on the day we announced our positive Phase 2b clinical trial results evaluating ertugliflozin in metastatic pancreatic cancer in March 2017, the closing price per ordinary share on Euronext Paris increased by 71% compared to the average of the closing price per ordinary share for the previous 20 trading days. Conversely, on the day we announced the negative results of our TRYbeCA-1 Phase 3 clinical trial in October 2021, the share price decreased by 39% compared to the average of the closing price per ordinary share for the previous 20 trading days. A significant decrease in our share price could have a significant adverse effect on our financial condition, reputation and prospects.

As a result of this volatility in our market and industry, holders of our equity securities may not be able to sell their ADSs or ordinary shares at or above the price originally paid for the security. The market price for our ADSs and ordinary shares may be influenced by numerous factors, some of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- 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, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- 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;
- share and ADS price and volume fluctuations attributable to inconsistent trading volume levels of our shares and ADSs;
- additions or departures of key management or scientific personnel;
- lawsuits threatened or filed against us, disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent 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;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination of a strategic alliance or the inability to establish additional strategic alliances;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

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 holders of our equity securities 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, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

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

Our ADSs are listed on The Nasdaq Stock Market LLC ("Nasdaq"), and our ordinary shares are listed on Euronext Paris. We cannot predict the effect our dual listing will have on the value of our ADSs and ordinary shares. However, the dual listing of our ADSs and ordinary shares may dilute the liquidity of these securities in one or both markets and may adversely affect the trading market or price for our ADSs or ordinary shares.

***We may not be able to meet the continued listing standards of Nasdaq, which require a minimum closing bid price of \$1.00 per share, which could result in our delisting and negatively impact the price of our ADSs and ordinary shares and our ability to access the capital markets.***

Our ADSs, each representing one ordinary share, are listed on The Nasdaq Global Select Market. The Nasdaq Stock Market LLC ("Nasdaq") provides various continued listing requirements that a company must meet in order for its securities to continue trading on the exchange. Among these requirements is the requirement that our ADSs trade at a minimum bid price of \$1.00 per share. On October 7, 2022, we received a written notice from the Listing Qualifications Department of Nasdaq, notifying us that our ADSs failed to maintain a minimum bid price of \$1.00 over the previous 30 consecutive business days as required by Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Requirement").

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days from the date of the notification letter, or until April 5, 2023, to regain compliance with the Minimum Bid Price Requirement. If at any time before April 5, 2023, the closing bid price of our ADSs is at least \$1.00 for a minimum of 10 consecutive business days, we will be deemed to have regained compliance with the Minimum Bid Price Requirement. In the event that we do not regain compliance by April 5, 2023, we may transfer the listing and trading of our ADSs to The Nasdaq Capital Market, provided that we meet the applicable standards for initial listing of our ADSs on the Nasdaq Capital Market (other than the Minimum Bid Price Requirement) and may be eligible for an additional 180 calendar day grace period by providing a written notice of our intention to cure the deficiency during this second compliance period by effecting a reverse share split, if necessary. If we do not regain compliance with the Minimum Bid Price Requirement by April 5, 2023, and we are ineligible for an additional grace period, Nasdaq will provide written notice that the ADSs are subject to delisting from The Nasdaq Global Select Market. In that event, we may appeal the determination to a Nasdaq hearings panel.

There is no assurance that our share price will trade at or above a minimum bid price of \$1.00 per share and if we fail to meet minimum listing requirements, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or will otherwise be in compliance with other Nasdaq listing criteria. Any such delisting could adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, collaborators and employees.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business will be harmed and the price of our securities could decline as a result.***

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the European Commission, FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds and raw materials used in the manufacture of our product candidates;

- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, and the trading price of the ordinary shares and ADSs may decline as a result.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ordinary shares and 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. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would 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 the ordinary shares and ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for the ordinary shares and ADSs could decrease, which could cause the price of the ordinary shares and ADSs or their trading volume to decline.

***We do not currently intend to pay dividends on our securities and, consequently, the ability of our shareholders and ADS holders to achieve a return on 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 share capital 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, our shareholders and ADS holders are not likely to receive any dividends for the foreseeable future and any increase in value will depend solely upon future appreciation. Consequently, holders of our equity securities may need to sell all or part of their holdings of ordinary shares or ADSs after price appreciation, which may never occur, as the only way to realize any future gains.

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. Please see the section of this Annual Report titled “Item 10.B—Memorandum and Articles of Association” for further details on the limitations on our ability to declare and pay dividends and the taxes that may become payable by us if we elect to pay a dividend. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

In addition, exchange rate fluctuations may affect the amount of euros 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 euros, if any. These factors could harm the value of our equity securities, and, in turn, the U.S. dollar proceeds that holders receive from the sale of ADSs.

***Future sales, or the possibility of future sales, of a substantial number of our ADSs or ordinary shares could adversely affect the market price of our ADSs and ordinary shares.***

As of December 31, 2022, 31,018,553 ordinary shares were issued and outstanding. Sales of a substantial number of shares of our ordinary shares or ADSs in the public market, or the perception that these sales might occur, could depress the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our shares are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the U.S. Securities Act of 1933, as amended, or the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly.

We have also filed a registration statement with the SEC to register the ordinary shares that may be issued under our equity incentive plans. The ordinary shares subject to outstanding options under our equity incentive plans, ordinary shares reserved for future issuance under our equity incentive plans and ordinary shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our securities. In addition, pursuant to the OCABSA Agreement, we may issue ordinary shares upon exercise of share warrants. In the event that such ordinary shares are sold in the public market, such sales of ordinary shares pursuant to the OCABSA Agreement could also have an adverse effect on 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.***

We are a French company with limited liability. 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, the interests of our shareholders or holders of our ADSs. See the sections of this Annual Report titled “Item 10. B—Memorandum and Articles of Association” and “Item 16.G—Corporate Governance.”

***U.S. holders of our equity securities may have difficulty enforcing civil liabilities against our company and directors and senior management and experts named herein.***

Certain members of our board of directors and senior management and certain experts named herein 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 or 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 European Economic Area, or EEA, Agreement, including France, 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. See “Item 10.B - Limitations Affecting Shareholders of a French Company;”
- under French law, certain investments in a French company relating to certain strategic industries by individuals or entities not residents in a Member State of the European Union or controlled by individuals of entities not resident in a Member State of the European Union are subject to prior authorization of the Ministry of Economy pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590). See “Item 10.B - Limitations Affecting Shareholders of a French Company;”. Within the context of the ongoing COVID-19 pandemic, the French government has included biotechnologies in the list of strategic industries by a Ministerial order (*arrêté*) of April 27, 2020. See section D "Risk Factors - Risks Related to our Financial Position and Capital Needs ";
- a merger (i.e., in a French law context, a stock for stock exchange following which our company would be dissolved without being liquidated 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 the unanimous approval of our shareholders;

- 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 and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the future 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 shareholders' meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, for the remaining duration of such director'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 of directors;
- our board of directors can be convened by our chairman or our managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;
- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice;
- 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 directors with or without cause;
- 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 director can be proposed at any shareholders' meeting without notice;
- our bylaws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the section of this Annual Report titled "Item 10.B —Memorandum and Articles of Association";
- transfers of shares shall comply with applicable insider trading rules and regulations and, in particular, with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of our bylaws relating to the number of directors and election and removal of a director from office, may only be modified by a resolution adopted by two-thirds of the votes held by our shareholders present, represented by a proxy or voting by mail at the meeting.

***Holders of our ADSs may not be able to exercise their right to vote the ordinary shares underlying such ADSs.***

Holders of our ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the amended and restated deposit agreement. The amended and restated 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 (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

Holders of our ADSs may instruct the depositary of their ADSs to vote the ordinary shares underlying such ADSs. Otherwise, holders of our ADSs will not be able to exercise voting rights unless they withdraw the ordinary shares underlying the ADSs they hold. However, a holder of our ADSs may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for a holder of our ADSs' instructions, the depositary, upon timely notice from us, will notify him or her of the upcoming vote and arrange to deliver our voting materials to him or her. We cannot guarantee to any holder of ADSs that he or she will receive the voting materials in time to ensure that he or she can instruct the depositary to vote his or her ordinary shares or to withdraw his or her ordinary shares so that he or she can vote them directly. Pursuant to the terms of our amended deposit agreement, in certain situations if, in the opinion of our management, the matter is not materially adverse to the interests of our shareholders, we may request that if the depositary does not receive timely voting instructions from a holder of ADSs, the depositary may give a proxy to a person designated by us to vote, in its discretion, the ordinary shares underlying the unvoted ADSs, as long as the matter is endorsed by our board. 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 a holder of ADSs may not be able to exercise his or her right to vote, and there may be nothing he or she can do if the ordinary shares underlying his or her ADSs are not voted as he or she requested.

***The right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to the holders of our ADSs.***

Under 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 amended and restated deposit agreement provides that the depositary will not make rights available to holders of our ADSs 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 amended and restated deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of our ADSs does not require registration of any securities under the Securities Act before making the option available to holders of our 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 holders of our ADSs will receive no value for these rights.

***Holders of our ADSs may be subject to limitations on the transfer of such ADSs and the withdrawal of the underlying ordinary shares.***

ADSs, which may be evidenced by ADRs, 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 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 amended and restated deposit agreement, or for any other reason subject to an ADS holder's right to cancel such ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of such 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, a holder of ADSs may not be able to cancel his or her ADSs and withdraw the underlying ordinary shares when he or she owes 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.

***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. This may limit the information available to holders of our ADSs or ordinary shares.***

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. In addition, our officers and directors are exempt from the reporting and "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 continue to file such reports, 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 we are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there is less publicly available information concerning our company than there would be if we were a U.S. domestic issuer.

***As a foreign private issuer, we are permitted and we follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq's corporate governance standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with the corporate governance standards of the Nasdaq Global Select Market.***

As a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq's corporate governance standards. However, Nasdaq rules provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq's corporate governance standards as long as notification is provided to Nasdaq of the intention to take advantage of such exemptions. We currently rely on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq's corporate governance standards, to the extent possible. Certain corporate governance practices in France, which is our home country, may differ significantly from Nasdaq corporate governance standards. For example, as a French company, neither the corporate laws of France nor our bylaws require a majority of our directors to be independent and we can include non-independent

directors as members of our remuneration committee, and our independent directors are not required to hold regularly scheduled meetings at which only independent directors are present.

We are also exempt from provisions set forth in Nasdaq rules which require an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. In addition, Nasdaq Marketplace Rule 5635 requires a U.S. domestic listed company to obtain shareholder approval: (1) prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the issuer; (2) prior to the issuance of securities in connection with a transaction other than a public offering involving the sale, issuance or potential issuance by the issuer alone, or together with sales by its officers, directors or substantial shareholders, of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value; and (3) prior to the issuance of securities when an equity compensation arrangement is made or materially amended, including prior to the issuance of common stock to the issuer's officers, director, employees or consultants for less than the greater of book or market value. While French law requires a French company to obtain prior shareholder approval to issue shares, its shareholders may pre-authorize the company's board of directors to issue shares such that shareholder approval is not required at the time of issuance.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.

Therefore, our shareholders may be afforded less protection than they otherwise would have under Nasdaq's corporate governance 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 our most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2023. 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. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer would likely be significantly more than costs we incur as a foreign private issuer. If we lost our foreign private issuer status, we would 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. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we would 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 herein and exemptions from procedural requirements related to the solicitation of proxies.

***U.S. holders of our ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.***

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we will be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, allocations of income with respect to any partnership, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, U.S. holders (as defined below under "Item 10. E. Taxation—Material U.S. Federal Income Tax Considerations") of our ADSs may suffer adverse tax consequences, including having gains realized on the sale of the ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders and having interest charges apply to distributions by us and the proceeds of sales of the ADSs. See "Item 10. E. Taxation—Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

The annual determination of whether we are a PFIC for a taxable year is fact-intensive and made after the close of such taxable year applying principles and methodologies that in some circumstances are unclear and subject to varying interpretations. For instance, whether we are a PFIC will depend on the composition of our income (including whether we will receive certain non-refundable grants or subsidies and whether such amounts and reimbursements of certain refundable research tax credits will constitute gross income for purposes of the PFIC rules). Whether we are a PFIC also will depend on the composition and value of our assets, including goodwill, which may be determined in large part by reference to the market value of our ADSs from time to time, which may fluctuate considerably. If our market capitalization declines while we hold a substantial amount of cash and cash-equivalents, which may depend on how quickly we utilize our cash proceeds from our global offerings in our business, we may be more likely to be characterized as a PFIC. Based on the composition of our gross income, assets, activities and market capitalization and the nature of our business and due to fluctuations in our stock price, we believe that we may have been characterized as a PFIC for our taxable year ending December 31, 2022. However, because our PFIC status is subject to a number of uncertainties and it is very early in the year, we cannot provide any assurances, and our U.S. counsel expresses no opinion, with respect to our PFIC status for any taxable year.

***If a U.S. holder is treated as owning at least 10% of our ADSs, such holder may be subject to adverse U.S. federal income tax consequences.***

If a U.S. holder (as defined below under “Item 10. E. Taxation—Material U.S. Federal Income Tax Considerations”) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ADSs, such U.S. holder will be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). Because our group includes at least one U.S. subsidiary (ERYTECH Pharma, Inc.), if we were to form or acquire any non-U.S. subsidiaries in the future, they may be treated as controlled foreign corporations. A U.S. shareholder of a controlled foreign corporation will be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by the controlled foreign corporations, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist U.S. holders in determining whether any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a controlled foreign corporation or whether such U.S. holder would be treated as a U.S. shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. holder that is a U.S. shareholder the information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting and tax paying obligations may subject a U.S. holder that is a U.S. shareholder to significant monetary penalties and may prevent from starting the statute of limitations with respect to such U.S. holder's U.S. federal income tax return for the taxable year in which such obligations was required. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

***We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the trading price of our ADSs or ordinary shares.***

We have identified a material weakness in our internal control over financial reporting that has not been remediated as of December 31, 2022. A material weakness is a deficiency, or 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.

If we are unable to remediate this material weakness, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our securities.

As of December 31, 2021, we concluded that our internal control over financial reporting was not effective as a result of a material weakness related to the monitoring of research and development projects, as the control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received did not operate at a sufficient level of precision.

In connection with our assessment as of December 31, 2022, our management concluded that this material weakness was not fully remediated, as our management identified that the control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received and the control related to the data and assumptions used to estimate the hospital costs accrual did not operate at a sufficient level of precision. Management considers these controls have to be redesigned to fully remediate the material weakness. As a result of this material weakness, management concluded our internal control over financial reporting was not effective as of December 31, 2022 at the reasonable assurance level.

During 2022, we continued to strengthen our process and internal controls over the monitoring of research and development costs. In particular, we (i) redesigned the process to track actual costs incurred against invoices received, (ii) adapted the methodology used to estimate the hospital cost accrual in the financial statements and (iii) worked on the implementation of a control designed to ensure the assumptions and the data used to estimate such costs are reasonable and accurate.

We believe the remediation measures described above improved the reliability of financial information related to the hospital costs accrual. Nevertheless, our management concluded that the material weakness was not fully remediated as of December 31, 2022.

To further improve our internal control over financial reporting and to specifically address the control deficiencies that led to our material weakness, we plan to deploy remediation efforts focused on:

- redesigning our control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received so that it can operate at an appropriate level of precision to detect and correct errors.
- redesigning our control over the data and assumptions used to estimate the hospital costs accrual so that it can operate at an appropriate level of precision to detect and correct errors.

We believe that these activities will further support the remediation of this material weakness. However, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the trading price of our ADSs or ordinary shares may decline as a result.

***If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

We are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), to furnish a report by management on, among other things the effectiveness of our internal control over financial reporting on an annual basis. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In connection with the preparation of our financial results for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. Our Management's Report on Internal Control over Financial Reporting included in this Annual Report describes this material weakness and includes our conclusion that our internal controls were not effective as of the end of the period covered by this Annual Report. While we have established certain procedures and control over our financial reporting processes, including initiating remediation efforts with respect to the material weakness, we cannot assure you that these efforts will prevent restatements of our financial statements in the future.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports, delays in our financial reporting, which could require us to restate our operating results or our auditors may be required to issue a qualified audit report on our financial statements. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404(a). In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal control may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in achieving and maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal control over financial reporting, as is the case currently, or our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy or completeness of our financial reports, the price of our ADSs or ordinary shares could decline and we may be subject to litigation, sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Failure to remediate any material weakness in our internal control over financial reporting, or to maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on Nasdaq.

#### **Item 4. Information on the Company.**

##### **4.A. History and Development of the Company**

Our legal and commercial name is ERYTECH Pharma S.A. We were incorporated as a société par actions simplifiée, or S.A.S., under the laws of the French Republic on October 26, 2004 and became a société anonyme, or S.A., on September 29, 2005. We are registered at the Register of Commerce and Companies of Lyon (*Registre du commerce et des sociétés*) under the number 479 560 013. In April 2014, we incorporated our wholly-owned U.S. subsidiary, ERYTECH Pharma, Inc. We maintained a U.S. office in Cambridge, Massachusetts from February 2016 to January 2023. In 2018, we entered into a lease agreement for a U.S. manufacturing facility in Princeton, New Jersey, United States (the “Princeton Facility”), which has been operational since the fourth quarter of 2019. In April 2022, we entered into an asset purchase agreement (the “Catalent Purchase Agreement”) by and among Erytech Pharma S.A., Erytech Pharma, Inc., Catalent Princeton, LLC (“Catalent”) and Catalent Pharma Solutions, Inc., pursuant to which we sold to Catalent, among other things, certain assets and inventory of materials located at the Princeton Facility for Catalent’s use in the manufacture of our lead product candidate at that time, eryaspase. In November 2022, we announced our decision to halt further development of eryaspase, which was until then, our lead product candidate. Completing the strategic review process that was initiated in November 2021, we announced in February 2023 a proposed strategic combination with Pherecydes Pharma S.A. (“Pherecydes”), a biotechnology company specializing in precision phage therapy to treat resistant and/or complicated bacterial infections, to create a global player in extended phage therapy and accelerate the development of a portfolio of drug candidates targeting pathogenic bacteria and potential other indications of high unmet medical needs.

Our principal executive offices are located at 60 Avenue Rockefeller, 69008 Lyon, France. Our telephone number at our principal executive offices is +33 4 78 74 44 38. Our agent for service of process in the United States is ERYTECH Pharma, Inc. Our website address is [www.erytech.com](http://www.erytech.com). The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited herein is not part of this Annual Report. The U.S. Securities and Exchange Commission maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements and other information regarding registrants, such as ERYTECH, that file electronically with the SEC.

Our actual capital expenditures for the years ended December 31, 2020, 2021 and 2022 amounted to €0.4 million, €0.2 million and €0.1 million, respectively. These capital expenditures were related primarily to the buildup of our fixed assets for our pharmaceutical facility and laboratory and to a lesser extent to the purchase of office and computer equipment. We do not capitalize clinical research and development costs until we obtain marketing authorization for a product candidate.

## **4.B. Business Overview**

### ***Overview***

We are a biopharmaceutical company focusing on innovative red blood cell-based therapeutics to treat severe forms of cancer and orphan diseases. We have developed ERYCAPS<sup>®</sup>, a proprietary platform using novel technology to encapsulate therapeutic drug substances inside erythrocytes, or red blood cells (“RBCs”). In April 2022, we presented ERYCEV<sup>™</sup>, our novel approach to RBC vesiculation, at the 24<sup>th</sup> European Red Cell Society (ERCS) Congress. We believe that RBC-derived extracellular vesicles, which are formed naturally during senescence and storage of mature RBCs, may potentially be an attractive drug delivery system. Utilizing our ERYCAPS<sup>®</sup> platform, RBCs can be loaded with active therapeutic compounds, and we believe the vesiculation of such cargo-loaded RBC-derived extracellular vesicles may facilitate the development of novel therapeutic approaches.

Our lead product candidate was Eryaspase, also referred to as GRASPA<sup>®</sup>, which targets the metabolism of cancer cells by depriving them of asparagine, an amino acid necessary for their survival and critical in maintaining the cells’ rapid growth rate. We developed eryaspase for the treatment of patients with severe forms of cancer, including pancreatic cancer, triple negative breast cancer (“TNBC”) and acute lymphoblastic leukemia (“ALL”). In October 2021, we announced that our Phase 3 clinical trial of eryaspase for the treatment of second-line advanced pancreatic cancer did not meet its primary endpoint of overall survival. To preserve capital resources and reduce costs, following this announcement in November 2021, we made a strategic decision to cease further patient enrollment for our proof-of-concept Phase 2 clinical trial of eryaspase for the treatment of TNBC in the European Union. The Steering Committee of this Phase 2 trial met in September 2022 to review the results of the 25 evaluable patients and concluded that no clinical benefit was demonstrated, possibly attributable to the immature closure of the trial and the small number of evaluable patients.

Furthermore, since 2017, we supported a Phase 2 clinical trial, initiated and sponsored by investigators of the Nordic Society of Pediatric Hematology and Oncology, for evaluation of the safety and pharmacological profile of eryaspase in ALL patients, who developed hypersensitivity reactions to prior asparaginase treatment or silent inactivation to pegylated L-asparaginase. As part of our plan at that time to submit a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (the “FDA”), we submitted an Initial Pediatric Study Plan in July 2022, and received feedback from the FDA in August 2022. After thorough evaluation of the feedback, which included a new request for additional data, and taking into account the changing competitive landscape, we decided to halt the BLA process of seeking approval. In light of the foregoing reasons, in November 2022, we announced our decision to halt further development of GRASPA<sup>®</sup> and to focus on ERYCEV<sup>™</sup> and other preclinical programs that we may develop in the future.

The only ongoing clinical trial with respect to GRASPA® is a Phase 1 investigator-sponsored clinical trial, referred to as the rESPECT trial, that we have supported for evaluating the safety of eryaspase in combination with modified FOLFIRINOX for the treatment of first-line advanced pancreatic cancer patients. The Georgetown Lombardi Comprehensive Cancer Center is the sponsor of this trial. We announced the enrollment of the first patient in this trial in January 2021, and in October 2021, after review of the safety data of six additional patients comprising the second treatment cohort, we announced the determination of the maximum tolerated dose. In January 2022, encouraging data from the study were presented at the American Society of Clinical Oncology (ASCO GI) Gastrointestinal Cancers Symposium. Treatment of the 19 patients enrolled has been completed, with final data expected to be reported in 2023.

In addition to ERYCEV™, we have developed and may develop other preclinical product candidates and programs. We believe that our ERYCAPS® platform has a broad range of potential applications and can be used to encapsulate a wide range of therapeutic agents for which long-circulating therapeutic activity or rapid and specific targeting is desired. For example, we developed erymethionase, a preclinical product candidate which encapsulates methionine-γ-lyase in RBCs and is designed to target the amino acid metabolism of cancer cells and induce tumor starvation. We also developed two preclinical programs, enzyme replacement and immune modulation, aimed at maximizing the value creation potential of our ERYCAPS® platform, which we believe may result in attractive partnering opportunities. Due to insufficient financial resources, the development of these preclinical programs is currently suspended.

On February 15, 2023, we announced a proposed strategic combination with Pherecydes to create a global player in extended phage therapy and accelerate the development of a portfolio of drug candidates targeting pathogenic bacteria and potential other indications of high unmet medical needs. The transaction would be structured as a merger by absorption of Pherecydes into the Company (the Company after the Proposed Merger, the "Combined Company"), pursuant to which the shareholders of Pherecydes would receive newly issued Erytech ordinary shares in consideration of the contribution of the assets and liabilities of Pherecydes (the "Proposed Merger"). The Extraordinary General Meetings of the Company and Pherecydes will be called upon to vote on the Proposed Merger, currently expected to be convened at the end of the first half of 2023 (or early second half of 2023).

### ***Corporate Information***

We were incorporated in 2004. In May 2013, we completed the initial public offering of our ordinary shares on Euronext Paris. In November 2017, we completed a global public offering, consisting of a U.S. initial public offering of American Depositary Shares, or ADSs, each representing one ordinary share, and a concurrent private placement in Europe and other countries outside of the United States and Canada of our ordinary shares. Our ordinary shares are listed on Euronext Paris under the ticker symbol "ERYP" and our ADSs are listed on the Nasdaq Global Select Market under the symbol "ERYP."

#### ***4.B.2. Our Strategy***

Our mission is to help patients live better, longer. Our vision is to position our Company, through the proposed acquisition of Pherecydes, as a leading global player in phage therapy to address antimicrobial resistance with an effective response. The key elements of our strategy to achieve this goal include the following:

##### ***Create a global player in extended phage therapy through international development***

After completing our strategic review process announced in November 2021, we announced in February 2023 a strategic combination with Pherecydes intended to create a global player in extended phage therapy and accelerate the development of a portfolio of drug candidates targeting pathogenic bacteria and potential other indications of high unmet medical needs. The strategy of the combined company in 2023 and 2024 would be to expand Pherecydes existing phage development programs focusing on the ongoing PhagoDAIR Phase 2 trial, by opening new investigation centers in Europe, as well as to expand the breadth of the clinical phage therapy portfolio with two additional sponsored Phase 2 trials with the opening of investigation centers in the United States for both studies. As part of this strategy of international development, we also intend to leverage our existing US presence to facilitate access to US investors and to clinical and regulatory stakeholders in view of future clinical developments.

##### ***Expand research & development competencies and capabilities***

We seek to build a research & development strategy leveraging our platforms and expertise, including drug-delivery with red blood cells (ERYCAPS®) or red blood cell-derived vesicles (ERYCEV™), formulation expertise and oncology experience to support phage and endolysins therapeutic approaches in anti-infectives fields like AMR and beyond (such as in food, cosmetics and animal health fields) in view of potentially broadening the scope to new therapeutic modalities building on the advanced technology platforms and capabilities of both companies.

##### ***Implement a global manufacturing strategy***

We and Pherecydes intend to merge our operations and relocate all teams to our current premises in Lyon, France, where they would benefit from presence in a major European hub for infectious diseases. We also plan to consolidate industrial partnerships and supply back-up plans.

#### ***Execute on research and development and commercialization opportunities that maximize the value of our proprietary platforms***

We seek to maximize shareholder value from our proprietary platforms technology through a combination of in-house development and well selected partnering opportunities. In some instances, we may elect to continue development and commercialization activities through the expansion of our in-house capabilities, but we will also evaluate and pursue collaborative arrangements with third parties for the development and distribution of our product candidates for specified indications and in specified territories where appropriate. We may also explore codevelopment or out-licenses of our platforms technology to third parties and the creation of spin-out companies. As we move our product candidates through development toward regulatory approval in the United States and Europe, we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force and distribution units or entering into collaborations with third parties for the distribution and marketing of any approved products.

#### ***4.B.3. Our Technology Platforms***

##### ***ERYCAPS® Platform Technology***

Our ERYCAPS® platform uses our proprietary technology to entrap active drug substances inside red blood cells using reversible hypotonic and hypertonic osmotic stress. Our platform technology uses transfusion-grade, standard packed red blood cells of all four blood groups (O, A, B and AB) from blood donors which we obtain from blood banks. We match the red blood cells used to the blood type of the patient receiving treatment. To allow the therapeutic compounds to enter into the red blood cells, we subject the red blood cells to a hypotonic solution. This causes swelling of cells and opening of pores in the cellular membrane. At this time, therapeutic molecules can enter the red blood cells. Once the desired concentration of molecules is reached inside the red blood cells, we subject the red blood cells to a hypertonic solution to restore the osmotic pressure to normal. This step causes water to flow out of the cell and the pores to close, rendering the cellular membrane impermeable to molecules above a specific size, including the molecules that have been trapped inside the cell.

The extent to which a red blood cell can swell, known as osmotic fragility, is not uniform and varies between packages of red blood cells. When we obtain a package of red blood cells from a blood bank, we measure a number of key hematological parameters, including the osmotic fragility of the particular sample. Based on the level of osmotic fragility measured, we are able to calculate the specific amount of osmotic pressure to apply in order to achieve the desired concentration of drug substance in each production batch. This patent-protected process allows us to reduce variations in the amount of drug substance to be encapsulated, which ensures that quantifiable amounts of drug substance can be captured in each batch. Our expertise in understanding osmotic fragility and optimizing the red blood cell encapsulation parameters is the cornerstone of our proprietary ERYCAPS® platform.

We believe that our ERYCAPS® platform technology is an innovative approach that offers several key potential benefits:

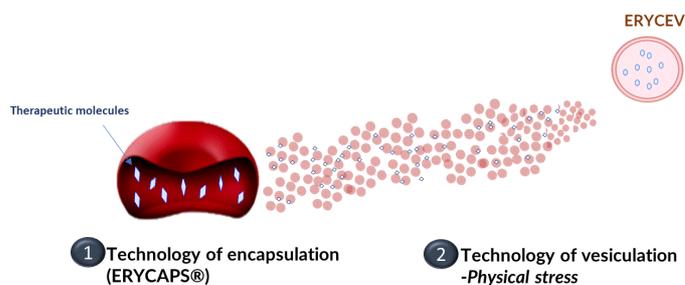
- ***Prolonged duration of activity.*** Red blood cells are biocompatible carriers that have a half-life of approximately one month in the body, and this duration of activity appears not to be significantly affected by our proprietary encapsulation process. This long half-life, coupled with the protection from the cellular membrane, allows encapsulated therapeutic drug substances to remain in the body longer, thereby increasing the duration of their therapeutic activity and their potential efficacy with lower administration doses and fewer injections. It has been shown that the encapsulation of L-asparaginase allows to extend its half-life from one day for free-form L-asparaginase to approximately two to three weeks for the encapsulated form.
- ***Decreased risk of side effects.*** The red blood cell membrane protects the body from toxicities associated with the trapped drug substance, which reduces the potential for adverse side effects from the drug.
- ***High reproducibility with rapid turnaround on commercial scale.*** Our encapsulation process is automated and is designed to produce batches of loaded red blood cells in a highly reproducible, reliable and rapid manner. At our cGMP-certified production facilities, the process for delivering eryaspase to patients typically takes approximately 24 hours from the start of production to delivery of the product candidate to the hospital. We have produced over 5,700 bags of eryaspase to date for use in clinical trials.
- ***Stability and ease of administration.*** After manufacturing and release of the product, eryaspase has shown to remain stable for five days in refrigeration including up to six hours at room temperature. This allows hospital staff to proceed with the administration at the best time and to maintain control of the treatment administration process
- ***Broad applicability.*** Our initial efforts have focused on encapsulating enzymes, such as L-asparaginase, that deplete nutrients necessary for the growth and proliferation of tumor cells, resulting in their starvation and death. Based on our

preclinical studies and clinical experience to date, we believe that a variety of additional therapeutic molecules can be encapsulated within red blood cells to induce tumor starvation, both for blood cancers and solid tumors. We focus on the use of our platform in oncology, immunoncology and enzyme disorders.

Our intellectual property portfolio contains issued patents and patent applications in the United States and foreign countries, including 16 patent families directed to our production process, our ERYCAPS® platform, our product candidates, methods of use and/or treatment, and related diagnostic tests. Our core patent covers eryaspase in the United States until the end of 2029, with potential extension to the end of 2034, and in Europe until 2025, with a potential extension to 2030.

### **Red blood cells derived vesicles**

The ERYCEV™ platform combines ERYCAPS® technology with a vesiculation technology to generate therapeutic vesicles from red blood cells (ERYCEV™).



### **Characteristics of ERYCEV™ products**

- **Drug profile**
  - Biocompatible
  - No genetic transfer due to its lack of both nuclear and mitochondrial DNA
  - Low-immunogenicity
  - Re-dosing
- **Mechanism of Action**
  - Natural tropism for macrophages & dendritic cells
  - Uptake by cancer cells
- **Broad range of administration routes**
  - Small size (95-120 nm)
  - Ability to cross blood -brain barrier (BBB)
  - Enhanced permeability and retention (EPR) effect
- **Functionalization**
  - Enhanced the target specificity and broad the nature of target cells

We successfully produced extracellular vesicles loaded with STING agonists that exerted measurable in vitro biological effects, the results of which have been presented at the annual conference of the European Red Cell Society (ERCS) in April 2022 and at the Extracellular Vesicles & Nanoparticle Therapeutics Europe congress in October 2022. A PCT was also filed in May 2021. Exosomes and extra-cellular vesicles have recently attracted much attention as they have been shown to transport a variety of active cargoes (such as nucleic acids, proteins, lipids, metabolites) from donor to recipient cells.

We have other feasibility studies with other nature of therapeutic molecules to evaluate the potential of our new platform.

#### 4.B.4. Our Pipeline

	Mode of action	Product Candidate or Program	Indication	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3	Status & Next Steps
DRUG LOADED RBC	Cancer metabolism	Graspa/eryaspase (RBC-loaded asparaginase)	Pancreatic cancer	[Red arrow from Discovery to Phase 1]					Trial sponsored by Georgetown University (USA); Results expected in Q2 2023
	Cancer vaccination	SQZ AAC – RBC-loaded antigens	HPV16+ solid tumors	[Blue arrow from Discovery to Phase 1]					Trial being performed by SQZ Biotech under IP license agreement
	Enzyme replacement	RBC-loaded enzymes	Metabolic diseases	[Red arrow from Discovery to Pre-clinical]					Preclinical POC established in PKU and ARG1D; Partnering being explored in rare GI disease
ERYCEV™	Immune modulation	RBCEV loaded with STINGa	Oncology	[Red arrow from Discovery to Pre-clinical]					Feasibility demonstrated <i>in vitro</i> using ERYCEV™ STINGa; <i>In vivo</i> experiments ongoing
	RNA targeting	RBCEV loaded with antisense RNA	Oncology	[Red arrow from Discovery to Pre-clinical]					<i>In vitro</i> POC ongoing

RBC: Red Blood Cells ; AAC: activating antigen carrier; RBCEV: RBC-derived extracellular vesicles ; GI: gastrointestinal ; PKU: phenylketonuria; ARG1D: arginase 1 deficiency; POC : proof of concept ; IP : intellectual property

#### 4.B.5. Eryaspase

As a preliminary matter, it should be noted that as a result of the earlier setback of a failed Phase 3 trial in pancreatic cancer, and a non-conclusive early readout of first patients in a Phase 2 trial in TNBC, both with the same product candidate, we have decided to halt further development with Eryaspase/GRASPA®, until then our lead candidate. The information detailed in this section presents the data obtained in our clinical trials with eryaspase.

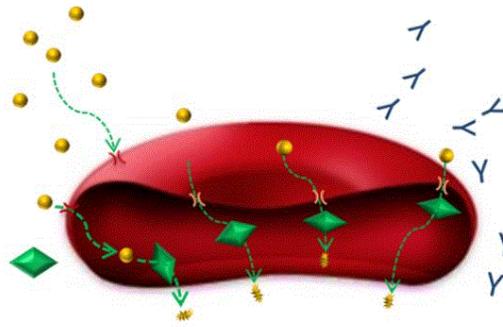
Eryaspase, our first product candidate developed using our proprietary ERYCAPS® platform consists of the enzyme L-asparaginase encapsulated inside erythrocytes, or red blood cells. L-asparaginase breaks down asparagine, a naturally occurring amino acid, into L-aspartic acid and ammonia. Asparagine is naturally produced by healthy cells in the body for their own use in protein synthesis. Cancer cells also need asparagine to grow and proliferate, even more than normal cells, but most cancer cells cannot produce enough asparagine and must rely on circulating asparagine to survive. Injection of L-asparaginase, either by intravenous or intramuscular modes of administration, can lower asparagine levels throughout the body, thereby depriving cancer cells of a key nutrient and causing them to starve and ultimately die. The use of L-asparaginase to deplete asparagine is a well-established treatment for ALL patients, and in particular, pediatric ALL patients. However, important side effects including allergies, coagulation disorders, pancreatic and hepatic toxicities can limit treatment compliance, particularly in adults, limiting the potential use of current, non-encapsulated L-asparaginases beyond ALL. We believe that encapsulating L-asparaginase in red blood cells, utilizing our proprietary ERYCAPS® platform, reduce the side effects of L-asparaginase, which we believe broadens the potential use of L-asparaginase outside the pediatric ALL setting, including for the treatment of aggressive solid and liquid tumors. Eryaspase has been administered to more than 659 patients in clinical trials and compassionate use programs to date.

Eryaspase is administered by intravenous infusion. Once administered, the red blood cells containing L-asparaginase circulate in the bloodstream and remove asparagine mainly through a mechanism of active transportation of asparagine into the red blood cells. Active transporters for asparagine are present in the membrane of red blood cells. They cause normal red blood cells to contain two to three times more asparagine within the cell than in the surrounding plasma. When L-asparaginase is encapsulated in the red blood cells, it causes the inner concentration of asparagine to decrease, which activates the natural mechanism of the red blood cell to draw asparagine circulating in the blood plasma into the red blood cell. This asparagine is rapidly degraded inside the red blood cells as well. When maintained long enough, this pumping and degradation activity leads to a systemic depletion of asparagine levels in the bloodstream without releasing L-asparaginase into the bloodstream. The red blood cell membrane also protects the encapsulated L-asparaginase from antibodies present in the patient's blood that would substantially lessen or neutralize the enzyme's activity or cause allergic reactions. As a result, the enzyme can remain active and potentially effective in the red blood cell for a longer period of time, while at the same time reducing the potential for toxicity and related side effects. Our research indicates that the encapsulation process does not significantly alter the life span of the red blood cell.

The following diagram illustrates the main mode of action of eryaspase:

Active transporters in membrane of RBC pump circulating asparagine into the RBC...

-  Asparaginase
-  Asparagine
-  Aspartate
-  Antibody



...where the encapsulated L-asparaginase hydrolyzes the asparagine into aspartate and ammonia

**Prolonged activity**  
**Reduced toxicity**

**Clinical Development of eryaspase (GRASPA®)**

The table below sets forth summary information regarding our clinical trials of eryaspase conducted to date.

Completed clinical trials

PHASE	TRIAL REFERENCE	# OF PATIENTS ENROLLED	AGE	INDICATION	PRIMARY ENDPOINTS	DOSE	REGION	DESIGN
<b>Metastatic Pancreatic Cancer</b>								
2b	GRASPANC 2013-03	141	18+	Second-line patients with metastatic pancreatic adenocarcinoma	• Efficacy (progression-free survival or overall survival) and safety of eryaspase in combination with chemotherapy	100 U/kg	EU	Randomized, open label, controlled
1	GRASPANC 2008-02	12	18+	Second-line	• Determination of the maximum tolerated dose (MTD) and recommended Phase 2 dose	25 / 50 / 100 / 150 U/kg	EU	Non-randomized, open label
<b>Acute Lymphoblastic Leukemia</b>								
2/3	GRASPALL 2009-06	80	1 to 55	Relapsed/refractory	• Mean duration (days) of ASNase activity >100 U/L • Incidence of allergic reactions (induction phase)	150 U/kg	EU	Randomized, open label
2a	GRAALL SA2-2008	30	55+	First-line	• Efficacy and safety of eryaspase with combination therapy and determination of the MTD in elderly	50 / 100 / 150 U/kg	EU	Non-randomized, open label
1/2	GRASPALL 2005-01	24	1 to 55	Relapsed/refractory	• Determination of the MTD and recommended Phase 2 dose	50 / 100 / 150 U/kg	EU	Randomized, open label
1/2	GRASPALL 2012-09	14	18+	First-line	• Determination of the MTD and recommended Phase 3 dose	50 / 100 / 150 / 200 U/kg	US	Non-randomized, open label
1	GRASPALL 2012-10-EAP	18	Up to 55	At risk - all lines	• Safety of eryaspase in combination with polychemotherapy	150 U/kg	EU	Non-randomized, open label
2	NOR-GRASPALL 2016 (NOPHO)	55	1 to 45	Second-line post PEG-asparaginase	• PK / PD, safety and immunogenicity	150 U/kg	EU	Single arm, open label
<b>Acute Myeloid Leukemia</b>								
2b	GRASPA-AML 2012-01 (ENFORCE 1)	123	65 to 85	First-line, unfit	• Overall survival	100 U/kg	EU	Multicenter, open label, randomized, controlled

<b>Solid Tumors</b>								
1	STUDY00002008 (rESPEct)	18	18+	First line patients with locally advanced and metastatic pancreatic cancer	Determination of the MTD, tolerability and safety of eryaspase in combination with the dose-modified FOLFIRINOX	25 / 50 / 75 / 100 U/Kg	US	Single arm, Open label
3	TRYbeCA-1	512	18+	Second-line patients with metastatic pancreatic adenocarcinoma	• Overall survival	100 U/kg	EU/US	Open label, randomized
2	TRYbeCA-2	27	18+	Metastatic or locally recurrent Triple-Negative Breast Cancer / 1st line	Objective response rate determined by an independent radiological review	100 U/kg	EU	Open label, randomized 1:1 (chemotherapy ± eryaspase)

### ***Eryaspase for the Treatment of Acute Lymphoblastic Leukemia (ALL)***

We were previously developing eryaspase, or GRASPA<sup>®</sup>, for the treatment of children and adults with ALL in combination with chemotherapy. We started the development of eryaspase in ALL in 2005 with a Phase 1 clinical trial in patients with relapsed and refractory ALL. The clinical trial was completed in 2009. We also completed a Phase 2 study in elderly patients with ALL in 2010. We have completed five clinical trials in ALL in Europe and in the United States in which a total of 166 patients with ALL were enrolled, of which 132 patients were treated with eryaspase.

Different hard-to-treat sub-indications of ALL were targeted in these trials, relapsed and refractory patients, adults and elderly patients and patients who were allergic to other asparaginases. We believe the results of our trials support our hypothesis that encapsulation could prolong asparaginase activity and reduce its side-effects. We also observed eryaspase to have an improved clinical benefit as compared to native L-asparaginase in our completed clinical trials, as described below.

In 2014, we completed a phase 2/3 clinical trial in 80 children and adults with relapsed ALL in which we evaluated the safety and efficacy of GRASPA<sup>®</sup> compared to free-form L-asparaginase derived from the bacteria *E. coli*, also known as native L-asparaginase. In this European trial, patients without a history of allergies to native L-asparaginase treatments were randomized to receive standard chemotherapy plus either GRASPA<sup>®</sup> or native L-asparaginase. Patients with a known allergy to native L-asparaginase treatments were treated with standard chemotherapy plus GRASPA<sup>®</sup>. The trial achieved both of its primary endpoints:

- *Lower Incidence of Allergic Reactions.* Among the non-allergic patients, none of the 26 patients treated with GRASPA<sup>®</sup> experienced an allergic reaction during the induction phase, compared to 13 patients out of 28, or 46%, of those treated with native L-asparaginase in the control group.
- *Superior Duration of L-Asparaginase Activity.* Among the non-allergic patients, the patients treated with GRASPA<sup>®</sup> maintained a mean duration of L-asparaginase activity above 100 U per liter for 18.9 days, with at most two injections during the first month of treatment. This result compared to a mean duration of activity of 8.5 days in the control group, who received up to eight injections of native L-asparaginase.

Eryaspase or GRASPA<sup>®</sup> was also observed to have an improved clinical benefit as compared to native L-asparaginase based on its achievement of the secondary efficacy endpoints:

- *Higher Complete Remission Rate.* At the end of the induction phase, the non-allergic patients in the GRASPA<sup>®</sup> treatment arm, or 76%, had achieved complete remission, or the disappearance of all signs of cancer in response to treatment, as compared to 46.4%, in the control arm. Among the allergic patients, 60% achieved complete remission after treatment with GRASPA<sup>®</sup>.
- *Improved Minimal Residual Disease Rate.* Among the non-allergic patients, nine out of 26, or 35%, achieved low levels of residual leukemic cells classified as minimal residual disease, or MRD, at the end of the induction phase, as compared to

seven out of 28, or 25%, of those in the control group. Among the allergic patients, six out of 26, or 23%, achieved MRD after treatment with GRASPA®.

- *Improved Overall Survival Rates.* 12-month overall survival rates among the non-allergic patients treated with GRASPA® were 76.9%, compared to 67.9%, for those in the control group. 12-month overall survival in the allergic group of patients was 50%. Based on three years of follow-up, a nominal improvement of overall survival was observed (HR = 0.73).

Treatment with GRASPA® was generally well tolerated. Drug-related adverse events generally consisted of allergic reactions, clotting problems, liver toxicities and pancreas disorders. None of the 52 patients receiving GRASPA® during the Phase 2/3 trial had an adverse event leading to discontinuation of the trial, as compared to 13 out of the 28 patients, or 46%, in the control arm. A total of three patients out of the 52 patients treated with GRASPA® during the trial experienced serious adverse events determined to be drug-related.

Based on the positive efficacy and safety results from our Phase 2/3 pivotal trial, we submitted a Marketing Authorization Application, or MAA, to the EMA for GRASPA® for the treatment of relapsed or refractory ALL in September 2015. Following discussions with the EMA, we withdrew the MAA in November 2016. We conducted activities designed to provide data regarding immunogenicity and pharmacodynamics of eryaspase, as well as comparability of eryaspase produced with native versus recombinant L-asparaginase, and resubmitted an MAA in October 2017. In June 2018, based on feedback from the EMA and FDA, it appeared that significant additional investment would be required in order to seek regulatory approval of eryaspase for the treatment of ALL. In the context of the rapidly changing and increasingly competitive landscape with newly-approved treatment options for ALL, the regulatory feedback and what we observed to be a limited market opportunity for eryaspase in ALL, we elected to withdraw our MAA in Relapse and Refractory ALL in the second half of 2018 to focus our development efforts on solid tumors. Despite this shift in focus, we continue to support the investigator-sponsored trial initiated in 2017 by the Nordic Society of Pediatric Haematology and Oncology, or NOPHO to evaluate eryaspase (GRASPA®) in ALL patients who have developed hypersensitivities to E-coli derived asparaginase. The trial protocol was amended in 2019 to increase the number of patients to be recruited up to 50 patients. The main objectives of this trial were to evaluate the pharmacokinetic and pharmacodynamic activity, safety and immunogenicity profile of eryaspase in combination with NOPHO's multi-agent chemotherapy protocol for ALL, administered as second-intention treatment for children or adult ALL patients, one year to 45 years of age, who experience hypersensitivity reactions to PEG-asparaginase or silent inactivation. The study, conducted by NOPHO through 21 clinical sites in the Scandinavian and Baltic countries, included 55 patients. The enrollment was completed in August 2020. Preliminary results were presented in March 2020 at the NOPHO Annual Meeting and final positive results were presented in December 2020 at the American Society of Hematology 2020 Annual Meeting. The primary objectives of the study were the activity and safety of eryaspase. Both objectives were met. Eryaspase demonstrated sustained asparaginase enzyme activity above the 100 U/L threshold at trough levels 14 days after the first administration by 54 of 55 treated patients. Eryaspase was generally well tolerated when combined with chemotherapy, and nearly all patients were able to receive the scheduled doses of asparaginase (median of 5 doses per patient). Of the 55 patients, only two patients had a severe allergic reaction and discontinued eryaspase.

Following positive results of a Phase 2 trial, sponsored by NOPHO, we have been in an extended dialogue with the U.S. Food and Drug Administration (FDA) to evaluate the possibility for an approval of GRASPA® in ALL patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. A pre-BLA meeting to discuss the submission of a Biologics License Application (BLA) took place in June 2021 after which we confirmed our intention to submit a BLA, subject to successful completion of remaining activities, which included the submission of additional information to the FDA, responses to additional data requests, and the submission of the Initial Pediatric Study Plan (iPSP). We submitted our iPSP in July 2022 and received feedback from the FDA in August 2022. After thorough evaluation of this feedback, which included a new request for additional data, and taking into account the changing competitive landscape, we decided to halt the BLA process of seeking approval.

### ***Eryaspase for the Treatment of Pancreatic Cancer and Other Solid Tumors***

Researchers have investigated the potential to target asparagine metabolism in solid tumor indications, and based on the observation that many solid tumors, like lymphoblasts, lack the asparagine synthetase, or ASNS, enzyme, a rationale for the use of asparaginase in solid tumors exists. L-asparaginase has been shown to have growth inhibitory effects in different solid tumor cell lines and in xenograft models. The toxicity profile of existing asparaginase products has, however, been prohibitive for their use in patients. Historically, Phase 1 clinical trials conducted by researchers have been modified or halted because of excess toxicity.

#### ***Completed Phase 1 Clinical Trial of Eryaspase for the Treatment of Pancreatic Cancer***

In 2011, we completed an open-label Phase 1 clinical trial in 12 patients with pancreatic cancer at four sites in France. The enrolled patients were separated into four cohorts of three subjects each. Eryaspase was administered as one injection of four different doses, 25 Units, or U, per kilogram, 50 U per kilogram, 100 U per kilogram or 150 U per kilogram. The primary endpoint of the trial was the determination of the maximum tolerated dose. Secondary endpoints included assessments of safety and exploratory measures of efficacy. No dose-limiting toxicities were reported, even at the highest dose administered in the trial.

### Phase 2b Clinical Trial for Eryaspase for the Treatment of Second-Line Metastatic Pancreatic Cancer

In 2014, we commenced a multi-center, open-label, randomized Phase 2b clinical trial to evaluate the efficacy of eryaspase as a second-line treatment for patients with metastatic pancreatic cancer. The trial was conducted at 16 sites in France and performed in collaboration with the Groupe Coopérateur Multidisciplinaire en Oncologie. Professor Pascal Hammel, a gastroenterologist-oncologist at Beaujon Hospital in Paris, was the principal investigator of the trial. The original recruitment objective was 90 patients. In February 2016, we elected to continue to enroll patients to increase the statistical power of the trial. In September 2016, we completed enrollment of 141 patients in this trial. In March 2017, we reported positive top-line results from this trial, which also included three data safety monitoring board, or DSMB, safety reviews. In September 2017, we presented the full results of this trial at the ESMO Congress in Madrid, Spain and the results of the trial were published in the European Journal of Cancer in November 2019.

#### *Trial Design*

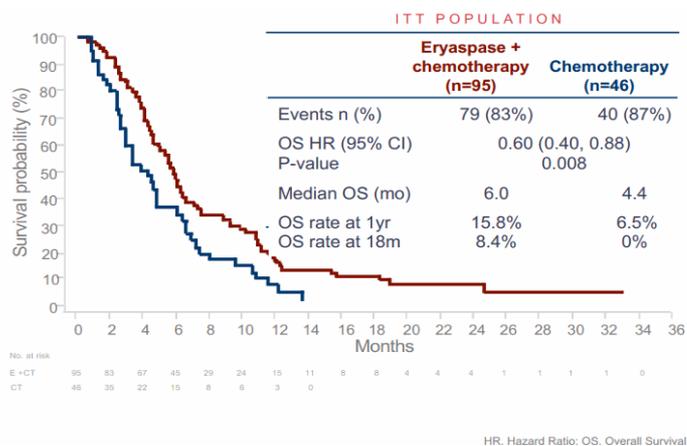
In this trial, patients in the active arm were treated with eryaspase in addition to the current standard of chemotherapy, consisting of either gemcitabine or FOLFOX, depending on which treatment the patient had received as first-line therapy. Patients in the control arm were patients treated with chemotherapy alone. Patients were randomized at a 2:1 ratio. Prior to enrolling each patient in this trial, we used a diagnostic test to assess the level of ASNS expression in such patient's cancer cells. We included both patients with no or low ASNS expression levels and patients with normal or high ASNS expression levels in the trial.

#### *Endpoints*

The co-primary endpoints of the Phase 2b clinical trial were progression-free survival, or PFS, and overall survival, or OS, rates, as measured by the hazard ratio, or HR, for the patients that were enrolled with no or low ASNS expression levels. The HR represents the chance of events occurring in the treatment arm relative to the chance of events occurring in the control arm. An HR of one means that there is no difference in survival between the two groups, while an HR of greater than one or less than one means that survival was better in one of the groups. The outcome of the trial would be considered positive if the HR was below 0.85 for the low or no ASNS expression group, irrespective of statistical significance. The secondary endpoints of the clinical trial included overall progression-free survival and overall survival rates, as measured by HR, in the entire patient population and for the patients enrolled with normal or high ASNS expression levels, as well as objective response rates and safety outcomes.

#### *Efficacy Results*

The primary objectives of the trial were met, with an overall survival HR of 0.65 and a progression-free survival HR of 0.72 in the patient population with no or low ASNS expression levels. This sub-group of the patient population constituted approximately 70% of the trial population. There was also an overall survival benefit in the entire patient population, with a statistically significant overall survival HR of 0.60 (nominal p-value = 0.008), meaning that a reduction in risk of death rate of 40% was observed. The PFS hazard ratio was 0.56 (nominal p-value = 0.011). The graph below shows the Kaplan-Meier overall survival curve of the trial in the entire patient population. A Kaplan-Meier plot is a graphical statistical method commonly used to describe survival characteristics. Similar results were observed for progression-free survival.



The baseline characteristics and demographics in the patient population were balanced, and overall survival and progression-free survival results appeared to be consistent across different sub-groups, including age, gender and prior treatment.

An unexpected finding from these results was that the ASNS expression level in the patients did not appear to be predictive of treatment efficacy. However, the ASNS expression level does appear to be a prognostic factor. Patients with high ASNS expression levels appear to have a worse prognosis, and their relative response to eryaspase seems to be relatively higher in this group than the

patients with no, low or normal ASNS expression levels. Based on this finding, we believe future clinical trials may be conducted in the entire patient population, independent of ASNS expression levels.

#### TRYbeCA-1 Trial

Following our positive Phase 2b clinical trial results, we launched TRYbeCA-1, a pivotal Phase 3 clinical trial of eryaspase for second-line metastatic pancreatic cancer. The TRYbeCA-1 trial evaluated eryaspase in combination with standard chemotherapy, compared to standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) alone, in 512 patients. Patients who met the eligibility criteria were randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/abraxane or irinotecan-based regimen) or chemotherapy alone until disease progression. The primary endpoint was overall survival. The main secondary endpoints included progression-free survival, objective response rate, disease control rate, quality of life and safety. Patient enrollment for the TRYbeCA-1 trial commenced in September 2018 in Europe and after receipt of IND approval from the FDA, we opened clinical sites in the United States. We obtained clinical trial authorizations in the United States and from 11 European countries, and as of the date of this Annual Report, the trial has been conducted in 90 clinical trial sites. We completed enrollment in December 2020 with 512 randomized patients.

The interim analysis was triggered when two-thirds of the total number of events had occurred (i.e. two-thirds of the number of deaths required to make the final analysis of the overall survival in the trial) have occurred. Those events were reached in October 2020. We published the results from the interim superiority analysis on February 8, 2021. This was the third review by the IDMC of the safety data of the patients enrolled and treated in the trial. The prior reviews took place at 150, 199 and 320 patients, respectively. No safety issues were identified and the IDMC recommended that we continue the trial as planned. TRYbeCA-1 reached the 390<sup>th</sup> event required for our Final Analysis in May 2021. We announced final results in October 2021. The trial did not meet its primary endpoint of overall survival. The prespecified subgroup of patients treated with eryaspase and an irinotecan-based chemotherapy demonstrated an interesting trend of survival benefit. Patients treated with eryaspase demonstrated superior disease control compared to patients treated with chemotherapy only. Other secondary endpoints showed nominal improvement. The safety profile of eryaspase was consistent with earlier clinical trials results and safety reviews. The clinical study report was completed in November 2022.

#### rESPECT trial

rESPECT (STUDY00002008) is a proof-of-concept investigator initiated Phase 1 clinical trial initiated by the Georgetown Lombardi Comprehensive Cancer Center evaluating the safety of eryaspase in combination with modified FOLFIRINOX for the treatment of first-line metastatic or locally advanced pancreatic cancer patients. The US Food and Drug Administration (FDA) reviewed IND/Investigational New Drug application and cleared the study to proceed enrolling patients in December 2019. The first patient was enrolled in January 2021. In October 2021, after review of the safety data of six additional patients comprising the second treatment cohort, we announced the determination of the maximum tolerated dose at 100 U/kg. The study completed enrollment with 18 patients treated. In January 2022, encouraging data from the study were presented at the American Society of Clinical Oncology (ASCO GI) Gastrointestinal Cancers Symposium.

#### ***Ongoing and Planned Clinical Development in Triple Negative Breast Cancer and Other Solid Tumors***

Following the results with eryaspase in the proposed treatment of second-line metastatic pancreatic cancer, we conducted a comprehensive evaluation to determine other potential solid tumor indications and selected metastatic TNBC as the next indication to evaluate in order to expand the potential use of eryaspase in solid tumors. TNBC is an aggressive and metabolically active form of breast cancer with high rates of symptomatic metastases. TNBC cells lack expression of estrogen and progesterone receptors and do not overexpress HER2. Scientific literature estimates that approximately 10% to 20% of the 600,000 breast cancers that are diagnosed each year in the United States and Europe in aggregate are classified as TNBC. As commonly-utilized hormone therapy and HER2 targeting agents are not treatment options for women with TNBC, there is significant unmet need for novel therapeutic approaches in this subtype of breast cancer. At the end of 2018, we launched a Phase 2 proof-of-concept clinical trial in this indication in the European Union, which we refer to as the TRYbeCA-2 trial. The trial was open for enrollment in three European Union countries and we announced enrollment of the first patient in June 2019. The TRYbeCA-2 trial was designed to evaluate eryaspase in combination with gemcitabine and carboplatine chemotherapy, compared to chemotherapy alone in approximately 64 patients, with previously untreated metastatic TNBC. Following the negative results of the TRYbeCA-1 study announced in October 2021, we have made a strategic decision to cease further enrollment in the TRYbeCA-2 trial. The trial had enrolled 27 patients, 26 of which were treated. The early readout from these patients enrolled in the TRYbeCA-2 trial were non-conclusive.

#### ***4.B.6. Other Development Programs***

We believe that our ERYCAPS® platform has broad potential application and can be used to encapsulate within red blood cells a wide range of therapeutic agents. The efficacy of the technology has been demonstrated mainly with asparaginase but it is also feasible to encapsulate within the red blood cell other enzymes, molecules or proteins for which long-circulating therapeutic activity or rapid and specific targeting is desired.

Today, we have focused our R&D works on extracellular vesicles (ERYCEV™), other projects based on our ERYCAPS® platform have been put on hold but are still presented in this document.

### ***Enzyme Replacement***

Outside of the oncology field, we also are studying the use of our ERYCAPS® platform to promote long-acting enzyme activity. Enzyme replacement is a preclinical development program designed to use our proprietary ERYCAPS® platform for enzyme-based therapies beyond oncology. We encapsulate therapeutic enzymes inside donor-derived red blood cells using our proprietary ERYCAPS® platform in order to create product candidates to target certain metabolic diseases. We believe that the encapsulation of the therapeutic enzymes in the red blood cells may be able to reduce the potential for allergic reactions and to allow the therapeutic substance to remain in the body longer as compared to non-encapsulated enzymes.

### ***Immune modulation***

We demonstrated the proof of concept to encapsulate tumor antigens or adjuvants within red blood cells as an innovative approach to cancer immunotherapy.

Based on our preclinical research on immune modulation, we believe that encapsulated tumor antigens can be targeted to key organs, such as the spleen, in order to induce an immune response, resulting in sustained activation of the body's immune system to fight cancers or to tolerance induction. In preclinical studies with three different antigens loaded in red blood cells, we have observed promising proof-of-concept data in three different tumor models. In these studies, we observed significantly increased antigen-specific CD8+ and CD4+ T-cell responses and delays in tumor growth when the encapsulated antigens were injected in mice with tumors, as compared to the injection of the unloaded antigens alone. As part of our value creation strategy, in 2019, we have granted to SQZ Biotechnologies an exclusive worldwide license to develop antigen-specific immune modulating therapies employing RBC-based approaches. Combining SQZ's proprietary and versatile cell engineering platform, Cell Squeeze®, with our intellectual property related to RBC-based therapeutics, rapid development of a broad pipeline of novel immunomodulatory products addressing multiple indications is envisaged.

### ***FERTUS Project***

Since April 2021, we have participated in the FERTUS (Functionally Enhanced Red Cells for Therapeutic Use) project with Sanquin Research, Erasmus MC and PAN-Biotech GMBH, granted by the Health of Holland/Erasmus. This project aimed to develop new therapies in rare diseases using modified cultured red blood cells expressing enzymes that are deficient in patients.

#### ***4.B.7. Manufacturing and Supply***

We currently have a manufacturing facility to manufacture our product candidates for Europe which is based in Lyon, France. This production facility complies with European cGMP.

For our clinical trials in the United States, we started manufacturing GMP-compliant batches out of our former manufacturing facility in Princeton, New Jersey in the fourth quarter of 2019. This Princeton Facility was designed with the ability to scale production to supply eryaspase to meet our anticipated clinical trial needs, including our supply requirements for U.S. patients in the ALL trial, and for our commercial needs in the United States if eryaspase had been approved. In connection with the transition to our Princeton Facility, we closed our small production facility in Philadelphia, Pennsylvania in January 2020. In April 2022, we entered into the Catalent Purchase Agreement, pursuant to which we sold to Catalent, among other things, certain assets and inventory of materials located at the Princeton Facility. Prior to the announcement of our decision to halt development of eryaspase in November 2022, we also had entered into an interim supply agreement with Catalent under which Catalent agreed to manufacture and supply us with eryaspase for our clinical and commercial uses of eryaspase in the United States.

It should be noted that the elements relating to the supply of eryaspase presented below concern the period prior to the announcement of the end of eryaspase development in November 2022 and are still ongoing.

In Europe, we purchase packed red blood cells from the French Blood Agency (Établissement Français du Sang). In the United States, we have supply agreements with the American Red Cross and the New York Blood Center. In the case of eryaspase, we had the manufacturing and logistics in place to deliver eryaspase to patients in approximately 24 hours from the start of production to delivery of the product candidate to the hospital. Once a prescription was written, we received an order for eryaspase from the hospital. We then sourced a pack of red blood cells, compatible with the patient's blood type, from one of our partner blood banks. After identification of the key parameters of the red blood cell unit, we encapsulated the L-asparaginase into the red blood cells using an automated process that took three to eight hours. Before release, the product must meet a number of quality control specifications, including the number of red blood cells in the packed product, the level of L-asparaginase activity, the amount of extracellular L-asparaginase in the blood and the integrity of the container holding the red blood cells. We then delivered the product to the hospital

using a third-party commercial overnight delivery service. We shipped the product at a refrigerated temperature of between two and eight degrees Celsius, or approximately 36 to 46 degrees Fahrenheit. At this temperature, the product has been shown to remain stable for five days. Once removed and ready for administration, the product remains stable for six hours at room temperature.

In May 2011, we entered into a worldwide supply agreement, as subsequently amended on April 4, 2014 and July 25, 2016, which we refer to as the 2011 Medac Agreement, under which Medac has agreed to supply us with their new, recombinant free-form L-asparaginase, called Spectrila, for which Medac obtained a European Union marketing approval in 2016. The 2011 Medac Agreement includes an exclusivity period, starting from the date of commercial authorization of eryaspase/GRASPA® for a duration of five years. The term of the 2011 Medac Agreement is until December 2028, provided, that Medac is entitled, upon expiration of the five-year exclusivity period, to terminate the agreement, upon five years' notice, in the event its supplier of the recombinant formulation of L-asparaginase discontinues supplying to Medac. The July 2016 amendment nullified the clauses providing that we could have been forced to refrain from any form of promotion of eryaspase/GRASPA® if such product was produced from a new formulation of asparaginase registered and marketed prior to eryaspase/GRASPA® as a first-line treatment. We are exclusively using this new recombinant formulation of L-asparaginase in eryaspase for new indications, including our former clinical trials for pancreatic cancer, and no longer intend to use the native form of asparaginase for eryaspase.

#### ***4.B.8. Commercialization***

As we are halting the industrial and commercial exploitation of our eryaspase/GRASPA® product candidate following the failure of clinical studies in solid tumors (pancreatic cancer and triple-negative breast cancer) and the termination of the marketing authorization application in ALL with the FDA, we have put an end to our plans to prepare for the commercialization phase, which included the construction of an internal sales and distribution unit or the conclusion of agreements with third parties for the distribution of its approved products. We had previously entered into agreements for the distribution of GRASPA® for the treatment of ALL in Israel with TEVA and for the distribution of GRASPA® for the treatment of ALL and AML in Europe with Orphan Europe, a member of the Recordati Group.

Following the withdrawal of the marketing authorization application in Europe for ALL and the refocusing on solid tumors, the marketing agreement with Orphan Europe to market and distribute eryaspase (licensee GRASPA®) for the treatment of ALL and AML in Europe has been terminated in the first half of 2019 with no financial consequences to us. The contract with TEVA is still in effect, although it does not currently entail any obligation.

#### 4.B.9. Intellectual Property

Our patent portfolio includes pending patent applications and issued patents in the United States and foreign countries. These patents and applications include 16 patent families we own in our own name with more than 310 granted patents, summarized below:

TECHNOLOGY	NUMBER OF PATENT FAMILIES	EXPIRATION YEARS FOR EACH PATENT FAMILY *	COUNTRIES IN WHICH PATENTS ARE ISSUED (OR ALLOWED/ACCEPTED)
RBC Encapsulation Platform	2	2024 - 2030 2033 - 2034	Japan, Europe, Australia, China, United States, South Korea, India, Canada, Chile, Russia, Hong Kong, Mexico, Israel
Eryaspase	3	2027 - 2029 2032 - 2033 2028 - 2029	Europe, United States, Australia, Singapore, Israel, Japan, South Korea, China, India, United Arab Emirates, Russia, Canada, Hong Kong
Other Onco-metabolism	4	2026 2034 - 2035 2035 - 2036 2038	Europe, Japan, China, Canada, South Korea, Australia, United States, Hong Kong, Israel, Mexico, Russia, Singapore
Rare Metabolic Disorders	3	2028 2033 - 2034 2037 - 2038	Europe, Israel, United States
Immunology	2	2030 2027 - 2028	Australia, Singapore, France, China, Israel, South Korea, Europe, United States, Japan, Canada, Hong Kong
Small Molecule	1	2028 - 2029	Israel, China, Singapore, South Korea, Canada
RBC-derived vesicles (ERYCEV™)	1	2041	United States, Europe, and Canada pending

\* This expiration year does not take into account supplementary patent protection that could be obtained for some of our patents in the United States, Europe, Japan and other countries. Expiration dates for U.S. patents not yet granted may be subject to patent term adjustment (PTA) and/or patent term extension (PTE).

Of our 16 patent families, 14 patent families currently include at least one issued patent.

The term of a U.S. patent may be eligible for patent term restoration under the Hatch-Waxman Act to account for at least some of the time the drug or method of manufacture is under development and regulatory review after the patent is granted. With regard to a drug or method of manufacture for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug or method of manufacture. Some foreign jurisdictions have analogous patent term extension provisions that allow for extension of the term of a patent that covers a device approved by the applicable foreign regulatory agency. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on the patents that we believe will provide the best exclusivity position if extended.

In addition to patent protection, we have trademark protection in many countries for our name, logo and several product candidates. None of our trademarks are subject to a third-party license.

#### 4.B.10. Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Significant competitive factors in our industry include product efficacy and safety; quality and breadth of an organization's technology; skill of an organization's employees and its ability to recruit and retain key employees; timing and scope of regulatory approvals; government reimbursement rates for, and the average selling price of products; the availability of raw materials and qualified manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities. We cannot ensure you that any of our products that we successfully develop will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

Our competitors may also succeed in obtaining European Commission, FDA or other regulatory approvals for their product candidates more rapidly than we are able to do, which could place us at a significant competitive disadvantage or deny us marketing exclusivity rights.

Market acceptance of our product candidates will depend on a number of factors, including:

- potential advantages over existing or alternative therapies or tests;
- the actual or perceived safety of similar classes of products;
- the effectiveness of our sales, marketing, and distribution capabilities; and
- the scope of any approval provided by the FDA, the European Commission, or foreign regulatory authorities.

Although we believe our product candidates possess attractive attributes, we cannot ensure that our product candidates will achieve regulatory or market acceptance, or that we will be able to compete effectively in the biopharmaceutical drug markets. If our product candidates fail to gain regulatory approvals and acceptance in their intended markets, we may not generate meaningful revenues or achieve profitability.

#### ***Competitive environment of ERYCEV™ platform***

Extracellular Vesicles (EVs) are considered as a new class of Drug Delivery System (DDS) with high competitive advantages compared to nanoparticles and viral-based systems that rely on their natural characteristics to transfer biological information between specific cells, to content different types of molecule (RNAs, lipids, proteins) and to be produced by a majority of cells.

Therapeutic EVs are a fast growing field and highly attractive one for therapeutic applications, represented by many actors (biotech & pharmaceutical) who own their own technology, segmented according 1) the nature cell source used for the production of EVs 2) the type of EV; if there are unmodified (native) or modified by the engineering of cell source or by the direct modification of EVs.

Our ERYCEV™ platform aims to develop modified EVs using Red Blood Cells (RBCs) from donor as the cell source for the production of RBC extracellular vesicles (RBCEVs). We will first focus on immuno-oncology applications and evaluate the potential of the platform in other therapeutic fields.

To our knowledge, Carmine Therapeutics was identified as the only competitor with a proprietary technology based on red blood cell derived EVs. Its REGENT technology is based on the modification of EVs after their production. The company is in the preclinical development phase and is positioned in the field of genetic diseases with the encapsulation of genetic material in RBCEVs.

The competitive landscape includes companies with technologies using other cell sources for the development of therapeutic EVs in the oncology field, including Codiak Bioscience, EV Therapeutic, ShiftBio, Ilias Biologics and MDImmune. Codiak is the only company in the early clinical development phase, and the others are in the research or preclinical stages of development with their first drug candidate. Other companies beyond the oncology field (genetic, neurologic, inflammatory diseased, infectiology) are also considered as potential competitors, including Capricor Therapeutics, Omnispirant, Exopharm, Coya therapeutics and AGS Therapeutics.

#### ***Competitive environment of ERYCEV-STINGa***

ERYCEV-STINGa is one of our potential drug-candidate, a candidate in the research stage of development which corresponds to RBCEVs loaded with a STING agonist (ADU-S100). ERYCEV-STINGa is positioned as a new generation of STINGa in the immuno-oncology field.

The competitive landscape is dominated by pharmaceutical companies with free forms of STINGa, including Eisai Co., Ltd; Takeda Pharmaceutical, F-Star Therapeutics, GlaxoSmithKline, Merck & Co, ImmuneSensor Therapeutics. Some biotechnology companies are developing modified forms based on the use of drug delivery systems. These companies are direct competitors and include d'Actym Therapeutics (ACTM-838, attenuated S. Typhimurium bacteria, modified to contain a STINGa), Mersana Therapeutics (XMT-2056, antibody-STINGa-conjugated), Synlogic (SYNB-1891, E.coli Nissle bacteria modified to contain STINGa). Mersana Therapeutics and Actym Therapeutics are expected to launch their phase 1 clinical trials in 2023.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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 registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

#### ***4.B.11. Government Regulation***

Government authorities in the United States at the federal, state and local level and in other countries 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 drug and biological products, or biologics, such as our product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

### ***U.S. Biological Product Development***

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, reputational harm, and/or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: preclinical and clinical. The preclinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial

will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether 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 are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials generally involve a small number of healthy volunteers 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 metabolism, pharmacologic action, side effect tolerability and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries, from several hundred to several thousand subjects, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In some instances, FDA may provide a condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 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 a finding that the research subjects or 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 drug 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 or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate 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 candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### *BLA and FDA Review Process*

Following trial completion, trial data is analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive preclinical and clinical testing. The application includes both negative or ambiguous results of preclinical and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be offered for sale in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription drugs. 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.

Once a BLA has been accepted for filing, which occurs, if at all, 60 days after the BLA's submission, the FDA's goal is to review BLAs within 10 months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening disease or condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by the FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with Good Manufacturing Practice or cGMP to assure and preserve the product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which 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. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive, time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP. 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. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

#### ***Other U.S. Regulatory Matters***

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific or educational programs must comply with state and federal fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement

requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects' entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow an entity to enter into supply contracts, including government contracts. In addition, even if an entity complies with FDA and other regulatory requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, and/or our commercial operations; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping and/or documentation requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

#### ***U.S. Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the BPCIA 2009. Biosimilarity, which requires that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the 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 is biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be 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. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the reference product. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting applications under the abbreviated approval pathway for the lesser of one year after the first commercial marketing, 18 months after approval if there is no legal challenge, 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

## ***European Union Drug Development***

In the European Union, our product candidates may also be subject to extensive regulatory requirements. Medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

### *European Union Marketing Authorizations*

To obtain an MA for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the 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, the centralized procedure may be optional.

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.

In principle, 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 (in case of centralized procedure) 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. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation

to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. 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 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, 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 the 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 is withdrawn in case 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 Union. 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 (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 10 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.

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 MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

#### *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 (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 (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.

#### *Orphan Medicinal Products*

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU; and (3) 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 product will be of significant benefit to those affected by that 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 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 designation, 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 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

#### *Post-Approval Requirements*

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.

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 each member state 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.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

## ***Other European Regulatory Matters***

### *Clinical trials*

The various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP.

On December 13, 2021, the Health Technology Assessment (HTA) Regulation No. 2021/2282 was adopted. It will be applicable from January 2025. The objective of this Regulation is to establish a permanent and viable European cooperation in the common clinical evaluation of new medicinal products (and certain new medical devices). Member States will be able to use common HTA methods, procedures and tools across the European Union. The Regulation will facilitate the exchange of information with health technology developers on their development plans for a given health technology. HTA will enable national health authorities to make informed decisions about pricing or reimbursement of health technologies that remain the national competence of Member States.

Regarding clinical trials, although Directive no. 2001/20/EC on the conduct of clinical trials sought to harmonize the regulatory framework for clinical trials in the European Union, setting out common rules for the monitoring and authorization of clinical trials in the EU, Member States have transposed and applied the provisions of this directive differently, resulting in significant variations in the regimes of different Member States. To improve this system, a new regulation, Regulation 536/2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. This regulation aims to harmonize and streamline the clinical trial authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing the transparency of clinical trials. It was published on June 16, 2014, but did not go into effect until January 31, 2022.

### **Rules applicable prior to the entry into force of Regulation (EU) no.536/2014**

In the European Union, the Clinical Trials Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which entered into application on January 31, 2022, harmonizes and streamlines clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency in all EU Member States, including France.

In France, for example, Directive No. 2001/20/EC has been implemented by Law 2004-806 of August 9, 2004 regarding the public health policy and Decree 2006-477 of April 26, 2006, modifying the section of the Public Health Code, or PHC, on biomedical research. The Act of August 9, 2004 was notably amended by Law No. 2012-300 of March 5, 2012, or the “*Loi Jardé*,” related to biomedical research involving human subjects, and French Order No. 2016-800 of June 16, 2016 related to clinical trials of medicinal products for human use, which adapted French law to the new provisions of Regulation No. 536/2014 of the European Parliament and of the Council of April 16, 2014 related to clinical trials of medicinal products for human use, which repealed Directive 2001/20/EC. The Jardé Act was inapplicable for a long time, and applicable since November 18, 2016, date of its enforcement decree. This Act specifies the modalities for carrying out research involving the human person. In particular, it specifies the definitions applicable to the various categories of research falling within its scope, the operation of the committees for the protection of persons (CPP), the procedures for requesting an opinion from the CPP and authorization from the ANSM, as well as the rules applicable to vigilance.

**Applicable provisions:** French Act No. 2012-300 of March 5, 2012, or the “*Loi Jardé*” related to research involving the human person, and French Order No. 2016-800 of 16 June 2016 related to research involving the human person have adapted French law to the new provisions of Regulation No. 536/2014. Article L. 1121-4 and L. 1123-8 PHC currently in force (as amended by Law 2004-806, Law 2012-300 Order 2016-800), establishes a system of prior authorization for interventional clinical trials only. This authorization is granted by the French Medicines Agency, or ANSM. The conduct of all clinical trials (interventional or not) also requires a favorable opinion of the competent Ethics Committee (*Comité de protection des personnes – CPP*).

**Ethics Committee assessment:** Under Article L. 1123-7 of the PHC, the competent Ethics Committee—selected randomly by drawing lots under Article L. 1123-6 of the PHC—shall notably assess whether the conditions in which the trial will be conducted are valid. This assessment should be based on whether: adequate protection is offered to individuals, in particular to participants; adequate information is provided to the participants and appropriate procedure is in place to obtain their informed consent; the project is relevant; the benefits/risks assessment is satisfactory; the objectives of the trial are adequate to the means implemented; the qualification of the investigator(s) is satisfactory; the conditions and amount of patients’ remuneration is compliant; and the method for recruiting participants is adequate.

**ANSM authorization:** The ANSM, after submission of the complete file containing not only information on the clinical protocol, but also specific product data and its quality control, as well as results of preclinical studies, may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of its research project and submit this amended or supplemented request to the ANSM. If the sponsor does not alter the content of its request, the request is considered rejected. Under

Article R. 1123-38 of the PHC, the time limit for the examination of a request for authorization cannot exceed 60 days from the receipt of the complete file. Under Article L. 1123-11 of the PHC, in the event of risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the Public Health Code, it may at any time request changes to procedures for the realization of research, and suspend or ban this research.

The decision of the ANSM of November 24, 2006 sets the rules for Good Clinical Practice, or GCPs, for clinical trials on medicines for human use as referred to in Article L. 1121-3 of the PHC. GCPs aim to ensure both the reliability of data arising from clinical trials and the protection of the persons participating in these clinical trials. GCPs apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers as well as Phase 2 to Phase 4 clinical trials.

Depending of the type of personal data processing carried out during clinical trials and the nature of such trials, it might be necessary to carry out formalities by the French Data Protection Authority, or the CNIL. The sponsor of the trial might have to file with the CNIL a compliance undertaking with one of CNIL's reference methodologies through a simplified notification procedure or file for a request of authorization. Patients then always shall have a right to access and correct their personal data, and to object to their processing/withdraw their consent, require their deletion or a limitation of the processing pursuant to the GDPR.

The main French legislative and regulatory texts relating to the conduct of clinical trials have been largely codified in the French Public Health Code (Articles L. 1121-1 to L. 1126-12 and Articles R. 1121-1 to R. 1125-26 in particular, govern clinical trials involving human beings) and include:

- Loi Jardé, Law No. 2012-300 of March 5, 2012, related to biomedical research involving human subjects;
- Order No. 2016-800 of June 16, 2016 related to research involving human beings;
- Decree No. 2016-1537 of November 16, 2016 related to research involving human beings;
- Decision of December 29, 2015 establishing the rules of Good Manufacturing Practice, as amended by Decision of November 26, 2020;
- Decision of November 24, 2006 establishing the rules for Good Clinical Practice;
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data;
- Law of January 6, 1978 on Information Technology, Data Files and Civil Liberties as amended and its implementing decrees; and
- Law No. 2018-493 of June 20, 2018 on the protection of personal data.

#### **Main rules applicable after the entry into force of Regulation (EU) no.536/2014:**

The Clinical Trials Regulation (EU) No 536/2014 entered into application on January 31, 2022. The Regulation is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency.

In accordance with Article 98 of the Clinical Trials Regulation, a transition period is open until January 31, 2025:

- until January 31, 2023, the application for authorization of clinical trials falls, at the sponsor's choice, under the regime of Directive No. 2001/20/EC or that of Clinical Trials Regulation. In the event of an option for the Directive, the clinical trial in question will continue to be covered by the Directive until 31 January 2025;
- until January 31, 2025, ongoing clinical trials approved under the 2001/20 directive before January 31, 2022 will continue to fall under the Directive; and
- as of January 31, 2025, only the Clinical Trials Regulation will be directly applicable in all EU Member States and all clinical trials will have to fall under its regime.

Under Clinical Trials Regulation, the sponsor may submit its application for a clinical trial authorization to:

- France only, in the case of a trial conducted in France only or in France and one or more non-EU countries. In this case, the evaluation of the file is carried out only by the ANSM and the Committee for the Protection of Persons (CPP) designated by random drawing;
- several Member States, in which case the evaluation of Part I of the dossier is carried out according to a coordinated procedure. In this framework, the sponsor must submit a single application for authorization via the portal associated with the EU database (CTIS), comprising a common scientific part evaluated jointly by all the EU Member States in which the trial will be carried out (with one of the Member States concerned acting as rapporteur Member State) and a national part covering the ethical aspects of the trial, evaluated independently by each Member State.

In France, the scientific review (Part I) is the responsibility of the ANSM and the ethical review (Part II) is the responsibility of the CPP.

The conclusion of the rapporteur Member State with regard to Part I of the assessment report is deemed to be the conclusion of all Member States concerned. However, the Member States concerned may disagree with this conclusion for a number of limited reasons, for example when they consider that participation in the clinical trial would lead to a subject receiving a treatment inferior to that of normal clinical practice on their territory. The Member State concerned may then refuse the clinical trial on its territory.

A "single" decision covering the conclusions of the Part I and Part II evaluations is issued by each of the Member States concerned and is notified to the sponsor on the dedicated European portal. The sponsor of a clinical trial conducted in France, and possibly in other Member States or third countries, notifies the Eudravigilance database without delay and at the latest within the deadlines set by Clinical Trials Regulation, of all relevant information on suspected serious and unexpected adverse reactions (SUSARs) resulting from clinical trials. If the competent bodies concerned consider that the adverse effects outweigh the benefits for the participants, they may require the immediate suspension or early termination of the trial at any time.

For investigational drugs other than placebos, the sponsor submits through CTIS once a year, for the duration of the clinical trial, an Annual Safety Report (ASR) for each investigational drug used in the clinical trial.

#### *Protection of Clinical Trial Subjects*

Under French law (Article L. 1121-2 PHC), a clinical trial may be undertaken only if (i) it is based on the latest stage of scientific knowledge and on sufficient preclinical testing, (ii) the foreseeable risk incurred by the subjects is outweighed by the benefit expected for these persons or the interest of the research, (iii) it aims at expanding scientific knowledge and the means possible to improve the human condition and (iv) the research was designed to reduce the pain, inconveniences, fear and other predictable inconvenience connected to the disease or to the research, by taking into account in particular the degree of maturity of minors and the capacity of understanding of adults unable to express an informed consent. All these conditions must be fulfilled in order to start a clinical trial.

A clinical trial (Article L. 1121-3 PHC) may be undertaken under the following technical conditions: (a) under the direction and the supervision of a qualified physician and (b) under adapted material and technical conditions, compatible with the rigorous imperatives of science and the safety of the clinical trial subjects.

Two documents must be provided to clinical trial subjects before the conduct of the trial. First, the patient must receive a patient information sheet which must contain in particular a description of the objective, the methodology and the time period of the research, as well as a description of the alternative treatments, the number of subjects expected to take part in the study, the anticipated benefits, the constraints and the foreseeable risks resulting from the administration of the products that are the object of the clinical trials but also the favorable opinion of the ethics committee and the authorization of the ANSM, and information on processing of personal data. The information communicated must be summarized in a written document delivered to the patient prior to any administration of products by the investigator or a physician (Article L. 1122-1 PHC).

Second, the patient must confirm his or her agreement to participate in the clinical study by signing an informed consent form (Article L. 1122-1-1 PHC). For each study, patient information must include a right to refuse to participate and to withdraw consent at any time and by any means without further consequences or prejudice. A clinical trial on a minor may be undertaken only if, in particular, the informed consent of the parents or legal representative has been obtained. Furthermore, a clinical trial on adults under guardianship requires the informed consent of the adult's legal representative.

#### *Responsibility of the sponsor and insurance obligation of the sponsor*

The sponsor shall indemnify the subject of the trial in case of damage arising as a consequence of the research, unless he proves that the damage does not result from his fault or the fault of any other person intervening in the trial (Article L.1121-10 PHC). The sponsor must have an insurance covering its civil liability and the liability of any person intervening in the research, for any damage arising from the trial for a minimum of 10 years as of the end of the trial (Article L.1121-10 PHC). In addition, any breach to the provisions concerning clinical trials may lead to significant administrative, criminal and/or reputational penalties.

Under French law, the State is responsible for compensating the damage resulting from a medical accident occurring during a clinical trial in the event of no fault, i.e. in the event of a medical accident for which no fault is found. In this respect, a mechanism provides for compensation by the National Office for Medical Accidents (*Office national des accidents médicaux*), as part of national solidarity.

#### ***France: Post-marketing requirements***

Any pharmaceutical product distributed in France will be subject to pervasive and continuing regulation by the ANSM, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing updated safety and efficacy information, distribution requirements, complying with promotion and advertising requirements. French law strictly regulates

labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities. Failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible administrative or criminal sanctions.

#### *France: Declaration of Financial Interests*

**"Transparency" or "French Sunshine Act":** The French Public Health Code (PHC) contains certain provisions regarding transparency of fees and rewards received by some healthcare professionals from industries, i.e. companies manufacturing or marketing health products, resulting from an Act No. 2011-2012 of December 29, 2011, amended by an Act No. 2016-41 of 26 January 2016, and corresponding implementing decrees. It results from these provisions (Article L.1453-1 and D. 1453-1 and seq. PHC) that companies manufacturing or marketing healthcare products (medicinal products, medical devices, etc.) in France shall publicly disclose (on a specific public website available at: <https://www.entreprises-transparence.sante.gouv.fr>) the advantages and fees paid to healthcare professionals amounting to 10 euros or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.). These rules apply to manufacturers of health products, regardless of the stage of development of their products and regardless of their nationality and/or the location of their registered office. In the event of non-compliance with any or all of these regulations, in addition to a significant risk to their reputation, the companies and healthcare professionals concerned may be subject to severe criminal sanctions.

**"Anti-gift":** The French Public Health Code also contains "anti-gift" provisions setting out a general prohibition of payments and rewards from industries, i.e. for persons providing health services or producing or marketing health products to offer or promise advantages, in cash or in kind, directly or indirectly, in particular to health professionals practicing in France, to students studying for these professions or to associations of these persons, including learned societies and national professional council, with limited exceptions and strictly defines the conditions under which such payments or rewards are lawful. These rules also apply to manufacturers of health products, regardless of the stage of development of their products and regardless of their nationality and/or the location of their registered office. The provisions resulting from an Act No. 2011-2012 were amended by an Order No. 2017-49 of January 19, 2017 ratified by the Law 2019-774 of July 24, 2019 which notably extended their application to a broader range of legal and physical persons - including social media influencers, specified the scope of the operations excluded from the prohibition and those authorized under some conditions, and provided for a new authorization process. The changes of the "anti-gift" rules were aimed to enter into force on a date provided by decree or, at the latest, on July 1, 2018. In the absence of implementing texts to date, the new provisions (Articles L. 1453-3 to L. 1453-14 PHC) entered into force on July 1, 2018. A decree of August 7, 2020 sets out the amounts for which the benefit, depending on the benefit provided, is considered negligible and does not require any declaratory action. A second decree of August 7, 2020 defines the amounts above which the agreement is subject to an authorization regime, with amounts less than or equal to these amounts requiring a simple declaration. The decree also provide with the declaration schedule to the competent authority. In the event of non-compliance with and or all these regulations, in addition to a significant risk to their reputation, the companies and healthcare professionals concerned may face significant criminal sanctions and, in the case of the healthcare professionals concerned, disciplinary sanctions.

#### *French Pharmaceutical Company Status*

We have the regulated status of pharmaceutical manufacturing establishment, which allows us to manufacture our product candidates. Obtaining a pharmaceutical manufacturing establishment license, either as a distributor or as a manufacturer requires the submission of an application dossier to the ANSM. The application package will vary depending on the type of application (distribution license or manufacturing license). The ANSM grants such license after verifying that the company has adequate premises, the necessary personnel and adequate procedures to carry out the proposed pharmaceutical activities.

#### *Data Privacy*

The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation ((EU) 2016/679), or GDPR, which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for controllers and processors of personal data, including stringent requirements relating the processing justified by law, like the consent of data subjects, expanded information about how personal data is used, requirements to conduct privacy impact assessments for high-risk processing for the rights and liberties of concerned individuals, a principle of limitations on the period of conservation of personal data and data breach notification and privacy by design requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to countries that do not ensure an adequate level of protection, such as the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA countries may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial

year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim compensation for damages resulting from infringement of the GDPR.

Following the United Kingdom's withdrawal and the expiration of the transition period, from January 31, 2020, companies doing business in the EU and the U.K. will be obliged to comply with both the GDPR and the U.K. GDPR. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the U.K. to continue without additional requirements. However, the U.K. adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the European Commission during this period. The relationship between the U.K. and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how U.K. data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the U.K. will be regulated in the long term.

Finally, the processing of health personal data can be subject to additional regulation of EU members, such as France, the Law n°78-17 of January 6, 1978 (*Loi Informatique et Libertés*) provides for a mechanism for declaring compliance with the repositories adopted by the French data protection authority (CNIL) for certain data health processing.

### ***Reimbursement and Health Reform***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the case of GRASPA®, we have entered into distribution arrangements with Orphan Europe and Teva for marketing in Europe and Israel, respectively, and those third parties will be responsible for obtaining coverage and reimbursement for GRASPA® in those territories if it is approved. Our agreement with Orphan Europe was terminated in the first half of 2019 without financial consequences to us. The agreement with Teva is still in effect, but, at this time, there are no current ongoing obligations under the agreement.

Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursement levels for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

To secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA, European Commission, or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, 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. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidates and could have a material adverse effect on our sales, results of operations and financial condition.

For example, the ACA has already had, and is expected to continue to have, a significant impact on the health care industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, since January 2017, former President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The 2020 federal

spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013 and which, due to subsequent legislative amendments, will stay in effect until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose implementing drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. 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.

We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. 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. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective market access will be supported by agreements with hospitals and products may be

reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates.

Historically, products launched in the European Union do not follow price structures similar to those in the United States and generally prices tend to be significantly lower. In the EU some countries may 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 entered into force on 11 January 2022. It will apply from 2025.

### ***Other Healthcare Laws and Compliance Requirements***

Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third party payors and patients may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, proposed sales, marketing and education programs of our product candidates that obtain marketing approval. The laws that may affect our ability to operate include, among others:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, 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, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by individuals, on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws prohibits individuals and entities from, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- HIPAA, which created additional federal, civil and criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided 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 certain ownership and investment interests held by physicians or their immediate family members;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes certain requirements on covered entities, and their business associates that perform functions or activities that involve individually identifiable health information on their behalf as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information; and
- State and/or foreign equivalents of each of the above federal laws and regulations, such as: state anti-kickback and false claims laws 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 that may be broader in scope than the federal requirements; 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 drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of

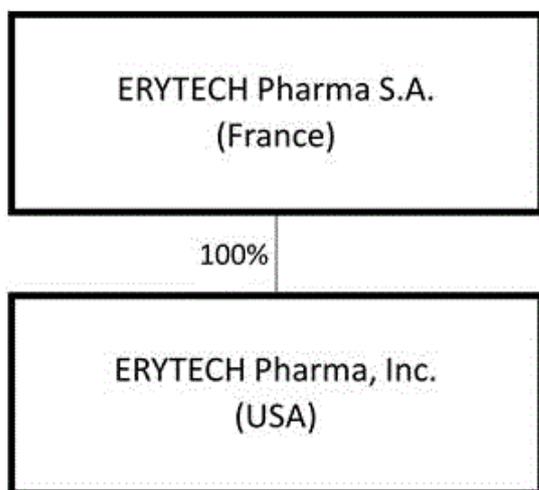
pharmaceutical sales representatives; and state and/or foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the U.S. federal Anti-Kickback Statute and certain federal criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of those statutes or specific intent to violate them in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or 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 or the civil monetary penalties statute.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. 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, for example, significant administrative, civil, and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from 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 non-compliance with these laws and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant administrative, civil, and criminal sanctions, including exclusions from government funded healthcare programs.

#### 4.C. Organizational Structure.

The following diagram illustrates our corporate structure:



#### 4.D. Property, Plants and Equipment.

Our principal executive offices are located at 60 Avenue Rockefeller, 69008 Lyon, France. We lease office and laboratory space, which together consist of approximately 1,400 square meters, in Lyon, France. The lease for this facility expires in June 2024. In July 2019, we entered into another lease in Lyon, France for additional offices and laboratory space, which together will consist of approximately 3,000 square meters. The lease for this facility expires in June 2029, and we will have the ability to terminate the lease either in June 2025 or June 2028. We believe our current leased space is sufficient to meet our current needs in Europe.

In February 2016, we opened our U.S. office in Cambridge, Massachusetts, for which the lease expired in January 2023. We do not currently have a physical office in the United States. In 2018, we entered into a lease for 3,000 square meters of manufacturing and office space in Princeton, New Jersey, under a lease that expires in June 2029. The Princeton Facility became operational in the fourth quarter of 2019 and had been used to produce GMP-compliant batches since then. Following the opening of the Princeton Facility, we terminated our agreement with the American Red Cross for the use of a manufacturing facility in Philadelphia, Pennsylvania in

January 2020. In April 2022, we entered into the Catalent Purchase Agreement, pursuant to which we sold to Catalent, among other things, certain assets and inventory of materials located at the Princeton Facility.

#### **Item 4.A. Unresolved Staff Comments.**

Not applicable.

#### **Item 5. Operating and Financial Review and Prospects.**

*You should read the following discussion of our operating and financial review and prospects in conjunction with our audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report. In addition to historical information, the following discussion and analysis contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements.”*

##### **Overview**

We are a biopharmaceutical company focusing on innovative red blood cell-based therapeutics to treat severe forms of cancer and orphan diseases. We have developed ERYCAPS<sup>®</sup>, a proprietary platform using novel technology to encapsulate therapeutic drug substances inside erythrocytes, or red blood cells (“RBCs”). In April 2022, we presented ERYCEV<sup>™</sup>, our novel approach to RBC vesiculation, at the 24<sup>th</sup> European Red Cell Society (ERCS) Congress. We believe that RBC-derived extracellular vesicles, which are formed naturally during senescence and storage of mature RBCs, may potentially be an attractive drug delivery system. Utilizing our ERYCAPS<sup>®</sup> platform, RBCs can be loaded with active therapeutic compounds, and we believe the vesiculation of such cargo-loaded RBC-derived extracellular vesicles may facilitate the development of novel therapeutic approaches. We are building a research & development strategy leveraging ERYTECH’s platforms and expertise, including drug-delivery with red blood cells (ERYCAPS) or red blood cell-derived vesicles (ERYCEV), formulation expertise and oncology experience to support phage and endolysins therapeutic approaches in anti-infectives fields like AMR and beyond (such as in food, cosmetics and animal health fields), or the development of novel carriers.

Since our inception, we have devoted substantially all of our financial resources to research and development efforts, including conducting preclinical studies and clinical trials of our product candidates, providing general and administrative support for our operations and protecting our intellectual property.

As of December 31, 2022, we had cash and cash equivalents amounted of €38.8 million (\$41.5 million). Historically, we have financed our operations and growth through private and public offerings of our equity securities, convertible notes, loans, public assistance programs in support of innovation, such as the conditional advances and subsidies from Bpifrance, a French public investment bank and from research tax credits.

Since our inception in 2004, we have incurred significant operating losses. Our net loss was €73.3 million, €53.8 million and €0.2 million for the years ended December 31, 2020, 2021 and 2022, respectively. We had a consolidated shareholders' equity of €23.5 million as of December 31, 2022, and we expect to incur significant expenses and substantial operating losses over the next several years as we continue our research and development efforts in Europe and the United States.

Considering the earlier setback of a failed Phase 3 trial in pancreatic cancer, and a non-conclusive early readout of first patients in a Phase 2 trial in TNBC, we announced in November 2022 our decision to halt further development with GRASPA<sup>®</sup>, which was until then our lead product candidate, and focus on our most promising preclinical programs.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents as of the date of this Annual Report will be sufficient to fund our operations until mid-2024. Refer to "Item 3.D.1 Risks Related to our Financial Position and Capital Needs" for further details.

Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, the receipt of milestone payments, if any, and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- continue the research and development of our other product candidates;

- seek to discover and develop additional product candidates;
- seek to attract and retain new and existing skilled personnel; and
- create additional infrastructure to support our operations as a public company listed in the United States.

Until such time that we can generate substantial revenue from product sales, we expect to finance these expenses and our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. 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 rights to third parties to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Moreover, no assurance can be given at this time as to whether we will be able to achieve these financing objectives. 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.

The consolidated financial statements as of and for the years ended December 31, 2020, 2021 and 2022 included in this Annual Report have been prepared in accordance with IFRS as issued by the IASB with no difference with the statutory consolidated financial statements and were approved and authorized for issuance by our board of directors on March 22, 2023. Due to the listing of our ordinary shares on Euronext Paris and in accordance with the European Union's regulation No. 1606/2002 of July 19, 2002 as amended, our statutory consolidated financial statements have also been prepared in accordance with IFRS as adopted by the European Union, or EU.

## Financial Operations Overview

### *Operating Income*

To date, we have not generated any revenue from the sale of products. Our ability to generate product revenue and to become profitable will depend upon our ability to successfully develop and commercialize product candidates. Because of the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount or timing of product revenue. Our operating income consists of other income and the net gain from the disposal of fixed assets related to the sale of the Princeton plant to Catalent.

### Research Tax Credit

The research tax credit (crédit d'impôt recherche), or CIR, is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies demonstrating that they have expenses that meet the required criteria, including research expenses located in France or, since January 1, 2005, within the European Union or in another state that is a party to the agreement in the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause, receive a tax credit which can be used against the payment of the corporate tax due the fiscal year in which the expenses were incurred and during the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenses taken into account for the calculation of the CIR only involve research and development expenses.

The main characteristics of the CIR are the following:

- the CIR results in a cash inflow from the tax authorities paid directly to us as we are not subject to corporate income tax;
- a company's corporate income tax liability does not limit the amount of the CIR;
- the CIR is not included in the determination of the corporate income tax.

As a result, we have concluded that the CIR meets the definition of a government grant as defined in IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance*. As no research and development expenditure is capitalized before obtaining a marketing authorization, the CIR related to a research program is entirely recognized in "other income" in our statement of income (loss).

### Subsidies

We have received financial assistance from Bpifrance and other governmental organizations in connection with the development of our product candidates. Bpifrance's mission is to provide assistance and support to emerging French enterprises to facilitate the development and commercialization of innovative technologies.

Funds are recognized in "other income" in our statement of income (loss) for the fiscal year in which the financed expenses were recorded.

### Revenue from Licenses or Other Contracts

Since January 1, 2018, agreements are analyzed and recorded in accordance with IFRS 15 *Revenue from contracts with customers*, or IFRS 15.

#### *Partnership with Orphan Europe for NOPHO clinical trial*

Pursuant to the terms of our distribution agreement, Orphan Europe agreed to finance the NOPHO trial for a total amount of €600 thousand. We recognized revenues related to this partnership under "other income" in our statement of income (loss).

#### *License agreement with SQZ Biotechnologies*

Pursuant to the terms of our license agreement with SQZ Biotechnologies, we granted to SQZ Biotechnologies an exclusive worldwide license to develop antigen specific immune modulating therapies employing red blood cell-based approaches. In accordance with IFRS 15, this agreement grants to SQZ Biotechnologies a right to use the underlying intellectual property. Consequently, the income is recognized when SQZ Biotechnologies can begin to use the licensed intellectual property.

### **Operating Expenses**

Our operating expenses consist primarily of research and development expenses and general and administrative expenses.

### Research and development expenses

We engage in substantial research and development efforts to develop innovative pharmaceutical product candidates.

Research and development expenses consist primarily of:

- services, subcontracting and consulting fees, that primarily include the cost of third-party contractors such as contract research organizations, or CROs, who conduct our clinical trials;
- personnel costs, including salaries, related benefits and share-based compensation, for our employees engaged in scientific research and development functions;
- purchases of raw materials, especially asparaginase, and transportation costs associated;
- depreciation and amortization expenses.

Since our inception, our research and development efforts have been related primarily to our completed and ongoing clinical trials of eryaspase for the treatment of pancreatic cancer, ALL and AML. In June 2018, we ceased the development program for eryaspase in ALL and focused our development efforts on eryaspase for the treatment of selected solid tumors. The resources that became available as a result of this strategic decision were allocated to what we estimate is a significantly larger unmet medical need and market opportunity for the potential treatment of solid tumors, including pancreatic cancer and TNBC. In November 2022 we decided to cease all Eryaspase developments (GRASPA®).

Our direct research and development expenses consist principally of external costs, such as fees paid to consultants, laboratories and CROs in connection with our clinical trials, and purchases of raw materials which we allocate to our specific research programs.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates and pursue later stages of clinical development of other product candidates, and will seek regulatory approvals for our product candidates, if clinical trial are successfully completed.

We cannot determine with certainty the duration or costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory

approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our ongoing, as well as any additional, non-clinical studies, clinical trials and other research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for eryaspase or any other product candidate that we may develop in the future.

A change in the outcome of any of these variables with respect to the development of product candidates that we are developing could mean a significant change in the costs and timing associated with the development of such product candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct non-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in enrollment in any clinical trials, we could be required to spend significant additional financial resources and time on the completion of clinical development.

#### General and Administrative

General and administrative expenses consists primarily of:

- services, subcontracting and consulting fees, mainly related to legal services, accounting and audit, IT, insurance costs and overhead costs;
- personnel costs including share-based compensation for personnel other than employees engaged in scientific research and development functions;

#### **Financial Income (Loss)**

Financial income (loss) relates primarily to:

- expenses and income on convertibles notes recognized in accordance with IFRS 9 (amortized cost and change in fair value of embedded derivatives),
- interest expenses incurred on financial liabilities and lease liabilities,
- income received from cash and cash equivalents and
- gains and losses on exchange rate variations on financial and investing operation.

#### **Income tax**

In the previous years we did not recognize current tax expense. Following the sales of the Princeton facility by our US subsidiary in April 2022 and the recognition of a net gain of €24.4 million, we performed a tax analysis to determine the extent of prior year federal and state tax losses which could be carried forward to offset the current year gain. As a result of this analysis, the company recorded an income tax expense of €0.5 million for the year ended December 31, 2022. Deferred tax assets resulting from temporary differences or tax losses carried forward are limited to the deferred tax liabilities with the same maturity, except where their allocation on future taxable income is probable.

### **5.A. Operating Results**

#### **5.A.1. Operating Income**

We generated operating income of €3,718 thousand in 2020, €4,180 thousand in 2021 and €30,998 thousand in 2022. The components of our operating income are set forth in the table below.

(in thousands of €)

	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Research Tax Credit	3,430	3,669	1,486
Subsidies	42	383	4,968
Revenues from licenses or other contracts	246	128	194
Net gain on disposal of tangible assets			24,351
<b>Operating income</b>	<b>3,718</b>	<b>4,180</b>	<b>30,998</b>

The Research tax credit (CIR) recognized for each of the years 2020 and 2021 ended were received in cash in 2021 and 2022, respectively. We expect to receive the CIR recognized for the 2022 year in 2023.

In 2022 the net sale of Princeton manufacturing plant was recorded in net gain on disposal of tangible assets. BPI conditional advance extinguishment in 2022 is recorded in subsidy for €4,895 thousand.

The reduction of the research tax credit in 2022 is mainly linked to the end of the clinical trial TRYbeCA1.

### Research and Development Expenses

Our research and development expenses amounted to €57,580 thousand in 2020, €45,100 thousand in 2021 (a decrease of 22% compared to 2020) and €19,907 thousand in 2022 (a decrease of 56% compared to 2021).

We have always focused our research and development expenses on the development of eryaspase for the treatment of pancreatic cancer, ALL and AML. In June 2018, the Company decided to focus its development efforts on eryaspase for the treatment of certain solid tumors (including pancreatic cancer). Final results from the TRYbeCA-1 trial were announced by the Company in October 2021. The trial did not meet its primary endpoint of overall survival. In 2022 the Company stopped its BLA application with the FDA on the ALL indication, shortly afterwards the Graspas® product development was also discontinued.

Our research and development expenses are broken down in the table below.

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,			% CHANGE	
	2020	2021	2022	2022/2021	2021/2022
ERYASPASE	28,469	17,486	1,143	(39 %)	(93 %)
ERYMETHIONASE	41	30	0	(26 %)	(100 %)
IMMUNOTHERAPIES	2	0		(100 %)	0 %
ENZYME THERAPIES	0	(1)		0 %	(100 %)
<b>Direct research and development expenses</b>	<b>28,512</b>	<b>17,515</b>	<b>1,144</b>	<b>(39 %)</b>	<b>(93 %)</b>
Consumables	3,695	3,094	332	(16 %)	(89 %)
IT Costs and maintenance	1,275	1,473	993	16 %	(33 %)
Services, subcontracting and consulting fees	4,179	2,467	1,398	(41 %)	(43 %)
Personnel expenses <sup>(1)</sup>	15,629	15,594	11,459	0 %	(27 %)
Depreciation and amortization expense	4,232	4,883	3,992	15 %	(18 %)
Other	58	74	588	28 %	695 %
<b>Indirect research and development expenses</b>	<b>29,068</b>	<b>27,585</b>	<b>18,763</b>	<b>(5 %)</b>	<b>(32 %)</b>
<b>Research and development expenses <sup>(2)</sup></b>	<b>57,580</b>	<b>45,100</b>	<b>19,907</b>	<b>(22 %)</b>	<b>(56 %)</b>

<sup>(1)</sup> Includes €531 thousand, €680 thousand and €(44) thousand related to share-based compensation expense for 2020, 2021 and 2022, respectively.

<sup>(2)</sup> €53,734 thousand, €41,914 thousand and €16,893 thousand of this amount are related to clinical trials for 2020, 2021 and 2022, respectively.

The change in research and development expenses for periods presented is mainly due to:

- A decrease in costs related to eryaspase of €10,983 thousand in 2021 and a decrease of €16,343 thousand in 2022 mostly because of the completion of our TRYbeCA-1 trial.
  - In 2021 compared to 2020, patient cost decreased by €6,601 thousand and CRO cost decreased €4,452 thousand.

- In 2022 compared to 2021, TRYbeCA-1 patient cost decreased by €5,263 thousand, CRO cost decreased €5,914 thousand, Grasp consumables and other production cost decreased by €1,548 thousand, other clinical vendors decreased by €1,778 thousand.
- In 2022 compared to 2021, TRYbeCA-2 cost decreased by €926 thousand (including €573 thousand for patient cost) and NOPHO clinical study cost decreased by €341 thousand.
- A decrease in consumable of €2,761 thousand in 2022, because no additional purchase of Eryaspase were made (in 2021 Eryaspase purchase to Medac amounted to €2,884 thousand).
- Personnel expenses are stable in 2021 compared to 2020. Personnel expenses decrease significantly of €4,135 thousand in 2022 with the transfer to Catalent end April 2022 of Princeton manufacturing facility employee and the restructuring plan in Lyon in the fourth semester 2022. The average number of full-time employees allocated to our research and development workforce was 166 in 2020, 152 in 2021 and 93 in 2022.
- An increase in depreciation and amortization expenses of €651 thousand in 2021 mainly related to the recognition of an impairment expense of €560 thousand in 2021 on a production process (Troy project) recognized in intangible asset.
- A decrease in depreciation and amortization expenses of € 891 thousand in 2022, mainly related to:
  - the decrease of depreciation of Princeton Manufacturing facility for €1,955 thousand (following the sale to Catalent in April 2022).
  - an impairment charge of €1.7 million in 2022 for the facilities, fixtures, equipment and rights of use of the Adenine production unit in France (refer to notes 4.1.3 and 4.2) compared to €560 thousand in 2021 (Troy project).

### **General and Administrative Expenses**

Our general and administrative expenses amounted to €14,970 thousand in 2020, €15,595 thousand in 2021 (an increase of 4% compared to 2020) and €13,887 thousand in 2022 (a decrease by 11% compared to 2021).

Our general and administrative expenses are broken down as follows:

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,			% CHANGE	
	2020	2021	2022	2020/2021	2021/2022
Consumables	224	226	93	1 %	(59 %)
IT Costs and maintenance	1,070	1,129	1,048	6 %	(7 %)
Services, subcontracting, and consulting fees	5,962	6,684	6,477	12 %	(3 %)
Personnel expenses <sup>(1)</sup>	6,573	6,174	5,013	(6 %)	(19 %)
Depreciation and amortization expense	686	494	627	(28 %)	27 %
Other <sup>(2)</sup>	455	888	630	95 %	(29 %)
<b>General and administrative expenses</b>	<b>14,970</b>	<b>15,595</b>	<b>13,887</b>	<b>4 %</b>	<b>(11 %)</b>

<sup>(1)</sup> Includes €532 thousand, €561 thousand and €442 thousand related to share-based compensation expense for 2020, 2021 and 2022, respectively.

<sup>(2)</sup> Includes €159 thousand, €82 thousand and €49 thousand related to share-based compensation expense (warrants allocated to directors and to the chairman of the board) for 2020, 2021 and 2022, respectively.

The increase in 2021 in G&A cost is related mostly to the increase of D&O insurance premium by €1,344 thousand.

The decrease of €1,708 thousand in 2022 G&A cost is mainly due to personnel expenses decrease for €1,160 thousand.

Our general and administrative expenses are mainly composed of:

- Services, subcontracting and consulting fees amounting to €5,962 thousand in 2020, €6,684 thousand in 2021 and €6,477 thousand in 2022. ; and
- Personnel expenses amounting to €6,573 thousand in 2020, €6,174 thousand in 2021 and €5,013 thousand in 2022. The average number of full-time employees allocated to our general and administrative workforce was 41 in 2020, 42 in 2021 and 26 in 2022.

### 5.A.2 Financial Income (Loss)

Our financial income (loss) amounted to €4,465 thousand in 2020, €2,720 thousand in 2021 and €3,089 thousand in 2022. It is broken down as follows:

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Financial income	889	5,422	4,453
Financial expenses	(5,354)	(2,702)	(1,364)
Financial income (loss)	<b>(4,465)</b>	<b>2,720</b>	<b>3,089</b>

Our financial income related mainly to:

- Net Foreign currency gains and (losses) of €(3,028) thousand in 2020, €3,570 thousand in 2021 and €2,891 thousand in 2022. The variations over the periods presented are due to the fluctuation of the Euro/USD conversion rate which was at the end of 2022 at 1.0666 with a significant decrease compared to the end of 2021 (at 1.1326) , and another significant decrease compared to the end of 2020 (at 1.2271).
- A net financial expense of €390 thousand in 2021 in connection with recognition of the convertible notes agreement signed with European High Growth Opportunities Securitization Fund in accordance with IFRS 9. A net financial expense of €45 thousand in 2022 for the research tax credit financing.

### 5.A.3 Income Tax

The Income tax in 2022 of €0.5 million represents the federal and state income tax following the capital gain on the sale of the Princeton manufacturing facility. The Princeton sale capital gain was partially offset by net operating losses carried forward up to €11.9 million / \$12.6 million (after section 382 study limitation calculation) and by research tax credit utilization.

## 5.B. Liquidity and Capital Resources

### 5.B.1. Sources of liquidity

#### Equity

We have financed our operations since our inception through several rounds of public and private financings that could be summarized as follows:

		<b>Gross proceeds (in millions of euros)</b>
Until 2012	Successive funding rounds : issuance of ordinary and preference shares	17.7
2013	Initial public offering on Euronext	17.7
2014	Follow-on offering	30.0
2015	Private placement	25.4
2016	Private placement	9.9
2017	Follow-on offering	70.5
2017	Global offering : U.S. initial public offering and concurrent private placement in Europe	123.6
2020-2021	Conversion of convertible notes	27.0
2021	Shares sold under the at-the-market (“ATM”) program	6.6
2021	Registered Direct Offering (april & december)	31.8
		<b>360.2</b>

In September 2020, we entered into a sales agreement with Cowen with respect to an ATM offering program pursuant to which we may issue and sell, from time to time at our sole discretion, ordinary shares in the form of ADSs to eligible investors at market prices, with aggregate gross sales proceeds of up to \$30 million, subject to the regulatory limit of 20% dilution (this threshold is calculated based on the total number of shares listed on Euronext during the twelve months before the issuance).

In February 2021, we sold shares under this ATM offering program resulting in gross proceeds of \$8.0 million, or €6.6 million, resulting in net proceeds of \$7.8 million or €6.4 million. As of the date of this Annual Report, \$22.0 million remained available for future issuance until September 2023, subject to the regulatory limit of 20% dilution.

#### Registered Direct Offering

In April 2021 the Group carried out a capital increase, with cancellation of preferential subscription rights, by means of an offer reserved for certain categories of persons, for a gross amount of €24,868,971.30, through the issuance of 4,137,932 new ordinary shares, with a nominal value of ten cents (€0.10), with attached warrants, each to subscribe one ordinary shares in the Company at a unit price of 6.01 euros.

In December 2021 the Group carried out a capital increase, with cancellation of preferential subscription rights, by means of an offer reserved for certain categories of persons, for a gross amount of €6,957,256.32, through the issuance of 3,078,432 new ordinary shares, with a nominal value of ten cents (€0.10), with attached warrants, each to subscribe one ordinary shares in the Company at a unit price of 2.26 euros.

#### Non-refundable grants and conditional advances

Since our inception, we have received non-refundable subsidies from Bpifrance in the amount of €2.7 million in connection with our preclinical research programs.

We have also received €4.9 million in three conditional advances from Bpifrance related to TEDAC research program.

The TEDAC research program, which is funded by non-refundable subsidies and conditional advances from Bpifrance, was funded according to a specified schedule set forth in the contract, subject to completion of milestones. The final research report was provided to BPI in 2021. Subsidies and conditional advance were received with the last milestone in 2021, for a cumulated amount of €7.0 million.

The conditional advance reimbursement in cash is initiated upon achieving cumulative sales of €10 millions of Grasca solid tumor product. Following the unsuccessful completion of Trybeca-1 and Trybeca-2 trial those sales will not happen. As a consequence in 2022 the extinguishment of the conditional advance has been recorded in subsidy income.

#### Research Tax Credit

The Company benefits from the provisions in Articles 244 *quater* B and 49 *septies* F of the French Tax Code related to the Research Tax Credit. The cumulative amount of research tax credit recognized for the years ended December 31, 2020, 2021 and 2022 was €8.6 million, of which €7.1 million are received as of today. The €3.7 million research tax credit (CIR) receivable outstanding at December 31, 2021 corresponds to the CIR for the year 2021 and was pre-financed by a bank in March 2022. The financing agreement was reimbursed in October 2022. The €1.5 million research tax credit (CIR) receivable outstanding at December 31, 2022 corresponds to the CIR for the year 2022.

#### Loans

- Convertible notes agreement ("OCABSA")

Refer to "Item 10.C. Material Contracts" for further information regarding our material contracts.

- *Bank loans*

In November 2020, we received two loans of €5.0 million each, in the form of State-Guaranteed Loan (Prêt Garanti par l'Etat, or PGE in France), with Bpifrance and Société Générale in the context of the COVID-19 pandemic. The loans bear interest at fixed rates of 1.67% and 0.25% per annum respectively, with an initial term of one year, extended to 6 years, with the first installment due in 2023. The French government guarantee 90% of the amount due. The Proposed Merger could trigger a request from BPI of early repayment.

#### **5.B.2. Cash Flows**

The table below summarizes our sources and uses of cash for the years ended December 31, 2020, 2021 and 2022.

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Net cash flows used in operating activities	(51,720)	(56,770)	(31,764)
Net cash flows used in investing activities	(1,475)	(345)	38,127
Net cash flows from (used in) financing activities	25,449	44,712	(1,768)
Exchange rate effect on cash in foreign currency	(981)	1,656	495
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(28,727)</b>	<b>(10,747)</b>	<b>5,090</b>

#### Cash flows used in operating activities

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Operating cash flow before change in working capital	(62,522)	(49,615)	(23,663)
Change in working capital	10,802	(7,153)	(8,098)
<b>Net cash flow used in operating activities</b>	<b>(51,720)</b>	<b>(56,770)</b>	<b>(31,764)</b>

Our net cash flows used in operating activities were €51,720 thousand, €56,770 thousand and €31,764 thousand for the years ended December 31, 2020, 2021 and 2022. The operating cash flow before change in working capital decreased since 2020 mainly due to the reduction of R&D costs. In 2020 the increase of working capital is related to the increase in hospital costs (associated accruals), for which there is a significant time difference between the provision of the services and the actual invoicing from the hospitals. In 2021 and 2022, the decrease of working capital is mainly related to the decrease of accruals for hospital costs as invoices are received and paid.

### Cash flows used in investing activities

We do not capitalize clinical research and development costs until we obtain marketing authorization for a product candidate.

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Acquisition of property, plant and equipment, net of disposal	(1,139)	(298)	(85)
Disposal of property, plant and equipment	83	0	37,630
Acquisition of intangible assets	(2)	0	0
Increase in non-current & current financial assets, net of decrease	(417)	(46)	581
<b>Net cash flow used in investing activities</b>	<b>(1,475)</b>	<b>(345)</b>	<b>38,127</b>

Our net cash flows used in investing activities were €1,475 thousand and €345 thousand and in the years ended December 31, 2020 and 2021, respectively.

The largest portion of our capital expenditures are related to the payment of the leasehold improvements of our manufacturing facility in Princeton, New Jersey, United States (€0.8 million in 2020).

Our net cash flow from investing activities were €38,127 thousand in 2022, as a result of the sale of our Princeton facility to Catalent in April 2022 (see line disposal of property, plant and equipment in the above table).

### Cash flows from (used in) financing activities

(in thousands of €)	FOR THE YEAR ENDED DECEMBER 31,		
	2020	2021	2022
Capital increases, net of transaction costs	118	34,631	—
Proceeds from borrowings	27,134	12,157	3,081
Repayments from borrowings	(62)	—	(3,081)
Repayment of lease liability, net of allowance received	(1,428)	(1,702)	(1,545)
Interests received (paid)	(326)	(374)	(223)
Other	12	—	—
<b>Net cash flow from (used in) financing activities</b>	<b>25,449</b>	<b>44,712</b>	<b>(1,768)</b>

Our net cash flows from financing activities were €25,449 thousand in 2020 and €44,712 thousand in 2021 .

In 2021, capital increases net of transaction costs were made of: the ATM offering for 6.4 million euros in February 2021, and two Registered Direct Offerings in April and December for respectively 22.4 million euros and 5.8 million euros.

In 2021, proceeds from borrowing were primarily the result of four tranches of convertible notes for a total amount of €12 million, net of issuance costs (€577 thousand) and a conditional advance within the scope of TEDAC project for a total amount of €734 thousand.

In 2020, proceeds from borrowing were primarily the result of the issuance of five tranches of convertible notes, in a total amount of €15.0 million (refer to section Item 10, section C. Material Contracts) and the collection of two loans in the form of State-Guaranteed Loan for €10.0 million.

Our net cash flows used in financing activities in 2022 was €(1,768) thousand. The proceeds and repayments of borrowings was related to the loan secured by the 2021 research tax credit receivable (see above).

### **5.B.3. Operating Capital Requirements**

As of December 31, 2022, the Company had cash and cash equivalents of 38.8 million euros. The Company believes that the cash and cash equivalents available will enable it to finance its activities until mid 2024.

For more information as to the risks associated with our future funding needs, see the "Item 3.D.1 Risks Related to our Financial Position and Capital Needs".

### 5.C. Research and Development

For a discussion of our research and development activities, see “Item 4.B—Business Overview” and “Item 5.A—Operating Results.”

### 5.D. Trend Information

For a discussion of trends, see “Item 5.A—Operating Results” and “Item 5.B—Liquidity and Capital Resources.”,see also "Item 2.9 -Events after the close of the reporting period".

### 5.E. Off-Balance Sheet Arrangements

During the periods presented, we did not and do not currently have any off-balance sheet arrangements as defined under Securities and Exchange Commission rules, such as relationships with other entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheet.

### 5.F. Material Cash Requirements from known contractual and other obligations

The following table discloses aggregate information about our material contractual obligations and the periods in which payments were due as of December 31, 2022. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

(in thousands of €)	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Convertible notes	—	—	—	—	—
Conditional advances	—	—	—	—	—
Bank loans	2,565	3,524	3,984	—	10,073
Other financial liabilities	—	40	—	—	40
Lease liabilities	775	1,048	920	712	3,455
Trade and fixed assets payables	1,562	—	—	—	1,562
<b>Total</b>	<b>4,902</b>	<b>4,612</b>	<b>4,904</b>	<b>712</b>	<b>15,130</b>

The amounts of contractual obligations set forth in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

Bank loans include a BPI loan, the Proposed Merger could trigger a request from BPI of early repayment (see note 4.8.3 of the consolidated financial statements).

### 5.G. 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 6. Directors, Senior Management and Employees.

### 6.A. Directors and Senior Management.

The following table sets forth information concerning our executive officers and directors as of the date of this Annual Report.

NAME	AGE	POSITION(S)
<b>Executive Officers</b>		
Gil Beyen	61	Chief Executive Officer and Director
Eric Soyer	56	Deputy General Manager, Chief Financial Officer and Chief Operating Officer
Iman El-Hariry, M.D., Ph.D. <sup>(1)</sup>	62	Chief Medical Officer
Jérôme Bailly, Pharm.D.	44	Deputy General Manager, Operations Chief Quality Officer and Qualified Person
Anne-Cécile Fumey	48	Human Resources Director
Karine Charton Ph.D.	40	Director Innovation & Valorization
<b>Non-Employee Directors</b>		
Jean-Paul Kress, M.D. <sup>(3)</sup>	57	Chairman of the Board
Sven Andréasson <sup>(2)(3)</sup>	70	Director
Philippe Archinard, Ph.D. <sup>(2)(3)(4)</sup>	63	Director
Luc Dochez, Pharm.D. <sup>(4)</sup>	48	Director
Martine Ortin George, M.D. <sup>(4)</sup>	74	Director
Melanie Rolli, M.D. <sup>(4)</sup>	50	Director
Hilde Windels <sup>(2)(5)</sup>	57	Director

<sup>(1)</sup> Employee of our wholly-owned U.S. subsidiary, ERYTECH Pharma, Inc.

<sup>(2)</sup> Member of the audit committee.

<sup>(3)</sup> Member of the remunerations and appointment committee.

<sup>(4)</sup> Member of the clinical strategy committee.

<sup>(5)</sup> As representative of Hilde Windels BV, the legal entity that holds this board seat.

Upon completion of the Proposed Merger, it is contemplated that Mr. Thibaut du Fayet, currently Chief Executive Officer of Pherecydes, will become Chief Executive Officer of Erytech, while Mr. Eric Soyer will remain Chief Operating Officer and Chief Financial Officer of Erytech.

Following the completion of the Proposed Merger, Mr. Jean-Paul Kress, Chairman of Erytech, will resign from his position and Mr. Didier Hoch, Chairman of Pherecydes, will become Chairman of the board of directors of Erytech, while Mr. Gil Beyen will become Vice-Chairman of the board of directors (and will remain Executive Chairman of Erytech Pharma, Inc.). It is also expected that the Erytech Board of Directors will be composed of an equal number of directors from the current Erytech and Pherecydes Boards.

#### Executive Officers

*Gil Beyen* has served as our Chief Executive Officer since May 2013 and as Chairman of our board of directors from May 2013 until June 2019. Prior to his appointment as Chief Executive Officer, he assisted our company in a consulting role as of 2012 and also served as Chairman of our supervisory board from August 2012 until May 2013. Mr. Beyen was co-founder and Chief Executive Officer of TiGenix (NYSE Euronext: TIG BB) for 12 years. Before founding TiGenix, he served as the head of the Life Sciences division of Arthur D. Little, an international management consulting firm, in Brussels. Mr. Beyen received an M.S. in Bioengineering from the University of Leuven (Belgium) and an M.B.A. from the University of Chicago.

*Eric Soyer* has served as our Chief Financial Officer and Chief Operating Officer since September 2015 and as our *Directeur Général Délégué*, or Deputy General Manager, since January 2019. Eric Soyer has more than 20 years of experience holding management positions in financial and operational fields at both public and private companies including the Chief Financial Officer of EDAP TMS and Managing Director of the French affiliate, Chief Financial Officer for a company operating nursing homes and post-care clinics, and Financial and legal director for an insurance services company. He started his career as a financial controller and cost accountant for Michelin Group. Mr. Soyer graduated from the ESC Clermont School of Management (France) and holds an M.B.A. from the University of Kansas and an Executive M.B.A. from the HEC Paris School of Management (France).

*Iman El-Hariry, M.D., Ph.D.* has served as our Chief Medical Officer and employee of our wholly-owned U.S. subsidiary, ERYTECH Pharma, Inc., since June 2015. Prior to her appointment as Chief Medical Officer, she served as President of Azure Oncology Consulting from July 2014 to June 2015 and also assisted us in a consulting role from November 2014 to June 2015. Dr. El-Hariry served as Vice President of Clinical Research at Synta Pharmaceuticals from November 2010 to July 2014 and as Global Head of Oncology at Astellas Pharma, Inc. from June 2009 to July 2010. From 2001 to 2009, she served as Director of Clinical Development, Oncology at Glaxo Smith Kline. Dr. El-Hariry is a licensed oncologist with an M.D. from Alexandria Medical School (Egypt) and a Ph.D. in Cancer Research from Imperial College of Science and Medicine (United Kingdom).

*Jérôme Bailly, Pharm.D.* has served as our Qualified Person since December 2011, as *Directeur Général Délégué*, or Deputy General Manager, since 2017 and as Chief Quality Officer since November 2020. Prior to his appointment as Chief Quality Officer, he held the position of Director of Pharmaceutical Operations from 2007 to November 2020. Prior to 2007, he was the Director of QA/Production at Skyepharma and Laboratoire Aguettant. Dr. Bailly holds a Pharm.D. and a degree in Chemical Engineering, specializing in Biopharmaceutical Engineering and Cellular Production from *École Polytechnique de Montréal* (Canada).

*Anne-Cécile Fumey* was appointed as our Human Resources Director in February 2016. Prior to joining our company, Mrs. Fumey served within several high-growth blue-chip companies. She was International HR Director with Clasquin Group and Senior HR Manager at National Bank of Canada in Montréal. Anne-Cécile Fumey started her career with BD where she was responsible for Human Resources management at the European headquarters, then within the Pharmaceutical Systems business unit, before being appointed Compensation and Benefits Manager France. Mrs. Fumey graduated from the Grenoble Institute of Political Studies (IEP) and has a postgraduate degree (DESS) in Human Resources Management from the Grenoble Graduate School of Management (IAE).

*Karine Charton* joined our Company in September 2017, leading early-stage business development. She was appointed Director Innovation and Valorization in 2022. In this role, she is leading our preclinical research and development team and external innovation efforts. Prior to joining the Company, Mrs. Charton was a researcher in charge of R&D programs in the non-profit company Généthon, dedicated to developing gene therapies for rare diseases, where she developed deep experience in innovative product development in the gene therapy space. She then moved to the Scientific Direction of AFM-Téléthon to support detection, valorization and follow-up of projects to be funded in the field of rare diseases.

#### **Non-Employee Directors**

*Jean-Paul Kress, M.D.* has served as Chairman of our board of directors since June 2019. Dr. Kress has served as the Chief Executive Officer of MorphoSys AG since September 2019. He previously served as President and Chief Executive Officer of Syntimmune Inc. (Cambridge, United States) from January 2018 until November 2018. Prior to joining Syntimmune, Dr. Kress served as Executive Vice President of International and Head of Global Therapeutic Operations at Biogen Inc from June 2017 to January 2018. He previously served as a member of the board of directors of Sarepta Therapeutics, Inc. from September 2015 to June 2017 and as a member of the board of directors of Quantum Genomics S.A.S. from June 2018 to June 2019. From September 2015 to June 2017, Dr. Kress served as Senior Vice President, Head of North America at Sanofi Genzyme. From July 2011 to September 2015, Dr. Kress served as President and Chief Executive Officer of Sanofi Pasteur MSD, one of the leading European vaccine companies. Prior to then, Dr. Kress worked at Gilead, Abbvie and Eli Lilly in senior commercial and business development roles in the United States and in Europe. Dr. Kress holds an M.D. degree from Faculté Necker-Enfants Malades in Paris, and graduate and post-graduate degrees in pharmacology and immunology from École Normale Supérieure in Paris.

*Sven Andréasson* has served as a member of our board of directors since 2013 (as representative of Galenos SPRL, the legal entity that held this board seat, and as a natural person since January 2022). Mr. Andréasson currently serves as a member of the Board of directors and the compensation committee of Mendus AB. Mr. Andréasson has also served as Senior Vice President, Corporate Development for Novavax, Inc. (United States), a pharmaceutical company, since June 2014. From 2012 to 2013, he served as Chief Executive Officer of Isconova AB (Uppsala, Sweden), a leading international vaccine adjuvant company acquired by Novavax in 2013, currently operating as Novavax AB. Prior to his role at Novavax AB, he served as Chief Executive Officer of Beta-Cell N.V. (Brussels, Belgium) from 2008 to 2012 and as Chief Executive Officer of Active Biotech AB (Lund, Sweden) from 1999 to 2008. Mr. Andréasson spent a number of years in roles at Pharmacia Corporation (merged with Pfizer Inc.), including President of Pharmacia SA, France, President of KabiPharmacia International and President of Pharmacia Arzneimittel GmbH. He has extensive experience in international biotechnology companies and in the pharmaceutical industry. Mr. Andréasson received his Bachelor of Science and Business Administration and Finance from Stockholm School of Economics and Business Administration (Sweden).

*Philippe Archinard, Ph.D.* has served as a member of our board of directors since 2013 and was previously a member of our supervisory board from 2007 to 2013. Dr. Archinard was appointed Executive Vice-President, Technological Innovation and Scientific Partnerships at Institut Mérieux since January 1, 2021. Dr. Archinard was Chairman and Chief Executive Officer of Transgene from 2004 until December 2020, after 15 years with bioMérieux, a global biotech company, in various roles including the management of its US subsidiary. Prior to joining Transgene, he served as chief executive officer of Innogenetics N.V., from 2000 to 2004. Dr. Archinard has also served as a member of the board of directors of NH TheraguiX. He has served as a member of

bioMérieux's board of directors since 2005 and continues to serve as a member of the board of directors of Transgene since his appointment in 2004. Dr. Archinard is a chemical engineer, holds a Ph.D. in biochemistry from the University of Lyon (France), and completed by Harvard Business School's Program for Management Development (PMD).

*Luc Dochez, Pharm.D.* has served as a member of our board of directors since 2015. Mr. Dochez is currently Chairman at Vico International BV, and Montis Biosciences BV, and Executive Chairman and at Primix Bioventures BV / Primix Invest. He is also a managing partner at DROIA N.V., a position he has held since October 2018. Prior to then, he served as Chief Executive Officer of Tusk Therapeutics Ltd., a private company focused on developing novel immuno-oncology products, from March 2015 until its acquisition by Roche in September 2018. Mr. Dochez has over 15 years of experience in the biotechnology industry. He served as the Chief Business Officer and Senior Vice President of Business Development of Prosensa Holding N.V., a biotechnology company, from November 2008 until its acquisition by BioMarin Pharmaceutical Inc. in January 2015. Before joining Prosensa, he served as Vice President of Business Development at TiGenix, Director Business Development at Methexis Genomics, and a consultant at Arthur D. Little. Mr. Dochez was a board member of Pharvaris BV, a Dutch company focused on rare diseases, as well as Bioncotech Therapeutics SL, a Spanish oncology company. Mr. Dochez holds a Pharm.D. degree and a postgraduate degree in business economics from the University of Leuven (Belgium) and an M.B.A. degree from Vlerick Management School (Belgium).

*Martine Ortin George, M.D.* has served as a member of our board of directors since 2014. She has extensive experience in the United States in clinical research, medical affairs and regulatory issues, acquired in small and large companies specialized in oncology. She currently serves as principal and senior executive consultant-life sciences for Global Development Inc. Dr. George previously served as a member of the board of directors of Maat Pharma from December 2021 until June 2022. Dr. George held the position of Vice President in charge of Global Medical Affairs for Oncology at Pfizer Inc., New York from 2010 to 2015. Previously, Dr. George held the positions of Senior Vice President and Chief Medical Officer at GPC Biotech, Princeton and Senior Vice President, Head of the Oncology Department at Johnson & Johnson, New Jersey. She is a qualified gynecologist and oncologist, trained in France and in Montreal. Dr. George began her career as Chief of Service at the Institut Gustave Roussy (France), was a visiting professor at the Memorial Sloan Kettering Cancer Center, New York, and then held positions of increasing responsibility at Lederle Laboratories (a predecessor company to Pfizer Inc.), Sandoz (now a division of Novartis AG) and Rhône-Poulenc Rorer (today part of Sanofi).

*Melanie Rolli, M.D.* was appointed to our board of directors effective March 12, 2020. Dr. Rolli currently serves as the Chief Executive Officer of Helsinn SA, a biopharma company with a strong focus in oncology and rare diseases, after serving as Chief Operating Officer of Helsinn SA from June 2022 until January 2023. Previously, Dr. Rolli was Chief Executive Officer of PIQUR Therapeutics AG, a Basel, Switzerland-based clinical stage biotechnology company dedicated to drug development of targeted therapies in various oncological and dermatological indications, a position she held from May 2019 until June 2022. She joined PIQUR in 2017 as Chief Medical Officer and took on additional responsibilities as Chief Operating Officer in 2018. Prior to joining PIQUR, Dr. Rolli was at Novartis Pharmaceuticals AG from 2003 to 2017, where she held positions of increasing responsibility across the drug development, safety, and medical affairs functions. Prior to joining Novartis, she worked as a post-doctoral cancer research physician at SCRIPPS Research Institute for Molecular and Experimental Medicine in La Jolla, California, and as a clinical researcher in Germany. Dr. Rolli graduated from the University of Heidelberg (Germany) with a doctorate in medicine and pharmacology.

*Hilde Windels* (acting as legal representative of Hilde Windels BV) has served as a member of our board of directors since 2014 and has served as the representative of Hilde Windels BV, the legal entity that holds this seat, since 2017. She has over 20 years of experience in corporate finance, capital markets and strategic initiatives. Ms. Windels currently serves as a member of the board of directors of MDx Health NV, Celyad SA, GIMV NV and private company Microphyt SA. She held the position of Chief Executive Officer of Antelope Dx BV until 2021. Prior to her role at Antelope Dx BV, she was Chief Executive Officer of Mycartis NV, a private immune diagnostics company in Belgium and a spin-out of Biocartis Group NV. Ms. Windels initially joined Biocartis in August 2011 as its Chief Financial Officer, a position she held until 2015 when she was appointed co-Chief Executive Officer, a position she held until 2017. From early 2009 to mid-2011, she worked as an independent chief financial officer for several private biotechnology companies. Ms. Windels served as Chief Financial Officer of Devgen from 1999 to 2008 and as a member of its board of directors from 2001 to 2008. Ms. Windels holds a Masters in Economics from the University of Leuven (Belgium).

## Diversity of the Board of Directors

Board Diversity Matrix (As of December 31, 2022)

<b>Country of Principal Executive Offices</b>	<b>France</b>
<b>Foreign Private Issuer</b>	<b>Yes</b>
<b>Disclosure Prohibited under Home Country Law</b>	<b>Yes</b>
<b>Total Number of Directors</b>	<b>8</b>

<b>Part I: Gender Identity</b>	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	3	5	0	0
<b>Part II: Demographic Background</b>				
Underrepresented Individual in Home Country Jurisdiction			0	
LGBTQ+			0	
Did Not Disclose Demographic Background			0	

### Family Relationships

There are no family relationships among any of our executive officers or directors.

### 6.B. Compensation.

The aggregate compensation paid and benefits in kind granted by us to our current executive officers and directors was €2.8 million for the year ended December 31, 2022. The fair value of share-based compensation granted to our executive officers and director during the year ended December 31, 2022 amounted to €1.3 million. The total amount set aside or accrued to provide pension, retirement or similar benefits for our executive officers was €275 thousand for the year ended December 31, 2022. We did not set aside any similar pension or retirement benefits for the benefit of our directors.

#### Director Compensation

At our combined general meetings of shareholders held on June 26, 2020, June 25, 2021 and June 24, 2022, shareholders set the total annual amount of the remuneration to be distributed among non-employee directors at €425 thousand for 2020, 2021 and 2022. The following table sets forth information regarding the compensation allocated to our non-employee directors for service on our board of directors during the year ended December 31, 2022. Gil Beyen, our Chief Executive Officer, is a director but does not receive any additional compensation for his services as a director.

NAME	FEES	WARRANTS <sup>(1)</sup>	TOTAL
Jean Paul Kress	€ 79,500	€ —	€ 79,500
Philippe Archinard	€ 66,000	€ —	€ 66,000
Luc Dochez	€ 43,500	€ —	€ 43,500
Sven Andreasson	€ 51,000	€ —	€ 51,000
Martine Ortin George	€ 51,000	€ —	€ 51,000
Hilde Windels BV	€ 51,000	€ —	€ 51,000
Melanie Rolli	€ 43,500	€ —	€ 43,500

<sup>(1)</sup> As required by SEC rules governing disclosures in this Annual Report, our equity grants (e.g., options, warrants or free shares) are required to be disclosed at their fair value on the date of grant and do not have any intrinsic value to their recipients if the strike price of the warrants is higher than the underlying share price.

#### Executive Committee Compensation

Our executive committee currently consists of (i) our Chief Executive Officer, (ii) our Chief Financial Officer, Chief Operating Officer and Deputy General Manager, (iii) our Chief Medical Officer (iv) our Vice President and Director of Pharmaceutical Operations and Qualified Person (v) our Human Resources Director and (vi) our Director Innovation & Valorization. The executive committee discusses and consults with the board and advises the board on our day-to-day management. The following table sets forth information regarding compensation allocated during the year ended December 31, 2022 to:

- Gil Beyen, our Chief Executive Officer;
- Eric Soyer, our Chief Financial Officer, Chief Operating Officer and Deputy General Manager; and
- Jérôme Bailly, our Chief Quality Officer, Deputy General Manager and Qualified Person

NAME AND PRINCIPAL POSITION	SALARY <sup>(2)</sup>	BONUS	EXCEPTIONAL BONUS	EQUITY AWARDS	ALL OTHER COMPENSATION	TOTAL
Gil Beyen <i>Chief Executive Officer</i>	€ 434,241 (1)	€ 130,263 <sup>(3)(6)</sup>			€ 7,923 (4)	€ 572,427
Jérôme Bailly <i>Chief Quality Officer, Deputy General Manager and Qualified Person</i>	€ 170,004	€ 35,700 (3)	€ 29,751 (8)		€ 12,455 (5)	€ 247,910
Eric Soyer <i>Deputy General Manager, Chief Financial Officer and Chief Operating Officer</i>	€ 259,996	€ 54,600	€ 45,499 (8)		€ 19,628 (7)	€ 379,723
All other executive committee members	€ 982,423	€ 151,284	€ 120,215		€ 15,326	€ 1,149,033

- (1) Of which \$341,296 (\$323,841) are allocated by our U.S. subsidiary, Erytech Pharma Inc., for Mr. Beyen's position as President of Erytech Pharma Inc.
- (2) Reflects gross remuneration before taxes.
- (3) Reflects compensation received for achievement of strategic goals related to (i) the successful development of eryaspase in the second-line pancreatic cancer indication, (ii) extension of the development plans of other ongoing clinical trials in oncological indications and (iii) securing additional financing.
- (4) Reflects benefits in kind related to vehicle rentals.
- (5) Reflects (i) €3,834 for benefits in kind related to vehicle rentals and (ii) €8,621 for retirement benefits.
- (6) Subject to approval of our shareholders at the next Annual General Meeting of Shareholders.
- (7) Reflects (i) €5,797 for benefits in kind related to vehicle rentals and (ii) €13,831 for retirement benefits.
- (8) Reflects the exceptional bonus received for the sale of the Princeton plant to Catalent in April 2022.

### ***Executive Compensation Arrangements***

For a discussion of our employment arrangements with our executive officers, see "Item 7.B.—Related Party Transactions—Arrangements with Our Directors and Executive Officers." Except the arrangements described in "Item 7.B.—Related Party Transactions—Agreements with Our Directors and Executive Officers," there are no arrangements or understanding between us and any of our other executive officers providing for benefits upon termination of their employment, other than as required by applicable law.

### **Limitations on Liability and Indemnification Matters**

Under French law, provisions of bylaws that limit the liability of directors are prohibited. However, French law allows *sociétés anonymes* to contract for and maintain liability insurance against civil liabilities incurred by any of their directors and officers involved in a third-party action, provided that they acted in good faith and within their capacities as directors or officers of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We have obtained directors' and officers' liability insurance for our directors and officers, which includes coverage against liability under the Securities Act. We have entered into agreements with our directors 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 and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity.

These agreements may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and executive officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment in our equity securities may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and 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 available personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our directors, executive officers, employees and other service providers, including:

- founder's share warrants (otherwise known as *bons de souscription de parts de créateurs d'entreprise*, or BSPCE), which are granted to our officers and employees;
- share warrants (otherwise known as *bons de souscription d'actions*, or BSA), which have historically only been granted to non-employee directors;
- restricted, or free, shares (otherwise known as *actions gratuites*); and
- stock options (otherwise known as *options de souscription et/ou d'achat d'actions*).

Our board of directors' authority to grant these equity incentive instruments and the aggregate amount authorized to be granted under these instruments must be approved by a two-thirds majority of the votes held by our shareholders present, represented or voting by authorized means, at the relevant extraordinary shareholders' meeting. Once approved by our shareholders, our board of directors can grant share warrants (BSA) for up to 18 months, and restricted (free) shares and stock options for up to 38 months from the date of the applicable shareholders' approval. The authority of our board of directors to grant equity incentives may be extended or increased only by extraordinary shareholders' meetings. As a result, we typically request that our shareholders authorize new pools of equity incentive instruments at every annual shareholders' meeting.

We have seven share-based compensation plans for our executive officers, non-employee directors and employees: the 2014 Plan, the 2016 Plan, the 2017 Plan, the 2018 Plan, the 2019 Plan, the 2020 Plan and the 2021 Plan or the Plans. In general, founder's share warrants and share warrants no longer continue to vest following termination of the employment, office or service of the holder and all vested shares must be exercised within post-termination exercise periods set forth in the grant documents. 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 numbers of shares issuable and/or the exercise price of the outstanding warrants.

As of December 31, 2022, employee warrants, non-employee warrants, employee stock options and free shares were outstanding allowing for the purchase of an aggregate of 1,804,768 ordinary shares at a weighted average exercise price of €6,51 (\$6,96) per ordinary share based on the exchange rate in effect as of such date (this weighted average exercise price does not include 583,721 ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price being paid).

### ***Founder's Share Warrants (BSPCE)***

Founder's share warrants have traditionally been granted to certain of our employees who were French tax residents because the warrants carry favorable tax and social security treatment for French tax residents. Similar to options, founder's share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary share on the date of grant. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants.

We have issued two types of founder's share warrants as follows:

Plan Title	BSPCE 2014	BSPCE 2012
Meeting date	April 2, 2013	May 21, 2012
Dates of allocation	January 22, 2014 June 23, 2015 May 6, 2016	May 31, 2012 July 18, 2013 July 17, 2014
Total number of BSPCEs authorized	19,500 <sup>(1)</sup>	33,787
Total number of BSPCEs granted	18,410 <sup>(2)</sup>	33,787 <sup>(3)</sup>
Start date for the exercise of the BSPCEs	For senior management, one-third was vested in 2015 and two-thirds were vested in 2016; for other employees, immediately upon each grant except for 6,500 BSPCE2014 which could not be exercised before July 1, 2017	From May to July 2012, 2013 and 2014
BSPCE expiry date	January 22, 2024	May 20, 2020
BSPCE exercise price per share	€12.250	€7.362
Number of shares subscribed as of December 31, 2022	15,000	184,190
Total number of BSPCEs granted but not exercised as of December 31, 2022	16,910	—
Total number of shares available for subscription as of December 31, 2022	169,100	—
Maximum number of new shares that can be issued	169,100	—

(1) 22,500 BSPCE<sub>2014</sub> were originally allocated by the board of directors on January 22, 2014. On December 4, 2014, the board of directors approved the conversion of 3,000 BSPCE<sub>2014</sub> into 3,000 BSA<sub>2014</sub>.

(2) Excludes 1,000 BSPCE initially allocated to a former officer which were forfeited following his resignation in January 2016 and 90 BSPCE allocated to a former employee which were forfeited.

(3) On June 26, 2020, the board of directors acknowledged the lapse of 15,368 BSPCE 2012 following their expiration.

Our shareholders, or pursuant to delegations granted by our shareholders, our board of directors, determines the recipients of the warrants, the dates of grant, the number and exercise price of the founder's share warrants to be granted, the number of shares issuable upon exercise and certain other terms and conditions of the founder's share warrants, including the period of their exercisability and their vesting schedule. However, notwithstanding any shareholder authorization, under applicable law, we are no longer eligible to issue any further founders' share warrants (BSPCE).

### Share Warrants (BSA)

Share warrants have historically only been granted to our non-employee directors. Similar to options, share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary share on the date of grant. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants.

As of December 31, 2022, we have issued eight types of share warrants as follows:

Plan title	BSA 2021	BSA 2020	BSA 2019	BSA 2018
Meeting date	June 25, 2021	June 26, 2020	June 21, 2019	June 28, 2018
Dates of allocation	July 27, 2021	July 28, 2020	October 9, 2019	April 12, 2019
Total number of BSAs authorized	100,000	100,000	200,000	50,000
Total number of BSAs granted	75,250	15,000	75,000	25,998
Start date for the exercise of the BSAs	July 27, 2023	July 28, 2022	October 9, 2021	One third as from 12 April 2020, one third as from 12 April 2021 and one third as from 12 April 2022

BSA expiry date	July 27, 2024	15,000 BSA <sub>2020</sub> have been declared lapsed on 4 November 2020 by the Board of Directors	75,000 BSA <sub>2019</sub> have been declared lapsed on 31 October 2022 by the Board of Directors	25,998 BSA <sub>2018</sub> have been declared lapsed on October 9, 2019 by the Board of Directors
BSA exercise price per share	€3.82	€6.97	€3.71	€6.82
Number of shares subscribed as of December 31, 2022	0	0	0	0
Total number of BSAs granted but not exercised as of December 31, 2022	13,500	0	0	0
Total number of shares available for subscription as of December 31, 2022	0	0	0	0
Maximum number of new shares that can be issued	13,500	0	0	0
BSA Expired (caducity)	61,750	15,000	75,000	25,998

Plan title	BSA 2017	BSA 2016	BSA 2014	BSA 2012
Meeting date	June 27, 2017	June 24, 2016	April 2, 2013	May 21, 2012
Dates of allocation	June 27, 2017 January 7, 2018	October 3, 2016 January 8, 2017	December 4, 2014 June 23, 2015	May 31, 2012 August 3, 2012 July 18, 2013 July 17, 2014 April 29, 2015 August 31, 2015
Total number of BSAs authorized	100,000	60,000	3,000 <sup>(1)</sup>	11,263
Total number of BSAs granted	95,500	60,000	3,000	10,760
Start date for the exercise of the BSAs	All BSA <sub>2017</sub> are exercisable since 7 January 2021	All BSA <sub>2016</sub> are exercisable since 8 January 2020	One-third vested in 2015 and two-thirds vested in 2016 for senior management	From May to July 2012, 2013, 2014 and 2015
BSA expiry date	<sup>(3)</sup>	October 3, 2021 January 8, 2022	January 22, 2024	May 20, 2020
BSA exercise price per share	<sup>(4)</sup>	<sup>(2)</sup>	€12.25	€7.36
Number of shares subscribed as of December 31, 2022	0	0	1,000	67,420
Total number of BSAs granted but not exercised as of December 31, 2022	33,750	0	2,900	0
Total number of shares available for subscription as of December 31, 2022	33,750	0	29,000	0
Maximum number of new shares that can be issued	33,750	0	29,000	0
BSA Expired (caducity)	61 750 <sup>(5)</sup>	60,000	0	4,018

<sup>(1)</sup> Reflects conversion of 3,000 BSPCE<sub>2014</sub> into 3,000 BSA<sub>2014</sub> pursuant to a decision of the board of directors on December 4, 2014.

<sup>(2)</sup> €18.52 for the 45,000 BSA granted on October 3, 2016. €13.60 for the 15,000 BSA granted on January 8, 2017.

<sup>(3)</sup> June 27, 2022 for the 55,000 BSA granted on June 27, 2017, January 7, 2023 for the 40,500 BSA granted on January 7, 2018.

<sup>(4)</sup> €26.47 for the 55,000 BSA granted on June 27, 2017. €18.00 for the 40,500 BSA granted on January 7, 2018.

<sup>(5)</sup> 33 750 BSA 2017 were declared lapsed by the Board of Directors on 15 February 2023 following their expiration.

Our shareholders, or pursuant to delegations granted by our shareholders, our board of directors, determines the recipients of the warrants, the dates of grant, the number and exercise price of the share warrants to be granted, the number of shares issuable upon exercise and certain other terms and conditions of the share warrants, including the period of their exercisability and their vesting schedule.

### **Free Shares (AGA)**

Under our Free Share Plans, we have granted free shares to certain of our employees and officers.

Free shares may be granted to any individual employed by us or by any affiliated company. Free shares may also be granted to our Chairman, to our Chief Executive Officer and to our Deputy General Managers. However, no free share may be granted to a beneficiary holding more than 10% of our share capital or to a beneficiary who would hold more than 10% of our share capital as a result of such grant. The maximum number of shares that may be granted or issued is 250,000 under the 2016 Free Share Plan, 300,000 under the 2017 Free Share Plan, 150,000 under the 2018 Free Share Plan, 400,000 under the 2019 Free Share Plan, the 2020

Free Share Plan and the 2021 Free Share Plan. In addition, under French law, the maximum number of shares that may be granted shall not exceed 10% of the share capital as at the date of grant of the free shares (30% if the allocation benefits all employees).

Our board of directors has the authority to administer 2016 Free Share Plan, 2017 Free Share Plan, 2018 Free Share Plan, 2019 Free Share Plan, 2020 Free Share Plan and 2021 Free Share Plan, or the Free Share Plans. Subject to the terms of the Free Share Plans, our board of directors determines the recipients, the dates of grant, the number of free shares to be granted and the terms and conditions of the free shares, including the length of their vesting period (starting on the grant date, during which the beneficiary holds a right to acquire shares for free but has not yet acquired any shares) and holding period (starting when the shares are issued and definitively acquired but may not be transferred by the recipient) within the limits determined by the shareholders. Our shareholders have determined that the vesting period should be set by the board of directors and should not be less than one year from the date of grant and that the optimal holding period should be set by the board of directors. From the beginning of the vesting period, the cumulated vesting and holding period should not be less than two years.

The board of directors has the authority to modify awards outstanding under our Free Share Plans, subject to the consent of the beneficiary for any modification adverse to such beneficiary. For example, the board has the authority to release a beneficiary from the continued service condition during the vesting period after the termination of the employment.

The free shares granted under our Free Share Plans will be definitively acquired at the end of the vesting period as set by our board of directors subject to continued service during the vesting period, except if the board releases a given beneficiary from this condition upon termination of his or her employment contract, or pursuant to the achievement of the performance conditions set out in the Free Share Plans.

The vesting of the free shares granted under the 2016 Free Share Plan, 2017 Free Share Plan and 2018 Free Share Plan is divided in three equal shares (33.33%), respectively following the first, second and third year following the date of grant. The vesting of the free shares granted under the 2019 Free Share Plan, the 2020 Free Share Plan and the 2021 Free Share Plan is in five tranches: the first (32%) one year following the date of grant, the second (32%) two years following the date of grant, the third (32%) three years following the date of grant, the fourth (2%) four years following the date of grant and the fifth (2%) five years following the date of grant.

At the end of the vesting period, the beneficiary will be the owner of the shares. However, the shares may not be sold, transferred or pledged during the holding period. In the event of disability before the end of the vesting period, the free shares shall be definitively acquired by the beneficiary on the date of disability. In the event the beneficiary dies during the vesting period, the free shares shall be definitively acquired at the date of the request of allocation made by his or her beneficiaries in the framework of the inheritance provided that such request is made within six months from the date of death.

As of December 31, 2022, the following free shares have been granted:

Date of grant	Denomination of the free shares	Competent body that granted the AGA	Beneficiaries	Number of AGA granted	Number of shares that can be subscribed as of December 31, 2022
<b>AGA 2016 (under the 2016 Free Share Plan)</b>					
October 3, 2016	AGA2016-03102016	Board of Directors	Executive Officers	59,001	—
October 3, 2016	AGA2016-03102016	Chief Executive Officer	Employees	52,260	—
January 8, 2017	AGA2016-08012017	Board of Directors	Executive Officers	15,000	—
June 27, 2017	AGA2016-27062017	Chief Executive Officer	Employees	8,652	—
October 3, 2017	AGA2016-03102017	Chief Executive Officer	Employees	16,650	—
January 7, 2018	AGA2016-07012018	Board of Directors	Executive Officers	40,500	—
<b>AGA 2017 (under the 2017 Free Share Plan)</b>					
June 27, 2017	AGA2017-27062017	Board of Directors	Executive Officers	45,000	—
June 27, 2017	AGA2017-27062017	Chief Executive Officer	Employees	29,475	—
January 7, 2018	AGA2017-07012018	Board of Directors	Executive Officers	27,000	—
January 7, 2018	AGA2017-07012018	Chief Executive Officer	Employees	86,940	—
<b>AGA 2018 (under the 2018 Free Share Plan)</b>					
January 6, 2019	AGA2018-06012019	Chief Executive Officer	Employees	36,150	—
April 12, 2019	AGA2018-12042019	Chief Executive Officer	Executive Officers	36,000	—
April 12, 2019	AGA2018-12042019	Chief Executive Officer	Employees	58,200	—
<b>AGA 2019 (under the 2019 Free Share Plan)</b>					
October 9, 2019	AGA2019-09102019	Board of Directors	Executive Officers	149,999	109,623
October 9, 2019	AGA2019-09102019	Board of Directors	Employees	150,942	42,485
February 25, 2020	AGA2019-25022020	Chief Executive Officer	Employees	50,037	22,202 <sup>(1)</sup>
<b>AGA 2020 (under the 2020 Free Share Plan)</b>					
July 28, 2020	AGA2020-28072020	Board of Directors	Executive Officers	125,938	125,938 <sup>(2)</sup>
July 28, 2020	AGA2020-28072020	Board of Directors	Employees	124,074	33,908
June 4, 2021	AGA2020-04062021	Chief Executive Officer	Executive Officers	13,333	13,333 <sup>(3)</sup>
June 4, 2021	AGA2020-04062021	Chief Executive Officer	Employees	37,498	9,833
<b>AGA 2021 (under the 2021 Free Share Plan)</b>					
July 27, 2021	AGA2021-27072021	Board of Directors	Executive Officers	126,000	126,000 <sup>(4)</sup>
July 27, 2021	AGA2021-27072021	Board of Directors	Employees	105,000	32,400
December 16, 2021	AGA2021-16122021	Chief Executive Officer	Employees	40,664	15,332
December 16, 2021	AGA2021-16122021	Chief Executive Officer	Executive Officers	52,667	52,667 <sup>(5)</sup>

Some free shares have lapsed following the departure of certain employees.

<sup>(1)</sup> On 27 February 2023, the Chief Executive Officer acknowledged that 13,721 free shares have lapsed following the departure of certain employees.

<sup>(2)</sup> On 27 February 2023, the Chief Executive Officer acknowledged that 5,000 free shares have lapsed following the departure of certain employees.

<sup>(3)</sup> On 27 February 2023, the Chief Executive Officer acknowledged that 5,000 free shares have lapsed following the departure of certain employees.

<sup>(4)</sup> On 27 February 2023, the Chief Executive Officer acknowledged that 22,500 free shares have lapsed following the departure of certain employees.

<sup>(5)</sup> On 27 February 2023, the Chief Executive Officer acknowledged that 10,000 free shares have lapsed following the departure of certain employees.

### **Stock Options (SO)**

Stock options issued pursuant to our Stock Option Plans provide the holder with the right to purchase a specified number of ordinary shares from us at a fixed exercise price payable at the time the stock option is exercised, as determined by our board of directors. Our Stock Option Plans generally provide that the exercise price for any stock option will be no less than 95% of the average of the closing sales prices per ordinary share during the 20 market trading days prior to the day of the board of directors' decision to grant the options. The maximum number of ordinary shares subject to stock options issued is 250,000 ordinary shares under the 2016 Stock Option Plan, 300,000 under the 2017 Stock Option Plan, 300,000 under the 2018 Stock Option Plan, 700,000 under the 2019 Stock Option Plan, 500,000 under the 2020 Stock Option Plan and 700,000 under the 2021 Stock Option Plan. Incentive stock options and non-statutory stock options may be granted under our Stock Option Plan.

Stock options may be granted to any individual employed by us or by any affiliated company. Stock options may also be granted to our Chairman, our General Manager and to our Deputy General Managers. In addition, incentive stock options may not be granted to owners of shares possessing 10% or more of the share capital of the company.

Our board of directors has the authority to administer and interpret the 2016 Stock Option Plan, 2017 Stock Option Plan, 2018 Stock Option Plan, 2019 Stock Option Plan, 2020 Stock Option Plan and the 2021 Stock Option Plan, or the Stock Option Plans. Subject to the terms and conditions of our Stock Option Plans, our board of directors determines the recipients, dates of grant, exercise price,

number of stock options to be granted and the terms and conditions of the stock options, including the length of their vesting schedules. Our board of directors is not required to grant stock options with vesting and exercise terms that are the same for every participant. The term of each stock option granted under our Stock Option Plan will generally be 10 years from the date of grant. Further, stock options will generally terminate on the earlier of when the beneficiary ceases to be an employee of our company or upon certain transactions involving our company.

The board of directors has the authority to modify awards outstanding under our Stock Option Plans, subject to the written consent of the beneficiary for any modification adverse to such beneficiary. For example, the board of directors has the authority to extend a post-termination exercise period.

Stock options granted under our Stock Option Plans generally may not be sold, transferred or pledged in any manner other than by will or by the laws of descent or distribution. In the event of disability, unless otherwise resolved by our board of directors, the beneficiary's right to exercise the vested portion of his or her stock option generally terminates six months after the last day of such beneficiary's service, but in any event no later than the expiration of the maximum term of the applicable stock options. In the event the beneficiary dies during the vesting period, then, unless otherwise resolved by our board of directors, the beneficiary's estate or any recipient by inheritance or bequest may exercise any portion of the stock option vested at the time of the beneficiary's death within the six months following the date of death, but in any event no later than the expiration of the maximum term of the applicable stock options.

As of December 31, 2022, the following options have been granted:

Date of grant	Denomination of the SOP	Competent body that granted the SOP	Beneficiaries	Number of SOP granted	Exercise Price	Number of shares that can be subscribed as of December 31, 2022
<b>SOP 2016 (under the 2016 Stock Option Plan)</b>						
October 3, 2016	SOP2016-03102016	Board of Directors	Executive Officers	21,999	€18.52	21,999
October 3, 2016	SOP2016-03102016	Chief Executive Officer	Employees	22,500	€18.52	3,000
January 8, 2017	SOP2016-08012017	Chief Executive Officer	Employees	3,000	€15.65	—
June 27, 2017	SOP2016-27062017	Chief Executive Officer	Employees	18,000	€26.47	9,000
October 3, 2017	SOP2016-03102017	Chief Executive Officer	Employees	30,000	€23.59	—
<b>SOP 2017 (under the 2017 Stock Option Plan)</b>						
June 27, 2017	SOP2017-27062017	Board of Directors	Executive Officers	12,000	€26.47	12,000
June 27, 2017	SOP2017-27062017	Chief Executive Officer	Employees	10,200	€26.47	1,200
January 7, 2018	SOP2017-07012018	Board of Directors	Executive Officers	40,500	€18.00	20,250
January 7, 2018	SOP2017-07012018	Chief Executive Officer	Employees	56,703	€18.00	8,100
<b>SOP 2018 (under the 2018 Stock Option Plan)</b>						
September 7, 2018	SOP2018-07092018	Board of Directors	Employees	24,000	€9.26	—
January 6, 2019	SOP2018-06012019	Chief Executive Officer	Employees	38,025	€6.38	4,875
April 12, 2019	SOP2018-12042019	Chief Executive Officer	Executive Officers	44,200	€7.20	31,200
April 12, 2019	SOP2018-12042019	Chief Executive Officer	Employees	32,705	€7.20	5,200
<b>SOP 2019 (under the 2019 Stock Option Plan)</b>						
July 31, 2019	SOP2019-31072019	Board of Directors	Executive Officers	59,123	€5.78	59,123
October 9, 2019	SOP2019-09102019	Board of Directors	Executive Officers	217,500	€4.25	180,000
October 9, 2019	SOP2019-09102019	Board of Directors	Employees	129,750	€4.25	21,000
February 25, 2020	SOP2019-25022020	Chief Executive Officer	Employees	41,950	€5.87	12,400
<b>SOP 2020 (under the 2020 Stock Option Plan)</b>						
July 28, 2020	SOP2020-28072020	Board of Directors	Executive Officers	247,500	€6.88	210,000
July 28, 2020	SOP2020-28072020	Board of Directors	Employees	126,500	€6.88	33,000
November 13, 2020	SOP2020-13112020	Chief Executive Officer	Executive Officers	75,000	€6.14	—
June 4, 2021	SOP2020-04062021	Chief Executive Officer	Employees	57,000	€4.78	21,500
<b>SOP 2021 (under the 2021 Stock Option Plan)</b>						
July 27, 2021	SOP2021-27072021	Board of Directors	Executive Officers	256,500	€3.71	189,000
July 27, 2021	SOP2021-27072021	Board of Directors	Employees	121,050	€3.71	37,350
December 16, 2021	SOP2021-16122021	Chief Executive Officer	Executive Officers	66,000	€2.14	51,000
December 16, 2021	SOP2021-16122021	Chief Executive Officer	Employees	83,000	€2.14	44,500

## 6.C. Board Practices.

Prior to May 2013, our company had a two-tier corporate governance system: an executive board was responsible for managing the company and a supervisory board oversaw and advised the executive board. We have now established a board of directors. Our board of directors currently consists of eight members, less than a majority of whom are citizens or residents of the United States. As permitted by French law, one of our directors, Hilde Windels BV, is a legal entity. This entity has designated an individual, Hilde Windels, to represent it and to act on its behalf at meetings of our board of directors. This representative has the same responsibilities to us and to our shareholders as he or she would have if he or she had been elected to our board of directors in his or her individual capacity.

Under French law and our bylaws, our board of directors must be comprised of between three and 18 members, without prejudice to the derogation established by law in the event of merger. Since January 1, 2017, the number of directors of each gender may not be less than 40%. As of the date of this Annual Report on Form 20-F, our board is composed of five men and three women. Any appointment made in violation of this limit that is not remedied within six months of this appointment will be null and void. Within these limits, the number of directors is determined by our shareholders. Directors are appointed, reappointed to their position, or removed by the company's ordinary general meeting, and in particular, any appointment which remedies a violation of the 40% limit must be ratified by our shareholders at the next ordinary general meeting. Their term of office, in accordance with our bylaws, is three years. Directors chosen or appointed to fill a vacancy must be elected by our board of directors for the remaining duration of the current term of the vacant director. The appointment must then be ratified at the next shareholders' general meeting. In the event the board of directors would be comprised of less than three directors as a result of a vacancy, the remaining directors shall immediately convene a shareholders' general meeting to elect one or several new directors so there are at least three directors serving on the board of directors, in accordance with French law.

The following table sets forth the names of our directors, the years of their initial appointment as directors of the board and the expiration dates of their current term.

	<b>CURRENT POSITION</b>	<b>YEAR OF INITIAL APPOINTMENT</b>	<b>TERM EXPIRATION YEAR<sup>(1)</sup></b>
Jean-Paul Kress	Chairman	2019	2025
Gil Beyen	Director	2013	2025
Sven Andréasson	Director	2022	2025
Philippe Archinard	Director	2013	2025
Luc Dochez	Director	2015	2025
Martine Ortin George	Director	2014	2023
Hilde Windels BV represented by Hilde Windels <sup>(2)</sup>	Director	2017	2023
Melanie Rolli	Director	2020	2023

<sup>(1)</sup> At the end of the ordinary general meeting convened to approve the accounts for the previous financial year during the year in which their term office expires.

<sup>(2)</sup> Hilde Windels BV was appointed as a director by our shareholders at our combined general meeting in June 2017. Hilde Windels BV has designated an individual, Hilde Windels, to represent it and to act on its behalf at meetings of our board of directors. She served as a member of the board of directors in her individual capacity from 2014 to 2017. Hilde Windels BV is a company controlled by Ms. Windels.

### Director Independence

As a foreign private issuer, under the listing requirements and rules of the Nasdaq Global Select Market, we are not required to have independent directors on our board of directors, except to the extent that our audit committee is required to consist of independent directors. Nevertheless, our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from, and provided by, each director concerning such director's background, employment and affiliations, including family relationships, our board of directors determined that all of our directors, except for Mr. Beyen, qualify as "independent directors" as defined under applicable rules of the Nasdaq Global Select Market and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and

circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our securities by each non-employee director and his or her affiliated entities (if any).

### **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 committee the responsibility to assist our board in this task. The audit committee also monitors our system of disclosure controls and procedures and internal control over financial reporting and reviews contingent financial liabilities. The audit committee, among other things, examines our balance sheet commitments and risks and the relevance of risk monitoring procedures. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors 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 of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

### **Corporate Governance Practices**

As a French *société anonyme*, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq corporate governance listing standards. However, the corporate governance standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq rules, with certain exceptions. We currently rely on these exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, which would otherwise require that (1) a majority of our board of directors consist of independent directors; (2) we establish a nominating and corporate governance committee; and (3) our remuneration committee be composed entirely of independent directors.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 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. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the 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 the 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 common stock be at least 33 1/3% of the outstanding shares of the company's voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Furthermore, we follow French corporate governance practices in lieu of the Nasdaq corporate governance rules that require shareholder approval prior to specified issuances of securities. More specifically, Nasdaq Marketplace Rule 5635 requires a U.S. domestic listed company to obtain shareholder approval: (1) prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the issuer; (2) prior to the issuance of securities in connection with a transaction other than a public offering involving the sale, issuance or potential issuance by the issuer alone, or together with sales by its officers, directors or substantial shareholders, of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value; and (3) prior to the issuance of securities when an equity compensation arrangement is made or materially amended, including prior to the issuance of common stock to the issuer's officers, director, employees or consultants for less than the greater of book or market value. While French law requires a French company to obtain prior shareholder approval to issue shares, its shareholders may pre-authorize the company's board of directors to issue shares such that shareholder approval is not required at the time of issuance.

## Board Committees

The board of directors has established an audit committee and a remuneration and appointments committee, which operate pursuant to rules of procedure adopted by our board of directors. The board of directors has also established a clinical strategy committee, which is responsible for analyzing and reviewing our clinical and regulatory strategy. Subject to available exemptions, the composition and functioning of all of our committees (other than the clinical strategy committee) will comply with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq Global Select Market and SEC rules and regulations.

In accordance with French law, committees of our board of directors will only have an advisory role and can only make recommendations to our board of directors. As a result, decisions will be made by our board of directors taking into account non-binding recommendations of the relevant board committee.

The board of directors of September 8, 2022 also updated its internal rules to include provisions relating to the establishment of a CSR committee. The actual implementation of a CSR committee is expected to occur following the completion of the Proposed Merger.

**Audit Committee.** Our audit committee assists our board of directors in its oversight of our corporate accounting and financial reporting and submits the selection of our statutory auditors, their remuneration and independence for approval. Mr. Andréasson, Dr. Archinard and Ms. Windels currently serve on our audit committee. Ms. Windels is the chairperson of our audit committee. Our board has determined that each of Mr. Andréasson, Dr. Archinard and Ms. Windels is 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. Windels is an “audit committee financial expert” as defined by SEC rules and regulations and that each of the members qualifies as financially sophisticated under the applicable exchange listing rules. The principal responsibility of our audit committee is to monitor the existence and efficacy of the company’s financial audit and risk control procedures on an ongoing basis.

Our board of directors has specifically assigned the following duties to the audit committee:

- examining the corporate and consolidated annual and interim financial statements;
- validating the relevance of the company’s accounting methods and choices;
- verifying the relevance of financial information published by the company;
- ensuring the implementation of internal control procedures;
- verifying the correct operation of internal controls with the assistance of internal quality audits;
- examining the schedule of work for internal and external audits;
- examining any subject likely to have a significant financial and accounting impact;
- examining the state of significant disputes;
- examining off-balance sheet commitments and risks;
- examining the relevance of risk monitoring procedures;
- establishing and overseeing procedures for the treatment of complaints or submissions identifying concerns regarding accounting, internal accounting controls, or auditing matters;
- examining any regulated agreements as well as monitoring any agreements relating to current operations and entered into under normal conditions;
- directing the selection of statutory auditors, their remuneration, and ensuring their independence;
- ensuring proper performance of the statutory auditors’ mission; and
- establishing the rules for the use of statutory auditors for work other than auditing of the accounts and verifying the correct execution thereof.

**Remuneration and Appointments Committee.** Mr. Andréasson, Dr. Archinard and Dr. Kress currently serve on our remuneration and appointments committee. Dr. Archinard is the chairperson of our remuneration and appointments committee.

Our board of directors has specifically assigned the following duties to the remuneration and appointments committee:

- formulating recommendations and proposals concerning (i) the various elements of the remuneration, pension and health insurance plans for executive officers and directors, (ii) the procedures for establishing the terms and conditions for setting the variable portion of their remunerations, and (iii) a general policy for awarding share warrants and founder’s warrants;

- examining the amount of the annual remuneration of the directors and the system for distributing such amount amongst the directors, taking into account their dedication and the tasks performed within the board of directors;
- advising and assisting the board of directors as necessary in the selection of senior executives and the establishment of their remuneration;
- assessing any increases in capital reserved for employees;
- assisting the board of directors in the selection and recruitment of new directors;
- ensuring the implementation of structures and procedures to allow the application of good governance practices within the company;
- preventing conflicts of interest within the board of directors; and
- implementing the procedure for evaluating the board of directors.

**Clinical Strategy Committee.** Dr. George, Mr. Dochez, Dr. Archinard and Dr. Rolli currently serve on our clinical strategy committee. Dr. George is the chairperson of our clinical strategy committee. Our clinical strategy committee is responsible for analyzing and reviewing our clinical and regulatory strategy. It meets, at least once a year, and makes recommendations to the board of directors regarding our clinical and regulatory development strategy.

Our board of directors has specifically assigned the following duties to the clinical strategy committee:

- analyzing and reviewing our clinical development focus; and
- analyzing and reviewing our regulatory approval strategies.

#### 6.D. Employees.

As of December 31, 2022, we had 49 employees.

Following the announcement in October 2021 of negative results for the TRYbeCA-1 clinical study, we had a strategic decision to carry out a major restructuring of our organization and refocusing of our activities. In connection with the foregoing:

- in May 2022, our Princeton, New Jersey production site was sold to Catalent, resulting in the transfer of 39 employees from Erytech Inc. to Catalent; and
- in the fourth quarter of 2022, we carried out a restructuring plan in France, which resulted in the terminations of 45 employees.

We consider our labor relations to be positive. At each date shown, we had the following headcount, broken out by department and geography:

	At December 31,		
	2020	2021	2022
<b>Function:</b>			
Research and preclinical development	24	23	18
Clinical, medical and regulatory affairs	37	28	4
Pharmaceutical operations	29	33	6
Manufacturing and supply	76	60	1
Management and administration	35	33	17
Business development and licensing	5	4	3
<b>Total</b>	<b>206</b>	<b>181</b>	<b>49</b>
<b>Geography:</b>			
France	145	123	41
United States	61	58	8
<b>Total</b>	<b>206</b>	<b>181</b>	<b>49</b>

## 6.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.”

### Item 7. Major Shareholders and Related Party Transactions

#### 7.A. Major Shareholders

The following table and accompanying footnotes set forth, as of December 31, 2022, 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 our current executive officers;
- each of our directors; and
- all of our current executive officers and directors 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 shares that vest within 60 days of December 31, 2022 and options and warrants that are currently exercisable or exercisable within 60 days of December 31, 2022. Shares subject to free shares that vest within 60 days of December 31, 2022 and shares subject to warrants currently exercisable or exercisable within 60 days of December 31, 2022 are deemed to be outstanding for computing the percentage ownership of the person holding these free shares and warrants 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 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 Exchange Act.

Our calculation of the percentage of beneficial ownership is based on 31,018,553 of our ordinary shares (including ordinary shares in the form of ADSs) outstanding as of December 31, 2022. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o ERYTECH Pharma S.A., 60 Avenue Rockefeller, 69008 Lyon, France.

NAME OF BENEFICIAL OWNER	NUMBER OF ORDINARY SHARES BENEFICIALLY OWNED	PERCENTAGE OF ORDINARY SHARES BENEFICIALLY OWNED
<b>Directors and Executive Officers:</b>		
Gil Beyen <sup>(1)</sup>	321,040	1.03 %
Eric Soyer <sup>(2)</sup>	26,264	*
Iman El-Hariry <sup>(3)</sup>	266,249	*
Jérôme Bailly <sup>(4)</sup>	27,798	*
Anne-Cécile Fumey	864	*
Karine Charton	400	*
Jean-Paul Kress <sup>(5)</sup>	97,123	*
Sven Andreasson <sup>(6)</sup>	6,751	*
Philippe Archinard <sup>(7)</sup>	17,050	*
Luc Dochez <sup>(8)</sup>	6,750	*
Martine Ortin George <sup>(6)</sup>	6,751	*
Hilde Windels BV <sup>(6)</sup>	6,751	*
Melanie Rolli	—	— %
All directors and executive officers as a group (13 persons) <sup>(9)</sup>	783,791	2.53 %

\* Represents beneficial ownership of less than 1%.

- (1) Consists of 4,840 ordinary shares and 316,200 ordinary shares issuable upon exercise of warrants and stock options that are exercisable within 60 days of December 31, 2022.
- (2) Consists of 6,264 ordinary shares and 20,000 ordinary shares issuable upon exercise of warrants that are exercisable within 60 days of December 31, 2022.
- (3) Consists of 266,249 ordinary shares issuable upon exercise of warrants and stock options that are exercisable within 60 days of December 31, 2022.
- (4) Consists of 3,798 ordinary shares and 24,000 ordinary shares issuable upon exercise of warrants that are exercisable within 60 days of December 31, 2022.
- (5) Consists of 97,123 ordinary shares issuable upon exercise of stock options that are exercisable within 60 days of December 31, 2022.
- (6) Consists of one ordinary share and 6,750 ordinary shares issuable upon exercise of warrants that are exercisable within 60 days of December 31, 2022. The 6,750 warrants were declared lapsed by the Board of Directors on 15 February 2023.
- (7) Consists of 10,300 ordinary shares and 6,750 ordinary shares issuable upon exercise of warrants that are exercisable within 60 days of December 31, 2022. The 6,750 warrants were declared lapsed by the Board of Directors on 15 February 2023.
- (8) Consists of 6,750 ordinary shares issuable upon exercise of warrants that are exercisable within 60 days of December 31, 2022. The 6,750 warrants were declared lapsed by the Board of Directors on 15 February 2023.
- (9) Consists of 26,469 ordinary shares and 757,322 ordinary shares issuable upon exercise of warrants and stock options that are exercisable within 60 days of December 31, 2022.

None of our principal shareholders have voting rights different than our other shareholders.

As of January 17, 2023, we estimate that approximately 10% of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held in the United States by approximately 17 holders of record including Bank of New York Mellon, the nominee of the Depository Trust Company, which held approximately 8.46% of our outstanding ordinary shares as of said date. The actual number of holders is greater than these numbers of record holders and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

## **7.B. Related Party Transactions.**

We have engaged in the following transactions with our directors, executive officers and holders of more than five percent (5%) of our outstanding voting securities and their affiliates, which we refer to as our related parties.

### **Agreements with Our Directors and Executive Officers**

#### ***Severance Pay***

On May 24, 2013, the board of directors approved terms for severance pay to be awarded under certain conditions to our then-executive officers, which included Gil Beyen, our Chief Executive Officer. The agreement provides that, in the event of expiration of the executive's term of office (except where renewal is rejected by the executive) or in the event of revocation (unless the executive has been revoked for gross negligence or willful misconduct as that term is defined by the labor chamber of the French Supreme Court), the executive is entitled to severance equal to 12 times the average of monthly remuneration (bonuses included) received during the 12 months preceding the revocation decision or the expiration of the executive's term of office. The payment of the compensation shall be subject to the performance of the following conditions: (i) respect of our company's budget and expenditures and (ii) at least one of the following conditions: (a) an agreement of collaboration or a current license, and (b) one product in an active phase of clinical development by the company. No related expense has been recorded to date.

#### ***Executive Employment Agreement with Gil Beyen***

Effective April 1, 2019, we and our U.S. subsidiary, ERYTECH Pharma, Inc., entered into an executive employment agreement with Mr. Beyen, or the Executive Employment Agreement, that provides for the terms of his employment and compensation as President of ERYTECH Pharma, Inc., including an annual base salary and variable compensation in an amount up to 50% of his base salary, based upon achievement of specified performance objectives. The Executive Employment Agreement also provides for severance pay in specified situations. In the event of Mr. Beyen's termination without "cause," he will be entitled to an amount equal to 12 times the average of monthly remuneration (bonuses included) received during the 12 months preceding his termination, subject to certain specified performance conditions. Mr. Beyen will also be entitled to these severance benefits (with no duplication) if Mr. Beyen is terminated without "cause" or resigns for "good reason" within 12 months following a change of control of our company. Any severance payments paid to Mr. Beyen under the Executive Employment Agreement are conditioned on Mr. Beyen executing a release. Pursuant to an Employee Confidential Information and Invention Assignment Agreement attached to his Executive

Employment Agreement, upon voluntary termination or termination for "cause," for a period of 12 months, Mr. Beyen cannot seek employment in any business in which we are engaged or plans to be engaged, or service that we provide or have plans to provide.

#### ***Employment Agreements with Eric Soyer***

In September 2015, we entered into employment agreement with Mr. Soyer. This employment agreement provides for an annual base salary and variable compensation in amounts up to 35%, increased up to 40% for the year 2023, as decided by the Board of directors in its decision dated February 15, 2023, of the executive's current base salaries, based upon achievement of specified performance objectives. This employment agreement also provide for severance pay in specified situations. In the event of the executive's termination in the absence of gross negligence or willful misconduct, the executive will be entitled to an amount equal to six months' base salary, plus an additional three months' base salary for each full year such executive has worked for us, up to a maximum of 12 months' base salary in total, including any additional indemnity as provided for by French law. In connection with a change of control of our company, if the executive is terminated in the absence of gross negligence or willful misconduct or resigns pursuant to suffering a diminution of the executive's job duties, or in the event of a mutually agreed termination (rupture conventionnelle) under French law, such executive will be entitled to an amount equal to 12 times the average of monthly remuneration, including bonuses, received during the 12 months preceding the termination. If a change of control of our company occurs within 24 months of the granting of bonus shares, such executive will be entitled to an amount intended to compensate for the potential loss of compensation in the event of cancellation of bonus shares granted or for the potential loss of favorable tax treatment in the event of the sale of such shares, in the context of this change of control. This agreement also provide for a 18-month non-compete clause, whereby the executive is entitled to an amount equal to 33% of his average monthly remuneration over the last twelve months.

#### ***Employment Agreements with Anne-Cécile Fumey and Karine Charton***

In February 2016 and September 2017 respectively, we entered into employment agreements with Mrs. Fumey and Mrs. Charton. Each employment agreement provides for an annual base salary and variable compensation in amounts ranging from 20% to 35% of the current base salaries, based upon achievement of specified performance objectives. These employment agreements do not provide any additional termination indemnity other than the one provided for by French law. Mrs. Charton's agreement provide for a 18-month non-compete clause, whereby Mrs. Charton is entitled to an amount equal to 33% of her average monthly remuneration over the last three months.

#### ***Employment Agreement with Iman El-Hariry***

In June 2015, our U.S. subsidiary, ERYTECH Pharma, Inc., entered into an employment agreement with Dr. El-Hariry that provides for an annual base salary and variable compensation in an amount up to 35% of her base salary, based upon achievement of specified performance objectives. This variable amount was increased from 35% to 40% of her base salary in January 2019. The agreement also provides for severance pay in specified situations. In the event of Dr. El-Hariry's termination without cause (as defined in Dr. El-Hariry's employment agreement), she will be entitled to an amount equal to six months' base salary, plus an additional three months' base salary for each full year she has worked for us, up to a maximum of 12 months' base salary in total. If Dr. El-Hariry resigns as a result of (i) a diminution of her job duties, (ii) a change in reporting or (iii) a relocation, she will be entitled to an amount up to 12 months' base salary compensation depending upon the length of her employment with us. In connection with a change of control, if Dr. El-Hariry is terminated within 12 months (a) by us, (b) by mutual agreement or (c) by her decision to resign after receiving an offer that is not at least equivalent to her position prior to the change in control, she will be entitled to a lump sum payment equal to one year's salary plus bonus (under the condition that she would not be eligible for the other severance benefits described above). Upon termination for any reason, our company may request Dr. El-Hariry to execute a non-competition agreement for a period of 12 months, whereby Dr. El-Hariry will be entitled to severance pay.

#### ***Employment Agreement with Jérôme Bailly***

In January 2007, we entered into an employment agreement with Dr. Bailly, which was amended as of January 2018. He is entitled to an annual base salary set at €170,000, and variable compensation, in an amount up to 25% of his base salary, upon achievement of specified performance objectives. This variable amount was increased from 25% to 30% of his base salary in January 2019 and from 30% to 35% of his base salary in January 2021. If a change of control of our company occurs within 24 months of the granting of bonus shares, Dr. Bailly will be entitled to an amount intended to compensate for the potential loss of compensation in the event of cancellation of bonus shares granted or for the potential loss of favorable tax treatment in the event of the sale of such shares.

His employment agreements also provide for severance pay in specified situations. In the event of the termination in the absence of gross negligence or willful misconduct, Dr. Bailly will be entitled to an amount equal to six months' base salary, plus an additional three months' base salary for each full year such executive has worked for us, up to a maximum of 12 months' base salary in total, including any additional indemnity as provided for by French law. In connection with a change of control of our company, if Dr. Bailly is terminated in the absence of gross negligence or willful misconduct or resigns pursuant to suffering a diminution of the

executive’s job duties, or in the event of a mutually agreed termination (*rupture conventionnelle*) under French law, Dr. Bailly will be entitled to an amount equal to 12 times the average of monthly remuneration, including bonuses, received during the 12 months preceding the termination. The payment of the compensations shall be subject to the performance of the following conditions: (i) respect of our company’s budget and expenditures and (ii) at least one of the following conditions: (a) an agreement of collaboration or a current license, and (b) one product in an active phase of clinical development by the company.

If a change of control of our company occurs within 24 months of the granting of bonus shares, such executive will be entitled to an amount intended to compensate for the potential loss of compensation in the event of cancellation of bonus shares granted or for the potential loss of favorable tax treatment in the event of the sale of such shares, in the context of this change of control. His employment agreement also provides for a 18-month non-compete clause, whereby Dr. Bailly is entitled to an amount equal to 33% of his average monthly remuneration over the last three months.

**Other Arrangements**

We have entered into other compensatory arrangements with our executive officers, which have been ratified by our board of directors. The primary arrangements are summarized in the table below.

NAME	TAX ASSISTANCE
Gil Beyen	X

**Director and Executive Officer Compensation**

See “Item 6.B—Compensation” for information regarding compensation of directors and executive officers.

**Equity Awards**

See “Item. 7A—Major Shareholders” for information regarding equity awards to our executive officers.

**Bonus Plans**

All our executive officers are entitled to a bonus ranging between 25% and 50% based on yearly objectives determined by our board of directors upon recommendation of our remuneration and appointments committee.

**Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and some of our executive officers. See “Item. 6B—Limitations on Liability and Indemnification Matters.”

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.

**Related-Party Transactions Policy**

We comply with French law regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy became effective in November 2017 upon the closing of our global offering and was subsequently amended in March 2020 to meet the new French law requirements arising from Law no. 2019-486 of May 22, 2019 (*Pacte law*) as described below.

For purposes of our policy only, a related person transaction is defined as (i) any transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are, were or will be participants in and the amount involved exceeds \$120,000, or (ii) any agreement or similar transaction under French law which falls within the scope of Article L. 225-38 of the French Commercial Code. A related person is any executive officer, director 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. Article L. 225-38 of the French Commercial Code covers any agreement or similar transaction entered into directly or indirectly between (i) the company and a corporate officer, a director, a shareholder holding more than 10% of the company’s voting rights or, if such shareholder is a corporate entity, its controlling shareholder within the meaning of Article L. 233-3 of the French

Commercial Code or between (ii) the company and another firm if a corporate officer or director of the company is the owner, a fully liable shareholder, a corporate officer, a director or a member of that other firm's supervisory board or, more generally, a person in any way involved in its management.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or 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 our board of directors for review, consideration 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 director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. Our General Counsel will conduct an assessment of our related person transactions, notably to determine whether such transactions relate to current operations and entered into under normal conditions (*portant sur des opérations courantes et conclues à des conditions normales*), which will be monitored at least annually by our audit committee.

In addition, under our Code of Business Conduct and Ethics, our employees and directors 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, our 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 a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director 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, our 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 our board of directors determines in the good faith exercise of its discretion.

#### **7.C. Interests of Experts and Counsel.**

Not applicable.

### **Item 8. Financial Information**

#### **8.A. Consolidated Statements and Other Financial Information.**

##### **Consolidated Financial Statements**

Our consolidated financial statements are included as part of this Annual Report, starting at page F-1.

##### **Dividend Distribution Policy**

We have never declared or paid any cash dividends on our ordinary shares. 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. See "Item 10. B—Memorandum and Articles of Association" for further details on the limitations on our ability to declare and pay dividends. Dividend distributions, if any in the future, will be made in euros and converted into U.S. dollars with respect to the ADSs, as provided in the amended and restated deposit agreement.

## **Legal Proceedings**

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

### **8.B. Significant Changes.**

Not applicable.

## **Item 9. The Offer and Listing.**

### **9.A. Offer and Listing Details.**

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol “ERYP” since November 10, 2017. Our ordinary shares have been trading on Euronext Paris under the symbol “ERYP” since May 7, 2013.

### **9.B. Plan of Distribution.**

Not applicable.

### **9.C. Markets.**

Our ADSs have been listed on Nasdaq under the symbol “ERYP” since November 10, 2017. Our ordinary shares have been listed on Euronext Paris under the symbol “ERYP” since May 7, 2013.

### **9.D. Selling Shareholders.**

Not applicable.

### **9.E. Dilution.**

Not applicable.

### **9.F. Expenses of the Issue.**

Not applicable.

## **Item 10. Additional Information.**

### **10.A. Share Capital.**

Not applicable.

### **10.B. Memorandum and Articles of Association.**

#### ***Corporate Purpose (Article 3 of the Bylaws)***

The Company’s corporate purpose in France and abroad includes the research, manufacturing, importation, distribution and marketing of investigational drugs, devices and medical equipment, and the provision of advisory services associated with these activities. The Company is authorized to engage in all financial, commercial, industrial, civil, property or security-related transactions that directly or indirectly relate to accomplishing the purposes stated above.

The Company may act directly or indirectly and do all these operations in all countries, for or on behalf of third parties, either alone or with partnership with third parties, association, group or creation of new companies, contribution, sponsorship, subscription, purchase of shares or rights, mergers, alliances, undeclared partnership or taking or giving in lease or in management of all property and rights or otherwise.

#### ***Directors (Articles 17-22 of the Bylaws)***

***Duties of the Board.*** Except for powers given to the Company’s shareholders by law and within the limit of the corporate purpose, the Company’s board of directors is responsible for all matters relating to the successful operations of the Company, including but not limited to, social and environmental issues associated with the Company’s activities, and, through its resolutions, governs matters involving the company.

**Appointment and Term.** The Company's board of directors must be composed of at least three members, but may not exceed 18 members, subject to the dispensation established by law in the event of merger. In appointing and electing directors, the Company seeks a balanced representation of women and men. The term of a director is 3 years, and directors may be re-elected at the Company's annual ordinary share meetings; however, a director over the age of 75 may not be appointed if such appointment would result in the number of directors over the age of 75 constituting more than one-third of the board. The number of directors who are also the Company's employees cannot exceed one-third of the board. Directors may be natural persons or legal entities except for the chairman of the board who must be a natural person. Legal entities appointed to the board must designate a permanent representative. If a director dies or resigns between annual meetings, the board may appoint a temporary director to fill the vacancy, subject to ratification at the next ordinary general meeting, or, if such vacancy results in a number of directors below three, the board must call an ordinary general meeting to fill the vacancy. If a director is absent at more than four consecutive meetings or placed with guardians, he or she will be deemed to have automatically resigned.

**Organization.** The board must elect a chairman from among the board members. The chairman must be a natural person, age 75 or younger, and may be removed by the board at any time. The board may also elect a natural person as vice president to preside in the chairman's absence and may designate up to two non-voting board observers.

**Deliberations.** At least half of the number of directors in office must be present to constitute a quorum. Decisions are made by a majority of the directors present or represented and, if there is a tie, the vote of the chairman will carry the decision. Meetings may be held as often as required; however, the chairman is required to call a meeting with a determined agenda upon the request of at least one-third of the directors if the board has not met for more than two months. French law and the Company's charter and bylaws allow directors to attend meetings in person or, to the extent permitted by applicable law and with specified exceptions in the Company's bylaws, by videoconference or other telecommunications arrangements. The board of directors can also make decisions by way of written consultation under the conditions provided by law.

**Directors' Voting Powers on Proposal, Arrangement or Contract in which any Director is Materially Interested.** Under French law, any agreement entered into, directly or through an intermediary, between the Company and any director that is not entered into in the ordinary course of the Company's business and upon standard market terms is subject to the prior authorization of the board of directors. The interested director cannot vote on such decision. The same provision applies to agreements between the Company and another company, except where such company is the Company's wholly owned subsidiary, if one of the Company's directors is the owner or a general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the Company's directors has an indirect interest.

**Directors' Compensation.** Director compensation for attendance at board meetings is determined at the annual ordinary general meeting. The general meeting may allocate an annual fixed sum and the board of directors allocates this sum among its members as it sees fit. In addition, the board of directors may allocate exceptional compensation (rémunération exceptionnelle) for missions or mandates entrusted to its members, for example as member or chair of one or more board committees, this remuneration is subject to the provisions regarding related-parties agreements. At the Company's combined general meetings of shareholders held on June 26, 2020, shareholders set the total annual attendance fees to be distributed among non-employee directors at €425 thousand for 2020, as well as to subsequent financial years until a new decision is made.

**Board of Directors' Borrowing Powers.** There are currently no limits imposed on the amounts of loans or borrowings that the board of directors may approve.

**Directors' Share Ownership Requirements.** The Company's directors are not required to own any of the Company's shares.

## Shareholder rights

### *Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 9, 16, 30, 33 and 34 of the Bylaws)*

**Dividends.** The Company may only distribute dividends out of the Company's distributable profits, plus any amounts held in the Company's reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.

**"Distributable Profits"** consist of the Company's statutory net profit in each fiscal year, calculated in accordance with accounting standards applicable in France, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to French law.

**Legal Reserve.** Pursuant to French law, the Company must allocate 5% of the Company's statutory net profit for each year to the Company's legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital.

**Approval of Dividends.** Pursuant to French law, the Company's board of directors may propose a dividend for approval by the shareholders at the annual ordinary general meeting.

Upon recommendation of the Company's board of directors, the Company's shareholders may decide to allocate all or part of any distributable profits to special or general reserves, to carry them forward to the next fiscal year as retained earnings or to allocate them to the shareholders as dividends. However, dividends may not be distributed when the Company's net assets are or would become as a result of such distribution lower than the amount of the share capital plus the amount of the legal reserves which, under French law, may not be distributed to shareholders. The amount of the Company's share capital plus the amount of the Company's legal reserves which may not be distributed was equal to €3,101,855.30 at June 24, 2022.

The Company's board of directors may distribute interim dividends after the end of the fiscal year but before the approval of the financial statements for the relevant fiscal year when the interim balance sheet, established during such year and certified by an auditor, reflects that the Company has earned distributable profits since the close of the last financial year, after recognizing the necessary depreciation and provisions and after deducting prior losses, if any, and the sums to be allocated to reserves, as required by law or the bylaws, and including any retained earnings. The amount of such interim dividends may not exceed the amount of the profit so defined.

**Distribution of Dividends.** Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by the Company's board of directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by the Company's board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Shareholders may be granted an option to receive dividends in cash or in shares, in accordance with legal conditions. The conditions for payment of dividends in cash shall be set at the shareholders' meeting or, failing this, by the board of directors.

**Timing of Payment.** Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

**Voting Rights.** Each share shall entitle its holder to vote and be represented in the shareholders' meetings in accordance with the provisions of French law and of the Company's bylaws. Ownership of one share implies, *ipso jure*, adherence to the Company's bylaws and the decisions of the shareholders' meeting.

In general, each shareholder is entitled to one vote per share at any general shareholders' meeting. Pursuant to the Company's bylaws, however, 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. Under French law, ordinary bearer shares are not eligible for double voting rights. Purchasers of ADSs or of ordinary shares deposited with the depository to receive ADSs, will be unlikely to meet the requirements to have double voting rights.

Under French law, treasury shares or shares held by entities controlled by the Company are not entitled to voting rights and do not count for quorum purposes.

**Rights to Share in the Company's Profit.** Each share entitles its holder to a portion of the corporate profits and assets proportional to the amount of share capital represented thereby.

**Rights to Share in the Surplus in the Event of Liquidation.** If the Company is liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of the Company's shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the number of shares respectively held by them, taking into account, where applicable, of the rights attached to shares of different classes.

**Repurchase and Redemption of Shares.** Under French law, the Company may acquire its own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, Regulation (EU) No. 596/2014 of April 16, 2014 provides for safe harbor exemptions when the acquisition is made for one of the following purposes:

- to decrease the Company's share capital, provided that such a decision is not driven by losses and that a purchase offer is made to all shareholders on a *pro rata* basis, with the approval of the shareholders at an extraordinary general meeting; in this case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;
- to meet obligations arising from debt securities that are exchangeable into equity instruments;

- to provide shares for distribution to employees or managers under a profit-sharing, free share or share option plan; in this case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or
- the Company benefit from a simple exemption when the acquisition is made under a liquidity contract complying with the general regulations of, and market practices accepted by the French Financial Markets Authority (AMF).

All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L. 20-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.

Under the Market Abuse Regulation 596/2014 of August 16, 2014 (MAR) and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading value on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of shares may result in the Company holding, directly or through a person acting on the Company's behalf, more than 10% of the Company's issued share capital. Shares repurchased by the Company continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as the Company holds them directly or indirectly, and the Company may not exercise the preemptive rights attached to them.

***Sinking Fund Provisions.*** The Company's bylaws do not provide for any sinking fund provisions.

***Liability to Further Capital Calls.*** Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

***Requirements for Holdings Exceeding Certain Percentages.*** None, except as described below under the sections of this exhibit titled "Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws)" and "Form, Holding and Transfer of Shares (Articles 13 and 15 of the Bylaws)—Ownership of Shares by Non-French Persons."

***Actions Necessary to Modify Shareholders' Rights***

Shareholders' rights may be modified as allowed by French law. Only the extraordinary shareholders' meeting is authorized to amend any and all provisions of the Company's bylaws. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

***Special Voting Rights of Warrant Holders***

Under French law, the holders of warrants of the same class (i.e., warrants that were issued at the same time and with the same rights), including founder's warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

***Rules for Admission to and Calling Annual Shareholders' Meetings and Extraordinary Shareholders' Meetings (Section IV of the Bylaws)***

***Access to, Participation in and Voting Rights at Shareholders' Meetings.*** Shareholders' meetings are composed of all shareholders, regardless of the number of shares they hold. Each shareholder has the right to attend the meetings and participate in the discussions (1) personally; (2) by granting proxy to any individual or legal entity of his choosing; (3) by sending a proxy to the Company without indication of the mandate; (4) by voting by correspondence; or (5) at the option of the board of directors at the time the meeting is called, by videoconference or another means of telecommunication, including internet, in accordance with applicable laws that allow identification. The board of directors organizes, in accordance with legal and regulatory requirements, the participation and vote of these shareholders at the meeting, assuring, in particular, the effectiveness of the means of identification.

Participation in shareholders' general meetings, in any form whatsoever, is subject to registration or registration of shares under the conditions and time limits provided for applicable laws.

The final date for returning voting ballots by correspondence is set by the board of directors and disclosed in the notice of meeting published in the French Journal of Mandatory Statutory Notices, or BALO (*Bulletin des Annonces Légales Obligatoires*). This date cannot be earlier than three days prior to the meeting unless otherwise provided in the bylaws. The Company's bylaws provide that the board of directors has the option to accept the voting ballots by correspondence beyond the limit set by applicable laws.

A shareholder who has voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which the Company sends to such shareholder either at the shareholder's request or at the Company's initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.

A shareholder may vote by correspondence by means of a voting form, which the Company sends to such shareholder either at the shareholder's request or at the Company's initiative, or which the Company includes in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on the Company's website at least 21 days before the date of the meeting. The voting form must be recorded by the Company three days prior to the shareholders' meeting, in order to be taken into consideration. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

To better understand the voting rights of the ADSs, ADS holders should carefully read the section in this exhibit titled "II. American Depositary Shares—Voting Rights."

**Notice of Annual Shareholders' Meetings.** Shareholders' meetings are convened by the Company's board of directors, or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances. Meetings are held at the Company's registered offices or at any other location indicated in the meeting announcement (*avis de réunion*). A meeting announcement is published in the BALO at least 35 days prior to a meeting, as well as on the Company's website at least 21 days prior to the meeting. In addition to the particulars relative to the Company, it indicates, notably, the meeting's agenda and the draft resolutions that will be presented. The requests for recording of issues or draft resolutions on the agenda must be addressed to the Company under the conditions provided for in the current legislation.

Subject to special legal provisions, the convening notice (*avis de convocation*) is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the BALO. Further, the holders of registered shares for at least a month at the time of the latest of the insertions of the convening notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. The latter may at any time expressly request by registered letter to the Company with acknowledgment of receipt that the aforementioned means of telecommunication should be replaced in the future by a mailing.

The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.

The convening notice may be addressed, where appropriate, with a proxy form and a voting by correspondence form, under the conditions specified in the Company's bylaws, or with a voting by correspondence form alone, under the conditions specified in the Company's bylaws. When the shareholders' meeting cannot deliberate due to the lack of the required quorum, the second meeting must be called at least ten days in advance in the same manner as used for the first notice.

**Agenda and Conduct of Annual Shareholders' Meetings.** The agenda of the shareholders' meeting shall appear in the convening notice of the meeting and is set by the author of the notice. The shareholders' meeting may only deliberate on the items on the agenda except for the removal of directors and the appointment of their successors which may be put to vote by any shareholder during any shareholders' meeting. Pursuant to French law and the Company's current share capital, one or more shareholders representing 5% of the Company's share capital may request the inclusion of items or proposed resolutions on the agenda. Such request must be received at the latest on the 25<sup>th</sup> day preceding the date of the shareholders' meeting, and in any event no later than the 20<sup>th</sup> day following the date of the shareholders' meeting announcement.

Shareholders' meetings shall be chaired by the Chairman of the board of directors or, in his or her absence, by a Deputy Chairman or by a director elected for this purpose. Failing that, the meeting itself shall elect a Chairman. Vote counting shall be performed by the two members of the meeting who are present and accept such duties, who represent, either on their own behalf or as proxies, the greatest number of votes.

**Ordinary Shareholders' Meeting.** Ordinary shareholders' meetings are those meetings called to make any and all decisions that do not amend the Company's bylaws. An ordinary meeting shall be convened at least once a year within six months of the end of each fiscal year in order to approve the annual and consolidated accounts for the relevant fiscal year or, in case of postponement, within the period established by court order. Upon first notice, the meeting may validly deliberate only if the shareholders present or represented by proxy or voting by mail represent at least one-fifth of the shares entitled to vote. Upon second notice, no quorum is required. Decisions are made by a majority of the votes cast by the shareholders present, or represented by proxy, or voting by mail. Abstentions will have the same effect of a "no" vote. In addition, pursuant to a recent AMF recommendation, French listed companies may be required to conduct a consultation of the ordinary shareholders meeting prior to the disposal of the majority of their assets, under certain circumstances.

**Extraordinary Shareholders' Meeting.** The Company's bylaws may only be amended by approval at an extraordinary shareholders' meeting. The Company's bylaws may not, however, be amended to increase shareholder commitments without the approval of each shareholder. Subject to the legal provisions governing share capital increases from reserves, profits or share premiums, the resolutions of the extraordinary meeting shall be valid only if the shareholders present, represented by proxy or voting by mail represent at least one-fourth of all shares entitled to vote upon first notice, or one-fifth upon second notice. If the latter quorum is not reached, the second meeting may be postponed to a date no later than two months after the date for which it was initially called. Decisions are made by a two-thirds majority of the votes cast by the shareholders present, represented by proxy, or voting by mail. The votes cast do not include the votes attached to shares for which the shareholder has not taken part in the vote, has abstained or has voted blank or naked.

## Limitations

### Ownership of ADSs or Shares by Non-French Residents

Neither the French Commercial Code nor the Company's bylaws presently impose any restrictions on the right of non-French residents or non-French shareholders to own and vote shares. However, non-French residents must file a declaration for statistical purposes with the Bank of France (*Banque de France*) within twenty working days following the date of certain direct foreign investments in the Company, including any purchase of the Company's 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 the share capital or voting rights or cross such 10% threshold. Violation of this filing requirement may be sanctioned by five years' imprisonment and a fine up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity. Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health and telecommunications. etc., pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590). The French government has adapted this foreign investment control procedure in France within the context of the ongoing COVID-19 pandemic in two ways: (i) the inclusion, by a Ministerial order (arrêté) of April 27, 2020, of biotechnologies in the list of critical technologies and (ii) the addition, by a Decree (décret) of July 22, 2020 as amended by Decree n°2020-1729 of December 28, 2020, of the threshold of 10% of voting rights of a company subject to French law whose securities are listed on a stock exchange as triggering the control procedure. The Decree of July 22, 2020, as extended by the Decree n° 2022-1622 of December 23, 2022, currently provides that this new 10% threshold will be effective until December 31, 2023 and a fast-track review procedure for foreign investments exceeding this threshold.

### Foreign Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that the Company 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.

### Availability of Preferential Subscription Rights

The Company's shareholders will have the preferential subscription rights described under "Ordinary Shares—Changes in Share Capital—Preferential Subscription Right." Under French law, shareholders have preferential rights to subscribe for cash issues of new shares or other securities giving rights to acquire additional shares on a pro rata basis. Holders of the Company's securities in the United States (which may be represented by ADSs) will not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. The Company may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, holders of the Company's securities in the United States will be unable to exercise any preferential subscription rights and their interests will be diluted. The Company is under no obligation to file any registration statement in

connection with any issuance of new shares or other securities. The Company intends to evaluate at the time of any rights offering the costs and potential liabilities associated with registering the rights, as well as the indirect benefits to the Company of enabling the exercise by holders of shares in the United States and ADS holders of the subscription rights, and any other factors the Company considers appropriate at the time, and then to make a decision as to whether to register the rights. The Company cannot guarantee that it will file a registration statement.

For holders of the Company's ordinary shares represented by ADSs, the depository may make these rights or other distributions available to ADS holders. If the depository does not make the rights available to ADS holders and determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, ADS holders will receive no value for them. The section herein titled "II. American Depositary Shares—Dividends and Other Distributions" explains in detail the depository's responsibility in connection with a rights offering. See also "*Risk Factors—The right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to the holders of our ADSs*" in the Company's Annual Report on Form 20-F to which this description is filed as an exhibit.

#### ***Provisions Having the Effect of Delaying, Deferring or Preventing a Change in Control of the Company***

Provisions contained in the Company's bylaws and French corporate law could make it more difficult for a third-party to acquire the Company, even if doing so might be beneficial to the Company's shareholders. These provisions include the following:

- under French law, the owner of 90% of the share capital or 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 the Company, including any purchase of the Company's 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 the Company's share capital or voting rights or cross such 10% threshold. See "Limitations Affecting Shareholders of a French Company;"
- under French law, certain investments in a French company relating to certain strategic industries, including biotechnologies, by individuals or entities not residents in a Member State of the European Union are subject to prior authorization of the Ministry of Economy pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590 of December 31, 2019, as amended by decree (arrêté) of April 27, 2020). See "Limitations Affecting Shareholders of a French Company;"
- a merger (i.e., in a French law context, a share for share exchange following which the Company's company would be dissolved into the acquiring entity and the Company's shareholders would become shareholders of the acquiring entity) of the Company's company into a company incorporated in the European Union would require the approval of the Company's board of directors as well as a two-thirds majority of the votes cast by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of the Company's company into a company incorporated outside of the European Union would require 100% of the Company's 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;
- the Company's shareholders have granted and may grant in the future the Company's board of directors broad authorizations to increase the Company's share capital or to issue additional ordinary shares or other securities, such as warrants, to the Company's shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for the Company's shares;
- the Company's shareholders have preferential subscription rights on a pro rata basis on the issuance by the Company 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 the Company's shareholders or on an individual basis by each shareholder;
- the Company's board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director for the remaining duration of such directors' 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 the Company's board of directors ;

- the Company’s board of directors can be convened by its chairman or its managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one third of the total number of directors;
- the Company’s board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors’ identification and ensuring their effective participation in the board’s decisions;
- the Company’s shares are nominative or bearer, if the legislation so permits, according to the shareholder’s choice;
- approval of at least a majority of the votes cast by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders’ general meeting is required to remove directors with or without cause;
- 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 director can be proposed at any shareholders’ meeting without notice;
- the Company’s bylaws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the section of this exhibit titled “Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws);”
- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of the bylaws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by two-thirds of the votes of the Company’s shareholders present, represented by a proxy or voting by mail at the meeting.

## **Disclosure of shareholdings**

### ***Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws)***

Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 233-10 of the French Commercial Code coming to directly or indirectly own, or cease to own, alone or in concert, a number of shares representing a fraction of the Company’s capital or voting rights greater or equal to 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% and 95% shall inform the Company as well as the French Financial Market Authority (AMF) of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds.

This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In the event of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code.

In addition, any shareholder, alone or acting in concert, crossing the 10%, 15%, 20% or 25% threshold shall file a declaration with the AMF pursuant to which it shall expose its intention over the following 6 months, including notably whether it intends to continue acquiring shares of the Company, it intends to acquire control over the Company, its intended strategy for the Company.

Further, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 30% threshold shall file a mandatory public tender offer with the AMF. Also, any shareholder holding directly or indirectly a number between 30% and 50% of the capital or voting rights and who, in less than 12 consecutive months, increases his/her/its holding of capital or voting rights by at least 1% company’s capital or voting rights, shall file a mandatory public tender offer.

## **Differences in Corporate Law**

*The Company is a société anonyme, or S.A., incorporated under the laws of France. The laws applicable to French sociétés anonymes differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to the Company and the Delaware General Corporation Law relating to shareholders’ rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and French law.*

	FRANCE	DELAWARE
Number of Directors	Under French law, a <i>société anonyme</i> must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the bylaws. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied will be null and void.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the chairman of the board), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors as well as the deliberations taken by the board member irregularly appointed.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.
Removal of Directors	Under French law, directors may be removed from office, with or without cause, at any shareholders' meeting without notice or justification, by a simple majority vote.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death or a resignation, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification by the shareholders by the next shareholders' meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors.
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months after the close of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing that, by the statutory auditors, or by a court appointed agent ( <i>mandataire ad hoc</i> ) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

	<b>FRANCE</b>	<b>DELAWARE</b>
Notice of General Meetings	<p>A meeting announcement is published in the French Journal of Mandatory Statutory Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the meeting. Subject to limited exceptions provided by French law, additional convening notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the French Journal of Mandatory Statutory Notices (BALO). Further, shareholders holding registered shares for at least a month at the time latest insertions of the notices shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice to registered shareholders may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. When the shareholders' meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice.</p> <p>The convening notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Commerce and Companies, the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail and, as the case may be, the email address to which they may send written questions. The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail and conditions in which they can obtain voting forms by mail.</p>	<p>Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.</p>

	FRANCE	DELAWARE
Proxy	Each shareholder has the right to attend the meetings and participate in the discussions (i) personally, or (ii) by granting proxy to his/her spouse, his/her partner with whom he/she has entered into a civil union or to another shareholder or to any individual or legal entity of his choosing; or (iii) by sending a proxy to the company without indication of the mandate (in this case, such proxy shall be cast in favor of the resolutions supported by the board of directors), or (iv) by voting by correspondence, or (v) by videoconference or another means of telecommunication in accordance with applicable laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period.
Shareholder Action by Written Consent	Under French law, shareholders' action by written consent is not permitted in a <i>société anonyme</i> .	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.
Preemptive Rights	Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a pro rata basis unless such rights are waived by a two-thirds majority of the votes cast by the shareholders present at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights have not been waived by the extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period shall not be less than five trading days. Preferential subscription rights are transferable during a period equivalent to the subscription period but starting two business days prior to the opening of the subscription period and ending two business days prior to the closing of the subscription period.	Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.

	FRANCE	DELAWARE
Sources of Dividends	<p>Under French law, dividends may only be paid by a French <i>société anonyme</i> out of “distributable profits,” plus any distributable reserves and “distributable premium” that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.</p> <p>“Distributable profits” consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years.</p> <p>“Distributable premium” refers to the contribution paid by the stockholders in addition to the par value of their shares for their subscription that the stockholders decide to make available for distribution.</p> <p>Except in case of a share capital reduction, no distribution can be made to the stockholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the bylaws.</p>	<p>Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus or (2) in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.</p>
Repurchase of Shares	<p>Under French law, a corporation may acquire its own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes:</p> <ul style="list-style-type: none"> <li>• to decrease its share capital with the approval of the shareholders at the extraordinary general meeting;</li> <li>• to meet obligations arising from debt securities, that are exchangeable into equity instruments; or</li> <li>• with a view to distributing the relevant shares to employees or managers under a profit-sharing, free share or share option plan.</li> </ul> <p>All other purposes, and especially share buy-backs for external growth operations by virtue of Article L. 20-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.</p> <p>Under the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) and in accordance with the General Regulations of the French Financial Markets Authority, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.</p> <p>No such repurchase of ordinary shares may result in the company holding, directly or through a person acting on its behalf, more than 10% of its issues share capital.</p>	<p>Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.</p>

	<b>FRANCE</b>	<b>DELAWARE</b>
Liability of Directors and Officers	Under French law, the bylaws may not include any provisions limiting the liability of directors. Civil liability of the directors may be sought for (1) an infringement of laws and regulations applicable to the company, (2) breach of the bylaws and (3) management failure.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: <ul style="list-style-type: none"> <li>• any breach of the director's duty of loyalty to the corporation or its stockholders;</li> <li>• acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;</li> <li>• intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or redemptions; or any transaction from which the director derives an improper personal benefit</li> </ul>
Voting Rights	French law provides that, unless otherwise provided in the bylaws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder. As from April 2016, double voting rights are automatically granted to the shares being registered since more than two years, unless the bylaws are modified in order to provide otherwise.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.
Shareholder Vote on Certain Transactions	Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: <ul style="list-style-type: none"> <li>• the approval of the board of directors; and</li> <li>• approval by a two-thirds majority of the votes cast by the shareholders present, represented by proxy or voting by mail at the relevant meeting or, in the case of a merger with a non-EU company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the board authority to decide a merger-absorption or to determine the terms and conditions of the merger plan).</li> </ul>	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: <ul style="list-style-type: none"> <li>• the approval of the board of directors; and</li> <li>• approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.</li> </ul>

	FRANCE	DELAWARE
Dissent or Dissenters' Appraisal Rights	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock. Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of merger or consolidation requires the holders to accept for their shares anything other than: <ul style="list-style-type: none"> <li>• shares of stock of the surviving corporation;</li> <li>• shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders;</li> <li>• cash in lieu of fractional shares of the stock described in the two preceding bullet points; or</li> <li>• any combination of the above.</li> </ul> In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.
Standard of Conduct for Directors	French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest ( <i>intérêt social</i> ). In addition, directors shall take into account social and environmental issues arising out of the company's activity.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

	FRANCE	DELAWARE
Shareholder Suits	<p>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.</p> <p>The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.</p>	<p>Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:</p> <ul style="list-style-type: none"> <li>• state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and</li> <li>• allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or</li> <li>• state the reasons for not making the effort.</li> </ul> <p>Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.</p>
Amendment of Bylaws	<p>Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws. However, the board of directors is authorized to (i) modify the bylaws as a result of a decision to move the company's registered office and (ii) to bring to the bylaws any modification rendered necessary by an amendment to an applicable law or regulation if the board of directors has been prior authorized by the extraordinary shareholders meeting for this purpose, and subject, in both cases, to ratification by the next extraordinary shareholders' meeting.</p>	<p>Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal the bylaws of the corporation. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors.</p>

## Changes in Share Capital

***Increases in Share Capital (Article 10 of the Bylaws).*** Pursuant to French law, the Company's share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of the Company's board of directors. The shareholders may delegate to the Company's board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

Increases in the Company's share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; and
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;

- by capitalization of profits, reserves or share premium; and
- subject to certain conditions, by way of offset against debt incurred by the Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings.

**Reduction in Share Capital.** Pursuant to French law, any reduction in the Company's share capital requires shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of the Company's board of directors. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

**Preferential Subscription Right.** According to French law, if the Company issues additional securities for cash, current shareholders will have preferential subscription rights to these securities on a *pro rata* basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe *pro rata* based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, the Company's share capital by means of a cash payment or a set-off of cash debts. The preferential subscription rights are transferable during the subscription period relating to a particular offering.

The preferential subscription rights will be transferable during a period starting two days prior to the opening of the subscription period and ending two days prior to the closing of the subscription period.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of the Company's shareholders or individually by each shareholder. The Company's board of directors and its independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

In the future, to the extent permitted under French law, the Company may seek shareholder approval to waive preferential subscription rights at an extraordinary general shareholders' meeting in order to authorize the board of directors to issue additional shares and/or other securities convertible or exchangeable into shares.

#### **Listing**

Our ADSs are listed on the Nasdaq Global Select Market under the symbol "ERYP." Our ordinary shares are listed on Euronext Paris under the symbol "ERYP."

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our ADSs is The Bank of New York Mellon. Our share register for our ordinary shares is maintained by Société Générale. The share register reflects only record owners of our ordinary shares. Holders of our ADSs are not treated as our shareholders and their names are therefore not entered in our share register. The depositary, the custodian or their nominees are the holder of the shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

### **LIMITATIONS AFFECTING SHAREHOLDERS OF A FRENCH COMPANY**

#### **Ownership of ADSs or Shares by Non-French Residents**

Neither the French Commercial Code nor our bylaws presently impose any restrictions on the right of non-French residents or non-French shareholders to own and vote shares. However, non-French residents must file a declaration for statistical purposes with the Bank of France (*Banque de France*) within twenty 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 the share capital or voting rights or cross such 10% threshold. Violation of this filing requirement may be sanctioned by five years' imprisonment and a fine up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity. Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.,

## Foreign 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.

## Availability of Preferential Subscription Rights

Our shareholders will have the preferential subscription rights described under “Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares—Changes in Share Capital—Preferential Subscription Right.” Under French law, shareholders have preferential rights to subscribe for cash issues of new shares or other securities giving rights to acquire additional shares on a pro rata basis. Holders of our securities in the United States (which may be represented by ADSs) will not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, holders of our securities in the United States will be unable to exercise any preferential subscription rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities. We intend to evaluate at the time of any rights offering the costs and potential liabilities associated with registering the rights, as well as the indirect benefits to us of enabling the exercise by holders of shares in the United States and ADS holders of the subscription rights, and any other factors we consider appropriate at the time, and then to make a decision as to whether to register the rights. We cannot assure you that we will file a registration statement.

For holders of our ordinary shares represented by ADSs, the depositary may make these rights or other distributions available to ADS holders. If the depositary does not make the rights available to ADS holders and determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, ADS holders will receive no value for them. The section of this prospectus titled “*Description of American Depositary Shares—Dividends and Other Distributions*” explains in detail the depositary’s responsibility in connection with a rights offering. See also “*Risk Factors—The right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to the holders of our ADSs*”.

## 10.C. Material Contracts.

The section below provides a summary of material contracts, for the two years immediately preceding this Annual Report.

### ***OCABSA Agreement with Alpha Blue Ocean***

We entered into an agreement on June 24, 2020 (the “**OCABSA Agreement**”) allowing the issuance for the benefit of the Luxembourg-based fund European High Growth Opportunities Securitization Fund, represented by its asset manager European High Growth Opportunities Manco SA., of 1,200 notes warrants (*bons d’émission*) (the “**Notes Warrants**” or “**BEOCABSA**”) giving right to convertible notes into new and/or existing shares (the “**Notes**”) with warrants attached (the “**Warrants**” and together with the Notes, the “**OCABSA**”), enabling a potential fund raising of up to EUR 60 million, subject to the regulatory limit of 20% dilution.

The main characteristics of the securities are described in the table below:

<b>BEOCABSA</b>	
Issuance date :	June 24, 2020, by decision of the Chief Executive Officer
Characteristics of the issuance	1,200 BEOCABSA issued for free for the benefit of European High Growth Opportunities Securitization Fund (the “ <b>Investor</b> ”), pursuant to the 25 <sup>th</sup> resolution of the extraordinary general shareholder’s meeting held on June 21, 2019.

Condition of exercise:	By tranches until June 25, 2022, upon request of the Company, it being specified that the Investor shall have the right to request the issuance of two tranches at any moment. Any request for a drawdown by the Company will be subject to the satisfaction of certain conditions precedent, including (i) the fact that the Company's closing price on Euronext Paris has been 150% higher than the nominal value of the Company's shares for more than 60 Trading Days prior to the request, or (ii) the fact that the Company has a number of shares that may be issued corresponding to at least 175% of the number of shares issuable upon conversion of the outstanding Notes and of the Notes to be issued upon the drawdown request. Each exercise of a Note Warrant will give rise to the issuance of 60 Notes with 33,670 Warrants attached (or of 30 Notes with 16,835 Warrants attached in the event where the Company's capitalization is less than EUR 50 million for 20 consecutive trading days).
Number of exercised BEOCABSA	540, by tranches of 9, respectively on July 6, 2020, August 24, 2020, November 17, 2020, December 7, 2020, December 22, 2020, March 2, 2021, May 19, 2021, July 22, 2021 and August 24 2021 (including 2 tranches issued upon request of the Investor) i.e. a total amount of EUR 27 million, resulting in the issuance of 540 Notes with 303 030 Warrants attached.
Number of outstanding BEOCABSA	0, as the BEOCABSA were exercisable in tranches over a period of 24 months from June 25, 2020, i.e. until June 25, 2022.
<b>Notes</b>	
Nominal value :	EUR 3,000,000 by tranches (EUR 50,000 by Note)
Issuance conditions:	Upon exercise of the Notes Warrants in one or more tranches of 60 Notes (or 30 Notes in the event where the Company's capitalization is less than EUR 50 million for 20 consecutive trading days), corresponding to a total nominal value of EUR 3 million (or EUR 1.5 million in case of issuance of a tranche of 30 Notes)
Interest:	No interest
Subscription price:	98% of their nominal value, i.e. EUR 2,940,000 by tranche (EUR 49,000 by Notes)
Maturity:	12 months from their issuance
Conversion into new shares	At the request of the holder, at any time from their issue until their maturity date, at the conversion ratio for a Note determined by the formula below: $N = V_n / P$ , where: "N" is the number of Shares issue upon conversion of the Notes to be granted to the Note holders, "Vn" is the nominal value of a Note, i.e. EUR 50,000, of which the conversion is requested, "P" is the conversion price (the "Conversion Price") of a Note, i.e. the higher of (i) 95% of the volume-weighted average trading price of the Company's shares on Euronext Paris during the 3 consecutive trading days expiring on the Trading Day immediately preceding the conversion date, (ii) the nominal value of the share and (iii) the minimum issuance price of a share as provided in the Resolution (or any resolution that may succeed it), i.e., to date 80% of the volume-weighted average (in the central order book and excluding off-market block trades) of the Company's share price on Euronext Paris during the 3 trading sessions prior to the pricing of the issue price, it being specified that the theoretical value of the Warrants will be taken into account and that the Shareholder's Meeting has set at 10 million the maximum number of shares that may be issued.
<b>Warrants</b>	
Number of Warrants to be issued :	10 % of the nominal value of the issued Notes (i.e. 33,670 by tranche of 60 Notes and 16,835 by tranche of 30 Notes), detached from the OCABSA as from their issuance.

Condition of exercise:	Exercise by the holder for a period of 5 years from the date of issue, each warrant giving the right to subscribe to one new share.
Exercise price:	8,91 €, representing a 20% premium of the lowest volume-weighted average price over the reference period preceding the issuance of the first tranche.

The use of the OCABSA Agreement as of the date of the Annual Report is described in the table below:

Operation	Date	Number of convertible notes	Number of shares issued upon conversion of convertible Notes	Operation	Date	Number of warrants	Number of shares issued upon conversion of warrants	Total number of shares issued
<b>Tranche 1</b>								
Issuance	07/06/2020	60		Issuance	07/06/2020	33 670		
Conversion		60	511 020					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			511 020	Number of shares issued			0	511 020
<b>Tranche 2</b>								
Issuance	08/24/2020	60		Issuance	08/24/2020	33 670		
Conversion		60	614 853					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			614 853	Number of shares issued			0	614 853
<b>Tranche 3 (Resulting from Investor Call No. 1 dated 12 November 2020)</b>								
Issuance	11/17/2020	60		Issuance	11/17/2020	33 670		
Conversion		60	475 442					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			475 442	Number of shares issued			0	475 442
<b>Tranche 4 (Resulting from Investor Call No. 2 dated 4 December 2020)</b>								
Issuance	12/07/2020	60		Issuance	12/07/2020	33 670		
Conversion		60	408 163					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			408 163	Number of shares issued			0	408 163
<b>Tranche 5</b>								
Issuance	12/22/2020	60		Issuance	12/22/2020	33 670		
Conversion		60	421 447					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			421 447	Number of shares issued			0	421 447
<b>Tranche 6</b>								
Issuance	03/02/2021	60		Issuance	03/02/2021	33 670		
Conversion		60	502 565					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			502 565	Number of shares issued			0	502 565
<b>Tranche 7</b>								

Operation	Date	Number of convertible notes	Number of shares issued upon conversion of convertible Notes	Operation	Date	Number of warrants	Number of shares issued upon conversion of warrants	Total number of shares issued
Issuance	05/19/2021	60		Issuance	05/19/2021	33 670		
Conversion		60	668 984					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			668 984	Number of shares issued			0	668 984
<b>Tranche 8</b>								
Issuance	07/22/2021	60		Issuance	07/22/2021	33 670		
Conversion		60	867 052					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			867 052	Number of shares issued			0	867 052
<b>Tranche 9</b>								
Issuance	08/24/2021	60		Issuance	08/24/2021	33 670		
Conversion		60	603,065					
Number of convertible notes outstanding		0		Number of warrants outstanding		33 670		
Number of shares issued (1)			603,065	Number of shares issued			0	603,065
Number of shares issued upon conversion of convertible Notes and exercise of warrants								5,072,591
Number of note warrants outstanding								0

<sup>(1)</sup> i.e. an average parity of 1 Convertible Note for 8,517 new shares for tranche 1, 10,248 new shares for tranche 2, 7,924 new shares for tranche 3, 6,803 new shares for tranche 4, 7,024 new shares for tranche 5, 8 376 new shares for tranche 6, 11 149 new shares for tranche 7, 14 450 new shares for tranche 8 and 10 062 new shares for tranche 9.

We issued nine tranches of €3.0 million (on July 6, 2020, August 24, 2020, November 17, 2020, December 7, 2020, December 22, 2020, March 2, 2021, May 19, 2021, July 22, 2021 and August 24, 2021), for a total amount of €27.0 million, for which all Notes were converted and no Warrants were exercised, as described in the table above. The OCABSA Agreement provides that the Note Warrants were exercisable in tranches over a period of 24 months from June 25, 2020, i.e. until June 25, 2022, accordingly, we can no longer decide to issue additional tranches as of the date of this Annual Report.

We publish and update the monitoring table relating to the OCABSA Agreement on our website ([https://erytech.com/wp-content/uploads/2022-06-25-ERY\\_Suivi-des-actions-OCABSA.pdf](https://erytech.com/wp-content/uploads/2022-06-25-ERY_Suivi-des-actions-OCABSA.pdf)).

#### ***At-the-Market (ATM) Program***

On September 21, 2020, we entered into a sales agreement with Cowen and Company, LLC (“**Cowen**”) pursuant to which we may issue and sell, from time to time at our sole discretion, ordinary shares in the form of ADSs to eligible investors at market prices, with aggregate gross sales proceeds of up to \$30 million, subject to the regulatory limit of 20% dilution (this threshold is calculated based on the total number of shares listed on Euronext without prospectus during the twelve months before the issuance).

We agreed to pay Cowen commission equal to 3.0% of the gross proceeds of the sales price of all ADSs sold through it as sales agent under the sales agreement. The offering of our ADSs pursuant to the sales agreement will terminate on the earliest of (1) the sale of all of the ordinary shares subject to the sales agreement, or (2) termination of the sales agreement by us or the agent. We and the agent may terminate the sales agreement at any time in our sole discretion upon ten (10) days’ prior notice. The agent may terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in the sales agent’s judgment, may materially impair the ability of the agent to sell the shares thereunder or a suspension or limitation of trading of our ADSs on Nasdaq.

In February 2021, we sold shares under this ATM program resulting in gross proceeds of \$8.0 million, or €6.6 million, and net proceeds of \$7.8 million, or €6.4 million.

### ***Registered Direct Offerings***

On April 29, 2021, we entered into subscription agreements with certain institutional and accredited investors providing for the issuance of an aggregate of 1,034,483 units (the “Units”), each Unit consisting of four ADSs, each representing one ordinary share, €0.10 nominal value per share, and three warrants, each to purchase one ordinary share, in a registered direct offering (the “April 2021 Offering”) at \$29.00 per Unit for aggregate gross proceeds to us of approximately \$30.0 million. Under the subscription agreements, the investors received warrants to purchase an aggregate of up to 3,103,449 ordinary shares representing 12.95% of the Company's share capital on a fully diluted basis prior to the offer. Such warrants became immediately exercisable and will expire two years from the date of issuance (i.e. May 4, 2023), subject to any extension of such exercise period as set forth therein. The warrants have an exercise price of €7.50 per share, subject to adjustment as set forth therein. The issuance of the 4,137,932 new shares underlying the ADSs resulted in an immediate capital increase of €24,868,971.30, representing approximately 19.12% of the Company's share capital and voting rights prior to the offering.

In connection with the offering, we also entered into a placement agency agreement with H.C. Wainwright & Co., LLC (“HCW”), pursuant to which HCW agreed to serve as the exclusive placement agent for us in connection with the registered direct offering. We agreed to pay HCW a placement agent fee equal to 7% of the gross proceeds from the sale of the Units in the offering, a non-accountable expense allowance of \$50,000, an accountable expense allowance of \$100,000 and clearing fees of \$15,950.

On December 14, 2021, we entered into a subscription agreement with Armistice Capital Master Fund Ltd. (“Armistice”), providing for the issuance of an aggregate of 769,608 Units in a registered direct offering (the “December 2021 Offering”) at \$10.20 per Unit for aggregate gross proceeds to us of approximately \$7.85 million. Under this subscription agreement, Armistice received a warrant to purchase an aggregate of up to 2,308,824 ordinary shares representing 6.8% of the Company's share capital on a fully diluted basis prior to the offer. Such warrant became immediately exercisable and will expire two years from the date of issuance (i.e. December 20, 2023), subject to any extension of such exercise period as set forth therein. The warrants have an exercise price of €2.83 per share, subject to adjustment as set forth therein. The issuance of the 3,078,432 new ordinary shares underlying the ADSs resulted in an immediate capital increase of €6,957,256.32, representing approximately 11.02% of the share capital and voting rights of the Company prior to the offering. We also entered into a placement agency agreement with HCW on substantially similar terms as the April 2021 agreement.

For additional information on our material contracts, please see “Item 4. Information on the Company,” “Item 6. Directors, Senior Management and Employees,” and “Item 7.B. Related Party Transactions” of this Annual Report on 20-F.

### ***Asset Purchase Agreement with Catalent***

On April 22, 2022, we and our wholly owned subsidiary, ERYTECH Pharma, Inc. (“US Subsidiary”), entered into an Asset Purchase Agreement (the “APA”) with Catalent Princeton, LLC (“Catalent”) and, solely for purposes of Section 6.17 of the APA, Catalent Pharma Solutions, Inc. Pursuant to the APA, we and our US Subsidiary sold to Catalent and Catalent acquired from the us and our US Subsidiary certain assets and liabilities associated with the facilities located in Princeton, West Windsor Township, New Jersey (the “Princeton Facility”) for an aggregate purchase price of \$44.5 million in cash (the “Transaction”). The Transaction closed on April 22, 2022 (the “Closing Date”).

The assets sold to Catalent are generally certain assets used prior to the Transaction by the us to operate the Princeton Facility and included the lease for the Princeton Facility, certain inventory of materials located at the Princeton Facility for Catalent's use in the manufacture of eryaspase, selected contracts, records, permits and tangible personal property. As part of the Transaction, Catalent extended offers of employment to approximately 40 people employed by US Subsidiary at the Princeton Facility. Catalent also assumed certain liabilities generally relating to the transferred assets arising from or relating to periods after the Closing Date, with the Company and US Subsidiary retaining all liabilities other than those assumed by Catalent, including liabilities relating to the transferred assets arising from or relating to periods before the Closing Date.

At the closing of the Transaction, (i) we, the US Subsidiary and Catalent entered into an agreement under which Catalent received certain transitional services from the Company and US Subsidiary related to the operation of the Princeton Facility for a period of up to nine months from the Closing Date, and (ii) we also agreed upon terms for the manufacture by Catalent of our former product candidate, eryaspase, and its supply for clinical and commercial use in the United States.

The APA contains representations, warranties and covenants made by us and the US Subsidiary regarding the transferred assets, as well as representations, warranties and covenants made by us, the US Subsidiary and Catalent relating to the Transaction.

Pursuant to the APA, we will indemnify Catalent against losses arising out of, relating to or resulting from (i) any inaccuracy in or breach of any of the representations or warranties made by us contained in the APA, (ii) any breach or non-fulfillment of any covenant or agreement made by us contained in the APA and (iii) any excluded asset or liability retained by us or the US Subsidiary. Catalent

will similarly indemnify us and the US Subsidiary against losses arising out of, relating to or resulting from (i) any inaccuracy in or breach of any of the representations or warranties of Catalent contained in the APA, (ii) any breach or non-fulfillment of any covenant or agreement of Catalent contained in the APA and (iii) any transferred asset or liability assumed by Catalent. The indemnification provisions are subject to certain limitations with respect to recovery for losses.

#### **10.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.

#### **10.E. Taxation.**

The following describes certain material U.S. federal income tax and French tax considerations relating to the acquisition, ownership and disposition of our ADSs by a U.S. holder (as defined below). This summary does not address all U.S. federal income tax and French tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of our ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities or notional principal contracts, including those that use the mark-to-market method of tax accounting;
- tax-exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code, respectively, and private foundations;
- governmental or international organizations;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold their ADSs as part of a “hedging,” “integrated,” “wash sale” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- certain former citizens or long-term residents of the United States;
- persons that received their ADSs pursuant to the exercise of any employee stock options or otherwise as compensation for the performance of services;
- persons that acquired their ADSs in connection with a trade or business, permanent establishment or fixed place of business outside of the United States, including a permanent establishment in France;
- pension plans;
- cooperatives;
- holders that own directly, indirectly or constructively 5% or more of our stock (by vote or value); and
- holders that have a “functional currency” other than the U.S. dollar.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the U.S. federal income tax consequences relating to an investment in the ADSs will depend in part upon the status of the partner in the partnership and the activities of the partnership. U.S. holders that are such partners or partnerships should consult their tax advisors regarding the U.S. federal income tax considerations of acquiring, owning and disposing of our ADSs in their particular circumstances.

For purposes of this discussion, a “U.S. holder” is a beneficial owner of our ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated 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;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust, or if such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based in part upon the representations of the depository and the assumption that each obligation in the amended and restated deposit agreement and any related agreement will be performed in accordance with its terms. Furthermore, a holder of an ADS generally should be treated as holding the underlying share represented by the ADS. As such, no gain or loss generally will be recognized upon an exchange of the ADS for the underlying share.

**Persons considering an investment in our ADSs should consult their tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of the ADSs, including the applicability of U.S. federal, state and local tax laws, French tax laws and other non-U.S. tax laws.**

### **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 and, unless otherwise noted, this discussion is the opinion of Gide Loyrette Nouel A.A.R.P.I, our French tax counsel, insofar as it relates to matters of French tax law and legal conclusions with respect to those matters.

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 description of the French income tax and wealth tax consequences set forth below is based on the Convention 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.

This discussion applies only to investors that are entitled to Treaty benefits under the “Limitation on Benefits” provision contained in the Treaty.

France has introduced a comprehensive set of new tax rules applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor’s net assets for the purpose of applying the French real estate wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. 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 urged to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of securities (including ADSs).

U.S. holders are urged to consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of securities in light of their particular circumstances, especially with regard to the “Limitations on Benefits” provision.

### ***Estate and Gift Taxes and Transfer 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 Convention 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 (as amended by 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 securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the *Code général des impôts* (French Tax Code, or FTC), purchases of shares or ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the French Financial Market Authority (AMF) are subject to a 0.3% French tax on financial transactions provided that the issuer’s market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year pursuant to Regulations BOI-ANNEX-000467-21/12/2022 issued on December 21, 2022. The Nasdaq Global Select Market is not currently acknowledged by the French AMF but this may change in the future. A list of French relevant companies whose market capitalization exceeds 1 billion

euros as of December 1 of the year preceding the taxation year is published annually and at least once a year, by the French State. As at December 1, 2022, our market capitalization did not exceed 1 billion euros.

Following the global offering, purchases of our securities may be subject to such tax provided that its market capitalization exceeds 1 billion euros and that the Nasdaq Global Select Market is acknowledged by the French AMF.

In the case where Article 235 ter ZD of the FTC is not applicable, transfers of shares issued by a French company, which is listed on a regulated or organized market within the meaning of the French Financial and Monetary Code, are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written statement (“acte”) executed either in France or outside France. Although there is no case law or official guidelines published by the French tax authorities on this point, transfers of ADSs should remain outside of the scope of the aforementioned 0.1% registration duties.

### ***Tax on Sale or Other Disposition***

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 ordinary shares or ADSs, provided such U.S. holder is not a French tax resident for French tax purposes and has not held more than 25% of our dividend rights, known as “*droits aux benefices 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 a non-cooperative State or territory as defined in Article 238-0 A of the FTC should 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 State or territories is published by decree and is in principal updated annually. This list was last updated on 2 March 2022, and currently includes American Samoa, Anguilla, the British Virgin Islands, Fiji, Guam, Palaos, Panama, Samoa, Seychelles, Trinidad and Tobago, 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 125 A III of the FTC, are currently American Samoa, Fiji, Guam, Palaos, 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 entitled to Treaty benefit will not be subject to French tax on any such capital gain unless the ordinary shares or 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 ordinary shares or ADSs through U.S. partnerships that are not resident for Treaty purposes are advised to consult their own tax advisors 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 benefit (and in both cases is not resident, established or incorporated in a non-cooperative State or territory as defined in Article 238-0 A of the FTC) and has held more than 25% of our dividend rights, known as “*droits aux benefices sociaux*,” at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives will be subject to a levy in France at the rate of 12.8% if such U.S. holder is an individual or 25% for corporate bodies or other legal entities. Special rules apply to U.S. holders who are residents of more than one country.

### ***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 12.8% when the recipient is an individual and 25% otherwise. Dividends paid by a French corporation in a non-cooperative State or territory, as defined in Article 238-0 A of the FTC, will generally be subject to French withholding tax at a rate of 75%. However, eligible U.S. holders, other than individuals subject to the French withholding tax at a rate of 12.8%, 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 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 ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, may be 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 advisors 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 depository with a treaty form (Form 5000) in accordance with the French guidelines (BOI-INT-DG-20-20-20-12/09/2012); or
- the depository 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 ordinary shares or 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, other than individuals subject to the French withholding tax at a rate of 12.8%, will be subject to French withholding tax at the rate of 25%, or 75% if paid in a non-cooperative State or territory (as defined in Article 238-0 A 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 depository to all U.S. holders registered with the depository. The depository will arrange for the filing with the French tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depository 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 depository 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.

Since the withholding tax rate applicable under French domestic law to U.S. holders who are individuals does not exceed the cap provided in the Treaty (i.e. 15%), the 12.8% rate shall apply, without any reduction provided under the Treaty.

Besides, please note that pursuant to Article 235 *quater* of the FTC and under certain conditions (in particular reporting obligations), a corporate U.S. Holder which is in a tax loss position for the fiscal year during which the dividend is received may be entitled to a deferral regime, and obtain a withholding tax refund. The tax deferral ends in respect of the first financial year during which this U.S. Holder is in a profit making position, as well as in the cases set out in Article 235 *quater* of the FTC. Also, pursuant to newly introduced Article 235 *quinquies* of the FTC and under certain conditions, a corporate U.S. Holder may be entitled to a refund of a fraction of the withholding tax, up to the difference between the withholding tax paid (on a gross basis) and the withholding tax based on the dividend net of the expenses incurred for the acquisition and conservation directly related to the income, provided (i) that these expenses would have been tax deductible had the U.S. Holder been established in France, and (ii) that the tax rules in the United States do not allow the U.S. Holder to offset the withholding tax.

### ***Real Estate Wealth Tax***

On January 1, 2018, the French wealth tax was replaced with a real estate wealth tax (*impôt sur la fortune immobilière*, or IFI). Individuals holding directly or indirectly through one or more legal entities real estate assets or rights with a value exceeding €1,300,000 may fall within the scope of the IFI. A general exclusion applies to real estate assets owned by companies carrying out a commercial or industrial activity when the taxpayer (together with the members of his/her household) holds directly or indirectly less than 10% of the share capital or voting rights of the company. ADSs owned by a U.S. holder should not fall within the scope of the IFI provided that such U.S. holder does not own (together with the members of his/her household) directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights of our share capital. U.S. holders holding directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights of our share capital should seek additional advice.

### **Material U.S. Federal Income Tax Considerations**

This section discusses certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of our ADSs by a U.S. holder that holds the ADSs as a "capital asset" for U.S. federal income tax purposes (generally, property held for investment). This discussion does not address estate, gift, or alternative minimum tax considerations, the Medicare net investment tax, the special tax accounting rules under Section 451(b) of the Code or any state, local or non-U.S. tax considerations of the acquisition, ownership and disposition of our ADSs.

This discussion is based on the the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax

considerations described herein. 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 herein concerning the tax consequences of the acquisition, ownership and disposition of our ADSs or that such a position would not be sustained by a court. U.S. holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of our ADSs in their particular circumstances.

**Passive Foreign Investment Company Considerations.** Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we will be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, allocations of income with respect to any partnership, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Furthermore, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the stock of another corporation is treated as directly holding and receiving its proportionate share of assets and income, respectively, of such other corporation.

The annual determination of whether we are a PFIC for a taxable year is fact-intensive and made after the close of such taxable year applying principles and methodologies that in some circumstances are unclear and subject to varying interpretations. For instance, whether we are a PFIC will depend on the composition of our income (including whether we will receive certain non-refundable grants or subsidies and whether such amounts and reimbursements of certain refundable research tax credits will constitute gross income for purposes of the PFIC rules). Whether we are a PFIC also will depend on the composition and value of our assets, including goodwill, which may be determined in large part by reference to the market value of our ADSs from time to time, which may fluctuate considerably. If our market capitalization declines while we hold a substantial amount of cash and cash-equivalents, which may depend on how quickly we utilize our cash proceeds from our global offerings in our business, we may be more likely to be characterized as a PFIC. Based on the composition of our gross income, assets, activities and market capitalization and the nature of our business, and due to fluctuations in our stock price, we believe that we may have been characterized as a PFIC for our taxable year ending December 31, 2022. However, because our PFIC status is subject to a number of uncertainties and it is very early in the year, we cannot provide any assurances, and our U.S. counsel expresses no opinion, with respect to our PFIC status for any taxable year.

If we are classified as a PFIC in any taxable year during which a U.S. holder owns our ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding taxable years during which such U.S. holder owns the ADSs, regardless of whether we continue to qualify as a PFIC, unless we cease to be a PFIC and such U.S. holder has made a “deemed sale” election. If a deemed sale election is made, such U.S. holder will be deemed to have sold the ADSs at their fair market value and any gain from such deemed sale would be subject to the special tax regime described below. After the deemed sale election, as long as we do not become a PFIC in a subsequent taxable year, such U.S. holder’s ADSs with respect to which such election was made will not be treated as ADSs in a PFIC and such U.S. holder will not be subject to the special tax regime described below. U.S. holders should consult their tax advisors as to the possibility and tax consequences of making a deemed sale election if we are a PFIC and cease to be a PFIC and such election becomes available.

If we are a PFIC in any taxable year during which a U.S. holder owns our ADSs, such U.S. holder generally will be subject to the following special tax regime, which applies to both (a) any “excess distribution” by us to such U.S. holder (generally, such U.S. holder’s ratable portion of distributions in any taxable year which are greater than 125% of the average annual distribution received by such U.S. holder in the shorter of the three preceding taxable years or such U.S. holder’s holding period for the ADSs) and (b) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution or gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over such U.S. holder’s holding period, (ii) the amount deemed realized in each taxable year had been subject to tax in each taxable year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder’s regular ordinary income rate for the current taxable year and would not be subject to the interest charge described in the next clause) and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those taxable years. In addition, dividend distributions made to such U.S. holder will not qualify for the preferential rates of taxation currently applicable to “qualified dividend income” discussed below under “*Distributions*.”

Certain elections, if available, may be made to alleviate some of the adverse tax consequences of PFIC status and, if made, would result in an alternative tax treatment of the acquisition, ownership and disposition of ADSs in a PFIC. If we are a PFIC for any taxable year during which a U.S. holder owns our ADSs and the U.S. holder makes a mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). In addition, the U.S. holder’s tax basis in the ADSs will be adjusted to reflect these income or loss amounts. Any gain or loss recognized on the sale or other disposition of the ADSs in a taxable year when we are a PFIC will be treated as ordinary income or loss (but, in the case of loss, only to the extent of the net amount of income previously included as a result of the mark-to-market

election), respectively. The mark-to-market election is available only if we are a PFIC and the ADSs are “regularly traded” on a “qualified exchange.” The ADSs will be treated as “regularly traded” in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement are disregarded). The Nasdaq Global Select Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to the U.S. holder.

If we are a PFIC for any taxable year during which a U.S. holder owns our ADSs, we expect to provide such U.S. holder, upon request, a “PFIC Annual Information Statement” with the information required to allow such U.S. holder to make a “qualified electing fund election” or “QEF Election.”

If a U.S. holder makes a QEF Election, the U.S. holder will be subject to current taxation on its pro rata share of our ordinary earnings and net capital gain for each taxable year that we are classified as a PFIC. Furthermore, any distributions paid by us out of our earnings and profits that were previously included in the U.S. holder’s income under the QEF Election will not be taxable to the U.S. holder. The U.S. holder will increase its tax basis in its ADSs by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the ADSs that is not included in the U.S. holder’s income. In addition, the U.S. holder will recognize capital gain or loss on the disposition of its ADSs in an amount equal to the difference between the amount realized and the U.S. holder’s adjusted tax basis in the ADSs. If the U.S. holder does not make and maintain a QEF election for the U.S. holder’s entire holding period for our ADSs by making the election for the first taxable year in which the U.S. holder acquired our ADSs, the U.S. holder will be subject to the special tax regime discussed above, unless the U.S. holder can properly make a “purging election” with respect to our ADSs in connection with the U.S. Shareholder’s QEF Election. A purging election may require the U.S. holder to recognize taxable gain on the U.S. holder’s ADSs. No purging election is necessary for a U.S. holder that timely makes a QEF Election for the first taxable year in which the U.S. holder acquired our ADSs.

U.S. holders should consult their tax advisors to determine whether any of the elections discussed above would be available and, if so, what the tax consequences of the alternative tax treatments would be in their particular circumstances.

If we are a PFIC for any taxable year during which a U.S. holder owns our ADSs, such U.S. holder generally will be subject to similar rules with respect to distributions we receive from and gains we recognize on the sale or other disposition of the stock any of our subsidiaries that are PFICs, or lower-tier PFICs, as if such distributions were indirectly received by or such sale or other disposition was indirectly carried out by such U.S. holder. U.S. holders should consult their tax advisors as to the application of the lower-tier PFIC rules in their particular circumstances.

If a U.S. holder owns ADSs during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to us, generally with the U.S. holder’s U.S. federal income tax return for that taxable year. U.S. holders should consult their tax advisors concerning PFIC reporting requirements in their particular circumstances.

**The U.S. federal income tax rules relating to PFICs are complex. U.S. holders are urged to consult their tax advisers with respect to the acquisition, ownership and disposition of our ADSs, the tax consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of the ADSs.**

**Distributions.** We do not expect to make any distribution in respect of our ADSs. Subject to the discussion above under “—*Passive Foreign Investment Company Considerations*,” if we make any distribution in respect of our ADSs, the gross amount of the distribution (including any amounts of foreign tax withheld in respect of such distribution) actually or constructively received by a U.S. holder with respect to the ADSs will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder’s pro rata share of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder’s adjusted tax basis in the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder’s holding period exceeds one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to “qualified dividend income” (as discussed below) if we are a “qualified foreign corporation” and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this purpose and which includes an exchange-of-

information provision or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. Our ADSs are currently listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we currently expect the ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later taxable years. The Company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Convention 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, signed on August 31, 1994, as amended and currently in force, or the U.S.-France Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-France Tax Treaty is satisfactory for purposes of the qualified dividend income rules and that it includes an exchange-of-information program. Therefore, subject to the discussion above under “—*Passive Foreign Investment Company Considerations*,” dividend distributions with respect to our ADSs generally will be “qualified dividend income” in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. Such dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any French withholding tax as either a deduction from gross income or a credit against its U.S. federal income tax liability, subject to generally applicable limitations. Generally, the credit is determined separately for different categories of income and cannot exceed the proportionate share of a U.S. holder’s U.S. federal income tax liability that such U.S. holder’s taxable income from foreign sources bears to such U.S. holder’s worldwide taxable income. For foreign tax credit limitation purposes, dividend distributions with respect to our ADSs generally will be treated as passive category income from foreign sources. The amount of a distribution with respect to the ADSs that is treated as a “dividend” may be lower for U.S. federal income tax purposes than it is for French income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. U.S. holders should consult their tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the U.S. dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the Depository receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

***Sale, Exchange or Other Taxable Disposition of the ADSs.*** A U.S. holder generally will recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ADSs in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder’s adjusted tax basis in those ADSs, determined in U.S. dollars. Subject to the discussion above under “—*Passive Foreign Investment Company Considerations*,” this gain or loss generally will be capital gain or loss. The adjusted tax basis in the ADSs generally will be equal to the cost of such ADSs. Capital gain from the sale, exchange or other taxable disposition of ADSs of a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder’s holding period determined at the time of such sale, exchange or other taxable disposition for such ADSs exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source gain or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided that the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder realizes will be U.S. source ordinary income or loss.

***Backup Withholding and Information Reporting.*** U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of ADSs that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an “exempt recipient.” In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder’s U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Furthermore, certain individual U.S. holders are required to report information relating to an interest in ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their U.S. federal income tax return.

U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their acquisition, ownership and disposition of our ADSs.

**THE DISCUSSION ABOVE IS A SUMMARY OF CERTAIN MATERIAL U.S. FEDERAL INCOME AND FRENCH TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs AND IS NOT TAX ADVICE. U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ADSs IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES.**

**10.F. Dividends and Paying Agents.**

Not applicable.

**10.G. Statement by Experts.**

Not applicable.

**10.H. Documents on Display.**

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will 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 will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at [www.erytech.com](http://www.erytech.com). We intend to post our Annual Reports 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](http://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.

**10.I. Subsidiary Information.**

Not required.

**10.J. Annual Reports to Security Holders**

Not Applicable.

## Item 11. Quantitative and Qualitative Disclosures About Market Risk.

### Liquidity Risk

As of December 31, 2022, our cash and cash equivalents were €38.8 million (\$41.5 million) and were primarily cash and term deposits that are convertible into cash in approximately 30 days notice without penalty. We believe that our cash and cash equivalents as of December 31, 2022 enable us to cover our cash requirements until mid-2024.

Combined company (including Pherecydes) cash runway would extend into Q3 2024, with a consolidated cash position of approximately €41 million as of December 31, 2022, and would enable funding of existing and new programs through multiple clinical milestones.

In the longer term the Group will need to seek additional funds, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches.

However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

### Foreign Currency Exchange Risk

We use the euro as our functional currency for our financial communications. However, a significant portion of our expenses, financial assets and liabilities are denominated in U.S dollars and are exposed to changes in foreign currency exchange rates. We also entered into a license agreement with SQZ Biotechnologies in 2019 and any potential revenues pursuant to this agreement will be made in U.S. dollars.

We do not currently engage in hedging transactions or the use of forward contracts but may in the future in order to minimize the impact of uncertainty in future exchange rates on cash flows. A deterioration of the U.S dollar to the Euro exchange rate of 1.1326 used for 2021 closing could impact our financial statements as follows:

(in thousands)	As of December 31, 2022		Sensitivity		
	USD	EUR	+ 1 %	+ 5 %	+ 10 %
<b>Financial assets</b>	<b>16,971</b>	<b>15,912</b>	<b>(158)</b>	<b>(758)</b>	<b>(1,447)</b>
<i>of which cash and cash equivalents</i>	<i>16,399</i>	<i>15,375</i>	<i>(152)</i>	<i>(732)</i>	<i>(1,398)</i>
<b>Financial liabilities</b>	<b>1,848</b>	<b>1,732</b>	<b>(17)</b>	<b>(82)</b>	<b>(157)</b>

As we advance our clinical development in the United States and potentially commercialize our product candidates in that market, we expect to face greater exposure to exchange rate risk and would then consider using exchange rate derivative or hedging techniques at that time. We expect to continue to enter into transactions based in foreign currencies that could be impacted by changes in exchange rates.

### Interest Rate Risk

We believe we have very low exposure to interest rate risk. Such exposure primarily involves our money market funds and time deposit accounts. Changes in interest rates have a direct impact on the rate of return on these investments and the cash flows generated.

The outstanding bank loans bear interest at a fixed rate, and therefore we are not subject to interest rate risk with respect to this loan.

### Credit Risk

We believe that the credit risk related to our cash and cash equivalents is not significant in light of the quality of the financial institutions at which such funds are held.

## Item 12. Description of Securities Other than Equity Securities.

### 12.A. Debt Securities.

Not applicable.

**12.B. Warrants and Rights.**

Not applicable.

**12.C. Other Securities.**

Not applicable.

**12.D. American Depositary Shares.**

The Bank of New York Mellon acts as the depository for the American Depositary Shares. The Bank of New York Mellon's depository offices are located at 240 Greenwich Street, New York, New York 10286. American Depositary Shares are frequently referred to as ADSs and represent ownership interests in securities that are on deposit with the depository. ADSs may be evidenced by certificates that are commonly known as American Depositary Receipts, or ADRs. The depository typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Société Générale. The Company has appointed The Bank of New York Mellon as depository pursuant to an amended and restated deposit agreement. A copy of the amended and restated deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-3. ADS holders may obtain a copy of the amended and restated deposit agreement from the SEC's website ([www.sec.gov](http://www.sec.gov)) and should refer to Registration Number 333-259690 when retrieving such copy.

An owner of ADSs may hold its ADSs either (1) directly (a) by having an ADR, which is a certificate evidencing a specific number of ADSs, registered in such owner's name, or (b) by having uncertificated ADSs registered in the owner's name in the Direct Registration System, or DRS, or (2) indirectly by holding a security entitlement in ADSs through the owner's broker or other financial institution that is a direct or indirect participant in the Depository Trust Company, or DTC. If an owner of ADSs decides to hold its ADSs directly, such owner is a registered ADS holder, also referred to as an ADS holder. This description assumes all owners are an ADS holder. If an owner of ADSs decides to hold the ADSs indirectly, such owner must rely on the procedures of its broker or other financial institution to assert the rights of ADS holders described in this section. Such indirect holder should consult with its broker or financial institution to find out what those procedures are. DRS is a system administered by DTC pursuant to which the depository may register the ownership of uncertificated ADSs, which ownership is confirmed by periodic statements sent by the depository to the registered holders of uncertificated ADSs.

An ADS holder will not be treated as one of the Company's shareholders and such ADS holder will not have shareholder rights. French law governs shareholder rights. The depository will be the holder of the ordinary shares underlying each owner's ADSs. A holder of ADSs will have ADS holder rights. An amended and restated deposit agreement among the Company, the depository and all persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depository. New York law governs the amended and restated deposit agreement and the ADRs. In the event of any discrepancy between the ADRs and the amended and restated deposit agreement, the amended and restated deposit agreement governs. The following is a summary of the material provisions of the amended and restated deposit agreement. More complete information is contained in the amended and restated deposit agreement and the form of ADR. Members of the public may obtain copies of those documents from the SEC's website at [www.sec.gov](http://www.sec.gov). A copy of the amended and restated deposit agreement is also filed as an exhibit to the Company's Annual Report on Form 20-F to which this description is also an exhibit.

## Fees and Expenses

Pursuant to the terms of the amended and restated deposit agreement, the holders of our ADSs will be required to pay the following fees

Persons depositing or withdrawing ordinary shares or ADSs must pay:	For:
\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	<ul style="list-style-type: none"><li>• Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights</li><li>• Cancellation of ADSs for the purpose of withdrawal, including if the amended and restated deposit agreement terminates</li></ul>
\$0.05 (or less) per ADS	<ul style="list-style-type: none"><li>• Any cash distribution to an ADS holder</li></ul>
A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been ordinary shares and the shares had been deposited for issuances of ADSs	<ul style="list-style-type: none"><li>• Distribution of securities distributed to holders of deposited securities which are distributed by the depository to an ADS holder</li><li>• Depository services</li></ul>
\$0.05 (or less) per ADS per calendar year	
Registration or transfer fees	<ul style="list-style-type: none"><li>• Transfer and registration of ordinary shares on the Company's share register to or from the name of the depository or its agent when an ADS holder deposits or withdraws shares</li></ul>
Expenses of the depository	<ul style="list-style-type: none"><li>• Cable (including SWIFT) and facsimile transmissions as expressly provided in the amended and restated deposit agreement</li><li>• Converting foreign currency to U.S. dollars</li></ul>
Taxes and other governmental charges the depository or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes	<ul style="list-style-type: none"><li>• As necessary</li></ul>
Any charges payable by the depository, custodian or their agents in connection with the servicing of deposited securities	<ul style="list-style-type: none"><li>• As necessary</li></ul>

The depository collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depository may collect its annual fee for depository services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depository may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depository may generally refuse to provide for-fee services until its fees for those services are paid.

From time to time, the depository may make payments to the Company to reimburse or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the amended and restated deposit agreement, the depository may use brokers, dealers, foreign currency or other service providers that are affiliates of the depository and that may earn or share fees, spreads or commissions.

The depository may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the amended and restated deposit agreement and the rate that the

depository or its affiliate receives when buying or selling foreign currency for its own account. The depository makes no representation that the exchange rate used or obtained in any currency conversion under the amended and restated deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to holders of ADSs, subject to the depository's obligations under the amended and restated deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

#### **Payment of Taxes**

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of such holder's ADSs. The depository may refuse to register any transfer of a holder's ADSs or allow them to withdraw the deposited securities represented by such holder's ADSs until such taxes or other charges are paid. It may apply payments owed to ADS holders or sell deposited securities represented by such holder's ADSs to pay any taxes owed and such holder will remain liable for any deficiency. If the depository sells deposited securities, it will, if appropriate, reduce the number of ADSs registered in the ADS holder's name to reflect the sale and pay to such holder any net proceeds, or send such holder any property, remaining after it has paid the taxes. An ADS holder's obligation to pay taxes and indemnify the Company and the depository against any tax claims will survive the transfer or surrender of such holder's ADSs, the withdrawal of the deposited ordinary shares as well as the termination of the amended and restated deposit agreement.

## **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.**

Not applicable.

### **Item 15. Controls and Procedures.**

#### **Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer (principal executive officer) and our chief financial officer and chief operating 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), as of December 31, 2022. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2022 as a result of the material weakness described below. We are undertaking the remedial steps to address the material weakness in our disclosure controls and procedures as set forth below under "Management's Plan for Remediation of the Current Material Weakness."

#### **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 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. 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 and chief operating officer (principal financial officer), management conducted an assessment 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). 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.

As of December 31, 2021, our management concluded that our internal control over financial reporting was not effective as a result of a material weakness related to the monitoring of research and development projects, as the control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received did not operate at a sufficient level of precision.

In connection with our assessment as of December 31, 2022, our management concluded that this material weakness was not fully remediated, as our management identified that the control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received and the control related to the data and assumptions used to estimate the hospital costs accrual did not operate at a sufficient level of precision. Management considers these controls have to be redesigned to fully remediate the material weakness. As a result of this material weakness, management concluded our internal control over financial reporting was not effective as of December 31, 2022 at the reasonable assurance level.

#### **Remediation Activities**

During 2022, we continued to strengthen our process and internal controls over the monitoring of research and development costs. In particular, we (i) redesigned the process to track actual costs incurred against invoices received, (ii) adapted the methodology used to estimate the hospital cost accrual in the financial statements and (iii) worked on the implementation of a control designed to ensure the assumptions and the data used to estimate such costs are reasonable and accurate.

We believe the remediation measures described above improved the reliability of financial information related to the hospital costs accrual. Nevertheless, our management concluded that the material weakness was not fully remediated as of December 31, 2022.

Notwithstanding the material weakness, our management has concluded that the financial statements included elsewhere in this Annual Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with IFRS.

#### **Attestation Report of Registered Public Accounting Firm**

Our independent registered public accounting firm has issued an attestation report on management's assessment of our internal control over financial reporting (refer to the financial statements beginning on page F-1 of this Annual Report).

Its report expresses an opinion that the Company did not maintain effective internal control over financial reporting as of December 31, 2022 because of the effect of the material weakness described above.

#### **Management's Plan for Remediation of the Current Material Weakness**

To further improve our internal control over financial reporting and to specifically address the control deficiencies that led to our material weakness, we plan to deploy remediation efforts focused on:

- redesigning our control over the reconciliation of estimated hospital costs incurred related to clinical trials sponsored by the Company with invoices received so that it can operate at an appropriate level of precision to detect and correct errors.
- redesigning our control over the data and assumptions used to estimate the hospital costs accrual so that it can operate at an appropriate level of precision to detect and correct errors.

#### **Changes in Internal Control over Financial Reporting**

Other than the remediation activities described above, there were no changes in our internal control over financial reporting during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Item 16. Reserved.**

Not applicable.

#### **Item 16A. Audit Committees Financial Expert.**

Our board of directors has determined that Ms. Windels is an audit committee financial expert as defined by SEC rules and regulations and each of the members of our board of directors has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Ms. Windels is independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.

**Item 16B. Code of Business Conduct and Ethics.**

We have adopted a Code of Business Conduct and Ethics, or the Code of Ethics, that is applicable to all of our employees, executive officers and directors. A copy of the Code of Ethics is available on our website at [www.erytech.com](http://www.erytech.com). The audit committee of our board of directors is responsible for overseeing the Code of Ethics and must approve any waivers of the Code of Ethics for employees, executive officers and directors. We expect that any amendments to the Code of Ethics, or any waivers of its requirements, will be disclosed on our website.

**Item 16C. Principal Accountant Fees and Services.**

KPMG S.A., or KPMG, has served as our independent registered public accounting firm for the years ended December 31, 2021 and 2022. Our accountants billed the following fees to us for professional services in each of those fiscal years, all of which were approved by our audit committee:

(in thousands of €)	Year Ended December 31,	
	2021	2022
Audit Fees	345	568
Audit-Related Fees	203	—
All Other Fees	—	—
<b>Total</b>	<b>547</b>	<b>568</b>

“Audit Fees” are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that KPMG 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.

“All Other Fees” are additional amounts billed for products and services provided by KPMG.

There were no “Tax Fees” billed or paid during 2021 or 2022.

**Audit and Non-Audit Services Pre-Approval Policy**

The audit committee has responsibility for appointing, setting compensation of and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the audit committee has adopted a policy governing the pre-approval of all audit and permitted non-audit services performed by our independent registered public accounting firm to ensure that the provision of such services does not impair the independent registered public accounting firm’s independence from us and our management. Unless a type of service to be provided by our independent registered public accounting firm has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Pursuant to its pre-approval policy, the audit committee may delegate its authority to pre-approve services to the chairperson of the audit committee. The decisions of the chairperson to grant pre-approvals must be presented to the full audit committee at its next scheduled meeting. The audit committee may not delegate its responsibilities to pre-approve services to the management.

The audit committee has considered the non-audit services provided by KPMG as described above and believes that they are compatible with maintaining KPMG’s independence as our independent registered public accounting firm.

**Item 16D. Exemptions from the Listing Standards for Audit Committees.**

Not applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.**

Not applicable.

**Item 16F. Change in Registrant’s Certifying Accountant.**

Not applicable.

**Item 16G. Corporate Governance.**

As a French *société anonyme*, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq corporate governance listing standards. However, the corporate governance standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq rules, with certain exceptions. We currently rely on these exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, which would otherwise require that (1) a majority of our board of directors consist of independent directors; (2) we establish a nominating and corporate governance committee; and (3) our remuneration committee be composed entirely of independent directors.

The following are the significant ways in which our corporate governance practices differ from those required for U.S. companies listed on Nasdaq:

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 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. However, if the laws of a foreign private issuer’s home country require that any such matter be approved by the board of directors or the 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 the 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 common stock be at least 33 1/3% of the outstanding shares of the company’s voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders’ general meeting or at an extraordinary shareholders’ general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders’ general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Furthermore, we follow French corporate governance practices in lieu of the Nasdaq corporate governance rules that require shareholder approval prior to specified issuances of securities. More specifically, Nasdaq Marketplace Rule 5635 requires a U.S. domestic listed company to obtain shareholder approval: (1) prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the issuer; (2) prior to the issuance of securities in connection with a transaction other than a public offering involving the sale, issuance or potential issuance by the issuer alone, or together with sales by its officers, directors or substantial shareholders, of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value; and (3) prior to the issuance of securities when an equity compensation arrangement is made or materially amended, including prior to the issuance of common stock to the issuer’s officers, director, employees or consultants for less than the greater of book or market value. While French law requires a French company to obtain prior shareholder approval to issue shares, its shareholders may pre-authorize the company’s board of directors to issue shares such that shareholder approval is not required at the time of issuance.

**Item 16H. Mine Safety Disclosure.**

Not applicable.

**Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

**PART III.**

**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.**

The exhibits listed below are filed as exhibits to this Annual Report.

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
1.1	<a href="#">Bylaws (statuts) of the registrant (English translation)</a>	20-F	001-38281	1.1	April 27, 2022
2.1	<a href="#">Amended and Restated Deposit Agreement</a>	F-3	333-248953	4.2	September 21, 2020
2.2	<a href="#">Form of American Depositary Receipt (included in Exhibit 2.1)</a>	F-3	333-248953	4.2	September 21, 2020
2.3*	<a href="#">Description of Securities</a>				
2.4	<a href="#">Sales Agreement, dated September 21, 2020, by and between the Registrant and Cowen and Company, LLC</a>	F-3	333-248953	1.2	September 21, 2020
4.1	<a href="#">Lease Agreement by and between the registrant and PFO2 SCPI (represented by PERIAL Asset Management SASU), dated June 9, 2015 (English translation)</a>	F-1	333-220867	10.1	October 6, 2017
4.2	<a href="#">Addendum #1 to the Lease Agreement by and between the registrant and PF02 SCPI (represented by PERIAL Asset Management SASU), dated December 30, 2016 (English translation)</a>	F-1	333-220867	10.2	October 6, 2017
4.3	<a href="#">Lease Agreement by and between the registrant and EUROGAL, dated December 6, 2017 (English Translation)</a>	20-F	001-38281	4.3	April 24, 2018
4.4#	<a href="#">Exclusive Distribution Agreement by and between the registrant and Abic Marketing Limited, dated as of March 28, 2011</a>	F-1	333-220867	10.5	October 6, 2017
4.5#	<a href="#">Exclusive Supply Agreement for L-asparaginase by and between the registrant and medac GmbH, dated as of December 12, 2008 and Addendum #1 to the Exclusive Supply Agreement for L-Asparaginase, dated August 19, 2009</a>	F-1	333-220867	10.6	October 6, 2017
4.6#	<a href="#">Exclusive Supply Agreement for recombinant L-asparaginase by and between the registrant and medac GmbH, dated as of May 3, 2011 and Addendum #1 to the Exclusive Supply Agreement for recombinant L-asparaginase, dated April 4, 2014</a>	F-1	333-220867	10.7	October 6, 2017
4.7	<a href="#">Addendum #2 to the Exclusive Supply Agreement for L-asparaginase by and between the registrant and medac GmbH, dated July 25, 2016</a>	F-1	333-220867	10.8	October 6, 2017
4.8#	<a href="#">Addendum #2 to the Exclusive Supply Agreement for recombinant L-asparaginase by and between the registrant and medac GmbH, dated July 25, 2016</a>	F-1	333-220867	10.9	October 6, 2017
4.9†	<a href="#">Form of indemnification agreement between the registrant and each of its executive officers and directors</a>	F-1	333-220867	10.11	October 6, 2017

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
4.10†	<a href="#">Summary of BSA Plans</a>	F-1	333-220867	10.12	October 6, 2017
4.11†	<a href="#">Summary of BSPCE Plans</a>	F-1	333-220867	10.13	October 6, 2017
4.12†	<a href="#">2016 Share Option Plan (English translation)</a>	F-1	333-220867	10.14	October 6, 2017
4.13†	<a href="#">2016 Free Share Plan (English translation)</a>	F-1	333-220867	10.15	October 6, 2017
4.14†	<a href="#">2017 Share Option Plan (English translation)</a>	S-8	333-222673	99.5	January 24, 2018
4.15†	<a href="#">2017 Free Share Plan (English translation)</a>	S-8	333-222673	99.6	January 24, 2018
4.16†	<a href="#">2018 Share Option Plan (English translation)</a>	S-8	333-232670	99.2	July 16, 2019
4.17†	<a href="#">2018 Free Share Plan (English translation)</a>	S-8	333-232670	99.3	July 16, 2019
4.18†	<a href="#">2018 BSA Subscription Plan (English translation)</a>	S-8	333-232670	99.4	July 16, 2019
4.19†	<a href="#">2019 Share Option Plan (English translation)</a>	20-F	001-38281	4.22	March 18, 2020
4.20†	<a href="#">2019 Free Share Plan (English translation)</a>	20-F	001-38281	4.23	March 18, 2020
4.21†	<a href="#">2019 BSA Subscription Plan (English translation)</a>	S-8	333-239429	99.4	June 25, 2020
4.22^	<a href="#">License and Collaboration Agreement by and between the registrant and SQZ Biotechnologies Company, dated June 24, 2019</a>	20-F	001-38281	4.24	March 18, 2020
4.23†	<a href="#">Executive Employment Agreement by and between the registrant and Gil Beyen, dated as of April 1, 2019</a>	20-F	001-38281	4.25	March 18, 2020
4.24†	<a href="#">2020 Share Option Plan</a>	20-F	001-38281	4.27	March 8, 2021
4.25†	<a href="#">2020 Free Share Plan (English translation)</a>	20-F	001-38281	4.28	March 8, 2021
4.26†	<a href="#">2020 BSA Subscription Plan</a>	20-F	001-38281	4.29	March 8, 2021
4.27†	<a href="#">Agreement for the issuance of and subscription to warrants giving access to notes convertible into new and/or existing shares with share subscription warrants attached</a>	20-F	001-38281	4.30	March 8, 2021
4.28†	<a href="#">2021 Share Option Plan</a>	20-F	001-38281	4.31	April 27, 2022
4.29†	<a href="#">2021 Free Share Plan (English translation)</a>	20-F	001-38281	4.32	April 27, 2022
4.30†	<a href="#">2021 BSA Subscription Plan</a>	20-F	001-38281	4.33	April 27, 2022
4.31	<a href="#">Terms and Conditions of the Warrants, dated as of April 29, 2021</a>	6-K	001-38281	10.2	May 3, 2021
4.32	<a href="#">Terms and Conditions of the Warrants, dated as of December 14, 2021</a>	6-K	001-38281	10.2	December 16, 2021
4.33	<a href="#">Asset Purchase Agreement by and among the registrant, Erytech Pharma, Inc., Catalent Princeton, LLC and Catalent Pharma Solutions, Inc., dated as of April 22, 2022</a>	6-k	001-38281	99.1	April 28, 2022
8.1	<a href="#">List of subsidiaries of the registrant</a>	F-1	333-220867	21.1	October 6, 2017
12.1*	<a href="#">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</a>				
12.2*	<a href="#">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</a>				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit Exhibit	File Date
13.1**	<a href="#">Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
15.1*	<a href="#">Consent of KPMG S.A.</a>				
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				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

\* Filed herewith.

\*\* Furnished herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

# Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

^ Portions of this document (indicated by "[\*\*\*]") have been omitted because they are not material and would likely cause competitive harm to ERYTECH Pharma S.A. if disclosed.

### SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

**ERYTECH Pharma S.A.**

By: /s/ Gil Beyen

Name: Gil Beyen

Title: Chief Executive Officer

Date: March 28, 2023

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## Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors,

### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated statements of financial position of Erytech Pharma S.A. and subsidiary (the Company) as of December 31, 2022, 2021 and 2020, the related consolidated statements of income (loss), comprehensive income (loss), changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 28, 2023 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matter*

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: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter 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.

#### *Estimate of hospital costs incurred in connection with the Company's TRYbeCA-1 clinical trial*

As discussed in Note 4.10 to the consolidated financial statements, the Company accrued hospital costs of €2,355 thousand as of December 31, 2022 mainly incurred in connection with the TRYbeCA-1 trial. These costs are measured as the excess of estimated costs incurred over invoices received. The hospital costs incurred are estimated based on an average cost per patient derived from actual costs incurred from hospitals which have completed their invoicing process for this trial.

We identified the evaluation of the estimated hospital costs incurred in connection with the Company's TRYbeCA-1 clinical trial as a critical audit matter. Challenging auditor judgement was required to evaluate the average costs per patient for hospitals that have not yet completed their invoicing process at year-end.

The following are the primary procedures we performed to address this critical audit matter. We compared the Company's prior year estimate of hospital costs incurred to invoices received to assess the Company's ability to accurately estimate. We assessed the Company's estimate of average cost per patient by confirming with certain hospitals involved in the TRYbeCA-1 clinical trial that they had completed their invoicing process, and recalculating the average patient costs for these sites. We reconciled relevant data such as number of active hospitals and number of randomized patients used by the Company in estimating costs incurred with the data collected by the Company's clinical department. We assessed the reasonableness of using the average cost per patient derived from costs incurred for hospitals which have completed their invoicing process to estimate unbilled costs for other hospitals by comparing the average number of treatment cycles for patients in hospitals which have completed their invoicing process to the average number of treatment cycles in other hospitals.

We have served as the Company's auditor since 2004.

Lyon, 28 March 2023  
KPMG Audit  
*A division of KPMG S.A.*

Stéphane Gabriel Devin  
*Partner*



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## Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors.:

### *Opinion on Internal Control Over Financial Reporting*

We have audited Erytech Pharma S.A.'s and subsidiary's (the Company) internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness, described below, on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2022, 2021 and 2020, the related consolidated statements of income (loss), comprehensive income (loss), changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements), and our report dated March 28, 2023 expressed an unqualified opinion on those consolidated financial statements.

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 company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness related to the monitoring of research and development projects, has been identified and included in management's assessment. The material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2022 consolidated financial statements, and this report does not affect our report on those consolidated financial statements.

### *Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### *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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

Lyon, 28 March 2023  
KPMG Audit  
*A division of KPMG S.A.*

Stéphane Gabriel Devin  
*Partner*

## CONSOLIDATED STATEMENT OF INCOME (LOSS)

(Amounts in thousands of euros, except loss per share)	Notes	12/31/2020	12/31/2021	12/31/2022
Revenues		—	—	—
Other income	3.1	3,718	4,180	30,998
<b>Operating income</b>		<b>3,718</b>	<b>4,180</b>	<b>30,998</b>
Research and development	3.2.1	(57,580)	(45,100)	(19,907)
General and administrative	3.2.2	(14,970)	(15,595)	(13,887)
<b>Operating expenses</b>		<b>(72,550)</b>	<b>(60,695)</b>	<b>(33,794)</b>
<b>Operating loss</b>		<b>(68,832)</b>	<b>(56,515)</b>	<b>(2,796)</b>
Financial income	3.5	889	5,422	4,453
Financial expenses	3.5	(5,354)	(2,702)	(1,364)
<b>Financial income (loss)</b>		<b>(4,465)</b>	<b>2,720</b>	<b>3,089</b>
Income tax	3.6	(3)	(2)	(521)
<b>Net loss</b>		<b>(73,300)</b>	<b>(53,797)</b>	<b>(228)</b>
<b>Basic / Diluted loss per share (€/share)</b>	<b>3.7</b>	<b>(3.99)</b>	<b>(2.27)</b>	<b>(0.01)</b>

The notes are an integral part of the accompanying Consolidated Financial Statements.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (LOSS)

(Amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
<b>Net loss</b>	<b>(73,300)</b>	<b>(53,797)</b>	<b>(228)</b>
<b>Elements that may be reclassified subsequently to income (loss)</b>			
Currency translation adjustment	400	(528)	187
<b>Elements that may not be reclassified subsequently to income (loss)</b>			
Remeasurement of defined benefit liabilities	(19)	68	235
Tax effect	—	0	—
<b>Other comprehensive income (loss)</b>	<b>381</b>	<b>(460)</b>	<b>422</b>
<b>Comprehensive income (loss)</b>	<b>(72,919)</b>	<b>(54,257)</b>	<b>194</b>

The notes are an integral part of the accompanying Consolidated Financial Statements.

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(Amounts in thousands of euros)	Notes	As of		
		December 31, 2020	December 31, 2021	December 31, 2022
<b>ASSETS</b>				
<b>Non-current assets</b>				
Intangible assets	4.1.1	589	15	5
Property, plant and equipment	4.1.2	20,862	18,960	393
Right of use	4.2	8,228	6,869	2,584
Other non-current assets	4.3	1,091	876	195
<b>Total non-current assets</b>		<b>30,770</b>	<b>26,720</b>	<b>3,177</b>
<b>Current assets</b>				
Inventories		—	—	—
Trade and other receivables	4.4	4	12	76
Other current assets	4.4	5,182	6,337	3,769
Cash and cash equivalents	4.5	44,446	33,699	38,789
<b>Total current assets</b>		<b>49,632</b>	<b>40,048</b>	<b>42,634</b>
<b>TOTAL ASSETS</b>		<b>80,402</b>	<b>66,768</b>	<b>45,811</b>

(Amounts in thousands of euros)	Notes	As of		
		December 31, 2020	December 31, 2021	December 31, 2022
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>				
<b>Shareholders' equity</b>				
Share capital		2,006	3,102	3,102
Premiums related to share capital		120,705	97,618	48,975
Reserves		(24,616)	(25,293)	(29,765)
Translation reserve		1,744	1,215	1,402
Net loss for the period		(73,300)	(53,797)	(228)
<b>Total shareholders' equity</b>	4.6	<b>26,539</b>	<b>22,845</b>	<b>23,487</b>
<b>Non-current liabilities</b>				
Provisions - non-current portion	4.7	652	524	419
Financial liabilities – non-current portion	4.8	14,379	15,232	7,547
Derivative liabilities - non current portion	4.8.1	288	—	—
Lease liabilities - non-current portion	4.90	9,197	8,162	2,680
Deferred tax		—	—	—
<b>Total Non-current liabilities</b>		<b>24,516</b>	<b>23,918</b>	<b>10,646</b>
<b>Current liabilities</b>				
Provisions - current portion	4.7	—	—	314
Financial liabilities – current portion	4.8	2,265	164	2,565
Derivative liabilities - current portion	4.8.1	129	—	—
Lease liabilities - current portion	4.90	1,607	1,817	775
Trade and other payables	4.1	20,910	14,154	5,115
Other current liabilities	4.1	4,436	3,870	2,909
<b>Total current liabilities</b>		<b>29,347</b>	<b>20,005</b>	<b>11,678</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>		<b>80,402</b>	<b>66,768</b>	<b>45,811</b>

The notes are an integral part of the accompanying Consolidated Financial Statements.

## CONSOLIDATED STATEMENT OF CASH FLOWS

(Amounts in thousands of euros)

	Notes	12/31/2020	12/31/2021	12/31/2022
<b>Cash flows from operating activities</b>				
<b>Net loss</b>		<b>(73,300)</b>	<b>(53,797)</b>	<b>(228)</b>
<b>Reconciliation of net loss and the cash used for operating activities</b>				
Gain or loss on exchange		3,028	(3,570)	(510)
Amortization and depreciation	3.4	4,991	5,377	4,619
Provision		57	135	445
Extinguishment of conditional advance	4.8.2			(4,895)
Change in fair value of derivative liabilities		(652)	(1,175)	—
Expenses related to share-based payments	3.3	1,179	1,323	447
(Gain) or loss on disposal of property plant and equipment (1)		22	17	(23,893)
Interest expense (income)		2,150	2,073	(169)
Income tax expense (income)	3.6	3	2	521
<b>Operating cash flow before change in working capital</b>		<b>(62,522)</b>	<b>(49,615)</b>	<b>(23,663)</b>
(Increase) decrease in inventories		358	—	—
(Increase) decrease in trade and other receivables	4.4	33	(8)	(63)
(Increase) decrease in other current assets	4.4	2,829	(94)	2,734
Increase (decrease) in trade and other payables	4.10	6,913	(6,477)	(9,220)
Increase (decrease) in other current liabilities	4.10	669	(574)	(1,548)
<b>Change in working capital</b>		<b>10,802</b>	<b>(7,153)</b>	<b>(8,098)</b>
Income tax paid		—	(2)	(3)
<b>Net cash flow used in operating activities</b>		<b>(51,720)</b>	<b>(56,770)</b>	<b>(31,764)</b>
<b>Cash flows from investing activities</b>				
Acquisition of property, plant and equipment	4.1.2	(1,139)	(298)	(85)
Acquisition of intangible assets	4.1.1	(2)	—	—
Increase in non-current & current financial assets	4.3	(421)	(192)	(5)
Disposal of property, plant and equipment	3.1	83	—	37,630
Decrease in non-current & current financial assets	4.3	4	145	586
<b>Net cash flow from/(used in) investing activities</b>		<b>(1,475)</b>	<b>(345)</b>	<b>38,127</b>
<b>Cash flows from financing activities</b>				
Capital increases, net of transaction costs	4.6	118	34,631	—
Subscription of warrants		12	—	—
Proceeds from borrowings, net of transaction costs	4.8	27,134	12,157	3,081
Repayment of borrowings	4.8	(62)	—	(3,081)
Allowance received from a lessor	4.9	188	—	—
Repayment of lease liability (IFRS 16)	4.9	(1,615)	(1,702)	(1,545)
Interests received (paid)		(326)	(374)	(223)
<b>Net cash flow from (used in) financing activities</b>		<b>25,449</b>	<b>44,712</b>	<b>(1,768)</b>
Exchange rate effect on cash in foreign currency		(981)	1,656	495
<b>Increase (Decrease) in cash and cash equivalents</b>		<b>(28,727)</b>	<b>(10,747)</b>	<b>5,090</b>
Net cash and cash equivalents at the beginning of the period	4.5	73,173	44,446	33,699
Net cash and cash equivalents at the closing of the period	4.5	44,446	33,699	38,789
Cash paid for interest		326	374	223

(1) including €24,350 thousand related to Catalent sale of Princeton manufacturing facility (see note 3.1) and disposal of other equipment for €457 thousand (see note 4.1.2).

The notes are an integral part of the accompanying Consolidated Financial Statements.

**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**

<u>(Amount in thousands of euros, except number of shares)</u>	Share capital	Premiums related to the share capital	Reserves	Translation reserve	Net income (loss)	Total shareholders' equity
<b>As of December 31, 2019</b>	<b>1,794</b>	<b>281,688</b>	<b>(136,607)</b>	<b>1,344</b>	<b>(62,659)</b>	<b>85,560</b>
Net loss for the period					(73,300)	(73,300)
Other comprehensive income			(19)	400		381
<b>Total comprehensive income (loss)</b>	<b>—</b>	<b>—</b>	<b>(19)</b>	<b>400</b>	<b>(73,300)</b>	<b>(72,919)</b>
Allocation of prior period loss		(54,208)	(8,451)		62,659	—
Allocation of reserves on premiums		(119,282)	119,282			—
Issue of ordinary shares	212	12,507				12,719
Share-based payment			1,179			1,179
<b>As of December 31, 2020</b>	<b>2,006</b>	<b>120,705</b>	<b>(24,616)</b>	<b>1,744</b>	<b>(73,300)</b>	<b>26,539</b>
Net loss for the period					(53,797)	(53,797)
Other comprehensive income			68	(528)		(460)
<b>Total comprehensive income (loss)</b>	<b>—</b>	<b>—</b>	<b>68</b>	<b>(528)</b>	<b>(53,797)</b>	<b>(54,257)</b>
Allocation of prior period loss (3)		(71,037)	(2,263)		73,300	—
Other			195			195
Transaction costs (2)		(3,811)				(3,811)
Issue of ordinary shares (1)	1,096	51,746				52,842
Issue of warrants		15				15
Share-based payment			1,323			1,323
<b>As of December 31, 2021</b>	<b>3,102</b>	<b>97,618</b>	<b>(25,293)</b>	<b>1,215</b>	<b>(53,797)</b>	<b>22,845</b>
Net loss for the period					(228)	(228)
Other comprehensive income			235	187		422
<b>Total comprehensive income (loss)</b>	<b>—</b>	<b>—</b>	<b>235</b>	<b>187</b>	<b>(228)</b>	<b>194</b>
Allocation of prior period loss (3)		(48,643)	(5,154)		53,797	—
Share-based payment			447			447
<b>As of December 31, 2022</b>	<b>3,102</b>	<b>48,975</b>	<b>(29,765)</b>	<b>1,402</b>	<b>(228)</b>	<b>23,487</b>

(1) of which €31,826 thousand as result of the Registered Direct Offerings in April (€24,867 thousand) and in December 2021 (€6,957 thousand) ; €6,616 thousand related to the ATM and €14,400 thousand related to the conversion of five tranches of OCABSA.

(2) Related to capital increase

(3) For each of the year presented the standalone net loss of Erytech Pharma SA has been allocated to the Premiums pursuant to a shareholders meeting decision.

The notes are an integral part of the accompanying Consolidated Financial Statements.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The Consolidated Financial Statements were authorized for issuance by the Board of Directors on March 22, 2023.

### 1. DESCRIPTION OF THE BUSINESS

ERYTECH Pharma S.A. (“**ERYTECH**,” and together with its subsidiary the “**Company**”) is incorporated in Lyon, France, and was founded in 2004 to develop and market innovative red blood cell-based therapeutics for cancer and orphan diseases.

The Company completed its initial public offering on Euronext Paris in May 2013, raising €17.7 million, and on the Nasdaq Global Select Market in November 2017, raising €124.0 million (\$144.0 million on a gross basis before deducting offering expenses).

The Company has incurred losses and negative cash flows from operating activities since its inception and had shareholders’ equity of €23,487 thousand as of December 31, 2022 as a result of several financing rounds, including an initial public offering. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenue from its product candidates in development.

The Company’s future operations are highly dependent on a combination of factors, including: (i) the success of its proposed merger with Pherecydes (strategic partnership, refer to note 2.9) ; (ii) the success of the research and development of this newly formed "Combined Company"; (iii) regulatory approval and market acceptance of the "Combined Company" proposed future products; (iv) the timely and successful completion of additional financing; and (v) the development of competitive therapies by other biotechnology and pharmaceutical companies. As a result, the Company is and should continue, in the short to mid-term, to be financed through the issuance of new debt or equity instruments.

The situation on the financial markets and uncertainty in the research and development result may impair the ability of the Company to raise capital when needed or on attractive terms.

The accompanying consolidated financial statements and related notes (the “**Consolidated Financial Statements**”) present the operations of ERYTECH Pharma S.A. and its subsidiary, ERYTECH Pharma, Inc.

Registered office of ERYTECH Pharma S.A.: 60 avenue Rockefeller, 69008, Lyon, France.

### Major events of 2022

#### Business

#### February 2022: Impact of the Conflict in Ukraine on Our Business

Beginning on February 24, 2022, Russia significantly intensified its military operations in Ukraine.

We are closely monitoring developments in the current context and will take appropriate measures as necessary. The war in Ukraine did not impact our financial results for the period ended on December 31, 2022. Our business does not conduct any trial in Ukraine, Russia or Belarus and does not have any asset or vendors located in these regions.

#### April 2022:

- Sale of ERYTECH’s U.S. cell therapy manufacturing facility to Catalent

Under the terms of an asset purchase agreement between the Group ERYTECH and Catalent (the “APA”), Catalent agreed to acquire ERYTECH’s state-of-the-art commercial-scale cell therapy manufacturing facility in Princeton, New Jersey, for a total gross consideration of \$44.5 million (€40.7 million) paid at closing. Catalent has extended offers of employment to approximately 40 people employed by Erytech at the Princeton facility.

The net profit on the sale of the property, plant and equipments, lease contract, after transaction cost ( \$3.3 million, €3.0 million) and before tax amounts to 26.6 million dollars (€24.3 million euros) and was recorded as other income in the consolidated statement of income (loss) .

- New vesiculation technology

The company presented its red blood cell vesiculation technology at the 24th Meeting of the European Red Cell Society (ERCS) in April 2022.

#### May 2022:

- The NOPHO trial evaluated the safety and pharmacological profile of eryaspase in acute lymphoblastic leukemia (ALL) patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. In December 2020, positive trial results were presented at the 2020 American Society of Hematology annual meeting. See section 2.2. – activities of the Group and 2.5 - events after the reporting period for further information.
- Following the Catalent transaction, the company continues to evaluate other strategic options for leveraging its ERYCAPS® platform with complementary assets and/or a broader corporate transaction.
- On May 25, 2022, the management of Erytech Pharma (France) informed the employees of the start of a collective redundancy procedure, a job protection plan, involving the cuts of 52 positions out of 109. The consultation phase of the CSE has ended on July 31, 2022. All terminations took place during the fourth quarter 2022.

#### July /August 2022:

ERYTECH Pharma announced that it no longer seek approval for Graspas® in hypersensitive acute lymphoblastic leukemia (ALL) following feedback from the U.S. Food and Drug Administration (FDA).

Following the sale of its production facility in Princeton, New Jersey, for \$44.5 million in April 2022, the Company appointed a specialized advisor to evaluate strategic options to leverage its ERYCAPS® platform with complementary assets and/or a broader corporate transaction.

#### October 2022

ERYTECH announced Receipt of Nasdaq Notice dated October 7, 2022, indicating that, based upon a closing bid price of less than \$1.00 per share for the Company's American Depositary Shares ("ADSs") for the prior 30 consecutive business day period, the Company no longer satisfies Nasdaq Listing Rule 5450(a)(1). The Notification Letter has no immediate effect on the listing of the ADSs and ERYTECH.

ERYTECH intends to regain compliance within the applicable compliance period and is currently evaluating its options to do so. During this time, the Company's ADSs will continue to be listed and trade on The Nasdaq Global Select Market and the Company's business and operations are not affected by the receipt of the Notification Letter.

#### November 2022

- Graspas program halted after FDA feedback on envisaged BLA submission in hypersensitive ALL

Considering also the earlier setback of a failed Phase 3 trial in pancreatic cancer, and a non-conclusive early readout of first patients in a Phase 2 trial in TNBC, both with the same product candidate, ERYTECH concluded to halt further development with Graspas®, L-asparaginase encapsulated in donor red blood cells, until then the lead candidate for ERYTECH, and focus on its most promising preclinical programs.

- Promising preclinical development with ERYCEV™, novel red blood cell vesiculation technology

RBC-derived extracellular vesicles are formed naturally during senescence and storage of mature RBCs and are a potentially attractive drug delivery system. Vesiculation of RBCs that have already been loaded with active therapeutic compounds utilizing the ERYCAPS® process, entails the potential of producing cargo-loaded RBC-derived extracellular vesicles for the development of novel therapeutic approaches. ERYCEV results to date illustrate the versatility of ERYTECH's encapsulation science in RBCs and its potential for leverage in further partnered developments.

- In connection with the halt of the Company's lead program Graspas, a restructuring program was initiated earlier this year. Those deep restructuring operations are fully implemented at the end of 2022.

The staff reduction in France was approved by labor authorities in September 2022 and is fully implemented. Combined with the approximately 40 people who transferred to Catalent after the sale of the Company's manufacturing facility in Princeton, the global team size was reduced by 75% compared to the start of this year. The Company has retained its R&D team and its expertise in key

functional areas to keep the ability to restart a pipeline of partnered development programs and maintain a fully operational dual listed company.

## **Major events of 2021**

### **Business**

#### March 2021

- On March 2, 2021, ERYTECH has called a 6th OCABSA tranche for net proceeds of €2.9 million and has made a placement of 744,186 newly issued shares in the United States through its at-the-market ((ATM) equity financing program for the net proceeds of €6.4 million.

#### April 2021

- The company announced a \$30.0 million Registered Direct Offering, after entering into definitive agreements with specified categories of investors for the purchase and sale of 1,034,483 units (“Units”), each Unit consisting of four ordinary shares in the form of American Depositary Shares (each an “ADS”) and three warrants, each to purchase one ordinary share (each a “Warrant”). The issuance of the 4,137,932 new ordinary shares underlying the ADSs resulted in an immediate capital increase of €24,868,971.30 (divided into a nominal amount of €413,793.20 and a total issuance premium of €24,455,178.10 and corresponding to a nominal value of ten cents (€0.10) plus an issuance premium of €5.91 per share issued), representing approximately 19.12% of the Company’s share capital and voting rights outstanding before the offering.

#### May 2021

- On May 19, 2021, ERYTECH has called a 7th OCABSA tranche for net proceeds of €2.9 million
- July and August 2021
- The U.S. Food and Drug Administration (FDA) granted eryaspase Fast Track designation for the treatment of acute lymphocytic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase (PEG-ASNase). On July 22, 2021 and August 24, 2021, ERYTECH has called a 8th and 9th OCABSA tranches for net proceeds of €5.7 million.

#### October 2021

- The Company announced Maximum Tolerated Dose Declared in a Phase 1 Investigator Sponsored Trial of Eryaspase in First-Line Pancreatic Cancer
- The Company announced Results from TRYbeCA-1 Phase 3 Trial of Eryaspase in Patients with Second-line Advanced Pancreatic Cancer. The trial did not meet its primary endpoint of overall survival.

#### December 2021

- The Company announced \$7.85 million Registered Direct Offering, after entering into definitive agreements with specified categories of investors for the purchase and sale of 769,608 units (“Units”), each Unit consisting of four ordinary shares in the form of American Depositary Shares (each an “ADS”) and three warrants, each to purchase one ordinary share (each a “Warrant”). The issuance of the 3,078,432 new ordinary shares underlying the ADSs will result in an immediate capital increase of €6,957,256.32 (divided into a nominal amount of €307,843.20 and a total issuance premium of €6,649,413.12 and

corresponding to a nominal value of ten cents (€0.10) plus an issuance premium of €2.16 per Share issued), representing approximately 11.02% of the Company's share capital and voting rights outstanding before the offering.

## **Major events of 2020**

### **Business**

#### February 2020:

- The Company received from Bpifrance a reimbursable advance of €2,979 thousand and a subsidy of €294 thousand (recorded in 2019) under the milestone n°6 of the TEDAC project.
- The Company entered into a strategic partnership with the German Red Cross Blood Donor Service Baden-Württemberg-Hessen (GRCBDS) for the supply of donor red blood cells to manufacture its product candidates, including eryaspase, in Europe and to complement the existing alliance with the French Blood Bank (EFS).

#### March 2020:

- The TRYbeCA-1 trial has continued to progress despite the challenges caused by the impact of the COVID-19 global pandemic, and patient enrollment has continued notwithstanding the increasing difficulties experienced by hospitals to organize the proper treatment and follow-up.
- The independent data monitoring committee (IDMC) of the TRYbeCA-1 trial reviewed the safety data of the first 320 patients enrolled and treated. In line with the two earlier safety reviews of the trial, no safety issues were identified, and the IDMC recommended the Company to continue the trial as planned.

#### April 2020:

- The U.S. Food and Drug Administration (FDA) has granted the Company Fast Track Designation for the development of eryaspase as a second-line treatment of patients with metastatic pancreatic cancer.

#### May 2020:

- The Company announced it will be part of EVIDENCE, a public-private consortium supported by the European Union in the framework of the EU Horizon 2020 program. The EVIDENCE consortium, consisting of leading experts in the field of red blood cell research, will explore how red blood cells are influenced by their extra-cellular environment.

#### June 2020:

- The Company announced that the ongoing Phase 2 clinical trial, sponsored by the Nordic Society of Paediatric Haematology and Oncology (NOPHO) of eryaspase in second-line acute lymphoblastic leukemia (ALL) patients has reached its target enrollment of 50 patients. Preliminary findings of the trial suggest that eryaspase achieved the target level and duration of asparaginase activity in these patients. Moreover, the addition of eryaspase to the combination chemotherapy was associated with an acceptable tolerability profile, enabling the majority of these patients to receive their fully intended courses of asparaginase. Recent data have confirmed that discontinuation of asparaginase therapy in ALL patients has been associated with inferior disease free survival.
- The Company signed a financing agreement with Luxembourg-based European High Growth Opportunities Securitization Fund, represented by its asset manager European High Growth Opportunities Manco SA (entities related to Alpha Blue Ocean), in the form of convertible notes with share subscription warrants attached ("OCABSA"), allowing a potential financing arrangement of up to a maximum of €60 million, subject to the regulatory limit of 20% dilution.

#### July/August 2020:

- As part of the convertible notes' agreement signed in June 2020, the Company issued two tranches of €3 million each (60 OCABSA) on July 6, 2020 and on August 24, 2020, respectively.

#### September 2020:

- The Company established a financing facility with the implementation of an at-the-market program on Nasdaq with Cowen allowing the Company to issue and sell ordinary shares in the form of American Depositary Shares ("ADSs"), to eligible investors at market prices, with aggregate gross sales proceeds of up to \$30 million (subject to a regulatory limit of 20% dilution), from time to time, pursuant to the terms of a sales agreement.

November 2020:

- The Company received two loans of €5.0 million each, in the form of State-Guaranteed Loan (Prêt Garanti par l'Etat, or PGE, in France) with Bpifrance and Société Générale in the context of the COVID-19 pandemic.

November/December 2020:

- As part of the convertible notes' agreement signed in June 2020, the Company issued three tranches of €3.0 million each (60 OCABSA) on November 17, 2020, December 7, 2020 and December 22, respectively.

December 2020:

- The Company announced positive results from eryaspase Phase 2 Trial in Acute Lymphoblastic Leukemia ("ALL"). The study confirms the potential of eryaspase as an attractive treatment option for ALL patients with hypersensitivity to PEG-asparaginase. The Phase 2 NOR-GRASPALL-2016 trial evaluated the safety and pharmacological profile of eryaspase in ALL patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. The trial was conducted by the Nordic Society of Pediatric Hematology and Oncology (NOPHO). Primary objectives of the trial were asparaginase enzyme activity and safety. Both endpoints were met.
- The Company announced the completion of enrollment in the TRYbeCA-1 Phase 3 trial in second-line pancreatic cancer.

**Management**

March 2020:

- Appointment of Melanie Rolli, M.D., as member of the Company's Board of Directors.

October 2020:

- Appointment of Stewart Craig as Chief Technical Officer

**2. ACCOUNTING RULES AND METHODS**

**2.1. Basis of preparation**

The Consolidated Financial Statements have been prepared in accordance with the underlying assumptions of going concern. The Company's loss-making situation is explained by the innovative nature of the products developed, therefore involving a multi-year research and development phase.

The Company has historically financed its growth by strengthening its equity in the form of capital increases and issuance of convertible notes.

The Board of Directors authorized the consolidated financial statements on a going concern basis as the Company will be able to fund its operations beyond the next 12 months after the closing date, considering:

- Cash and cash equivalents held by the Company amounted to €38.8 million as of December 31, 2022. They are composed of cash and term deposits readily available without penalty;
- The cash consumption forecast for the next 12 months after the closing date.

In the longer term, the Company will have to find additional funding. Various financing sources are considered among which the issuance of new debt or equity instruments and partnership agreements.

The Consolidated Financial Statements have been prepared in accordance with the historical cost principle with the exception of certain categories of assets and liabilities measured at fair value in accordance with IFRS.

All amounts are expressed in thousands of euros, unless stated otherwise.

## 2.2 Statement of compliance

The Consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standard Board (“IASB”) and were authorized for issuance by the Board of Directors of the Company on March 22, 2023. They will be subject to the approval of the General Meeting on June 23, 2023.

Due to the listing of ordinary shares of the Company on Euronext Paris and in accordance with the European Union’s regulation No. 1606/2002 of July 19, 2002, the Consolidated Financial Statements of the Company are also prepared in accordance with IFRS, as adopted by the European Union (EU).

As of December 31, 2022, all IFRS that the IASB had published and that are mandatory are the same as those endorsed by the EU and mandatory in the EU. As a result, the Consolidated Financial Statements comply with International Financial Reporting Standards as published by the IASB and as adopted by the EU.

IFRS include International Financial Reporting Standards (“IFRS”), International Accounting Standards (“IAS”), as well as the interpretations issued by the Standing Interpretations Committee (“SIC”), and the International Financial Reporting Interpretations Committee (“IFRS IC”). The main accounting methods used to prepare the Consolidated Financial Statements are described in the corresponding notes. These methods were used for all periods presented.

The new applicable standards, amendments and interpretations since January 1, 2022 have had no significant impact on the Company’s consolidated financial statements.

Recently issued accounting pronouncements that may be relevant to the Company’s operations are as follows:

- Amendments to IAS 1 - *Classification of liabilities as current or non-current; Disclosure of Accounting Policies, effective on January 1, 2024;*
- Amendments to IAS 8 - *Definition of Accounting Estimates, effective on January 1, 2023 .*

The Company does not expect any significant impact resulting from the future adoption of these standards

## 2.3 Basis of consolidation

In accordance with IFRS 10 *Consolidated Financial Statements* (“IFRS 10”), an entity is consolidated when it is controlled by the Company. The Company controls an entity when it is exposed 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. All intercompany balances, transactions and dividends are eliminated in full. The Company has one subsidiary for which no non-controlling interest is recognized.

	<b>Date of Incorporation</b>	<b>Percent of Ownership Interest</b>	<b>Accounting Method</b>
ERYTECH Pharma, Inc.	April 2014	100%	Consolidated

There was no change in the consolidation scope over the years presented.

## 2.4. Foreign currencies

### *Functional Currency and Translation of Financial Statements into Presentation Currency*

The Consolidated Financial Statements are presented in euros, which is also the functional currency of the parent company, ERYTECH Pharma S.A. (the “**Parent Company**”). The statement of financial position of the consolidated entity having a functional currency different from the euro are translated into euros at the closing exchange rate (spot exchange rate at the statement of financial position date) and the statement of income (loss), statement of comprehensive income (loss) and statement of cash flow of such consolidated entity are translated at the average exchange rate for the period, except if exchange rates or the volume and size of transactions fluctuate significantly. The resulting translation adjustment is included in other comprehensive income (loss) as a cumulative translation adjustment.

<b>Exchange rate (USD per EUR)</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	<b>12/31/2022</b>
Weighted average rate	1.1413	1.1835	1.0539
Closing rate	1.2271	1.1326	1.0666

### *Conversion of Foreign Currency Transactions*

Foreign currency transactions are converted to functional currency at the exchange rate applicable on the transaction date. At the closing date, foreign currency monetary assets and liabilities are converted at the exchange rate prevailing on that date. The resulting exchange gains or losses are recorded in the consolidated statement of income (loss) in “Financial income (loss)”.

## 2.5 Use of estimates and judgments

Preparation of the consolidated financial statements in accordance with the rules prescribed by the IFRS requires the use of estimates and the formulation of assumptions having an impact on the financial statements. These estimates can be revised where the circumstances on which they are based change. The actual results may therefore differ from the estimates initially formulated. The Company has not identified any environmental risks that would require significant new estimates or judgments. The use of estimates and judgment relate primarily to the measurement of:

- the hospital costs accrual (see note 4.10).
- recoverable value of right-of-use and tangible fixed assets (see note 4.1 and 4.2).
- the share-based payments in accordance with IFRS 2 (see note 3.3.3);
- the fair value of the convertible notes' agreement and its classification in accordance with IFRS 9 and IAS 32 (see note 4.8.1);

## 2.6 Presentation of the statement of income (loss) & statement of financial position

The Company presents its statement of income (loss) by function. As of today, the main activity of the Company is the research and development. Consequently, only “research and development expenses” and “general administrative expenses” functions are considered to be representative of the Company's activities. The detail of the expenses by nature is disclosed in note 3.2.

## 2.7 Presentation of the statement of cash flows

The consolidated statements of cash flows are prepared using the indirect method and separately present the cash flows associated with operating, investing, and financing activities.

## 2.8 Segment reporting

In accordance with IFRS 8 *Operating Segments* (“**IFRS 8**”), reporting by operating segment is derived from the internal organization of the Company’s activities; it reflects management’s viewpoint and is established based on internal reporting used by the chief operating decision maker (the Chief Executive Officer) to allocate resources and to assess performance.

### Information per business segment

The Company operates in a single operating segment: the conducting of research and development of innovative red blood cell-based therapeutics for cancer and orphan diseases in order to market them in the future.

### Information per geographical segment

<b>Income from external customers (amounts in thousands of euros)</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	<b>12/31/2022</b>
France	61	0	60
United States	185	128	134
<b>Total</b>	<b>246</b>	<b>128</b>	<b>194</b>

<b>Non current assets (amounts in thousands of euros)</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	<b>12/31/2022</b>
France	8,414	6,325	3,140
United States	21,265	19,520	37
<b>Total</b>	<b>29,679</b>	<b>25,845</b>	<b>3,177</b>

### **2.9 Events after the close of the reporting period**

**On January 20, 2023**, Erytech Pharma received from the French tax authorities a notice of tax audit. This tax audit concerns the fiscal years ending on 12/31/2020 and 12/31/2021. The Company awaits the comments of the tax authorities following the first meeting held on February 8, 2023.

**On February 15, 2023** ERYTECH and PHERECYDES announced a Proposed Combination intending to create a Global Leader in extended phage therapies.

This strategic combination would build on complementary expertise and capabilities of both companies to accelerate development of extended phage therapies for antimicrobial resistance (AMR), in particular via the phase II PhagoDAIR study conducted by PHERECYDES, as well as other anti-infective fields and therapeutic areas with high unmet medical needs.

Under the terms of the Memorandum of Understanding, PHERECYDES shareholders would receive 15 new ERYTECH shares for every 4 PHERECYDES shares they currently own. Upon completion of the transaction, PHERECYDES shareholders are expected to hold approximately 49.5% of the share capital and voting rights of ERYTECH.

Transaction is expected to close at the end of the second quarter of 2023.

### **3. NOTES RELATED TO THE CONSOLIDATED STATEMENT OF INCOME (LOSS)**

### 3.1 Operating income

#### Accounting policies

##### Research tax credit

The research tax credit (Crédit d'Impôt Recherche or "CIR") (the "Research Tax Credit") is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Union or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that (a) can be used for the payment of the corporate tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, (b) as applicable, can be reimbursed in cash. The expenses taken into account for the calculation of the Research Tax Credit involve only research expenses.

The Company has benefited from the Research Tax Credit since its inception.

The CIR is presented under operating income as it meets the definition of government grant as defined in IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance* ("IAS 20").

##### Subsidies

Subsidies received that are not repayable by the Company are recognized as operating income where there exists reasonable assurance that the Company will comply with the conditions attached to the subsidies and the subsidies will be received.

Subsidies that are upfront payments are presented as deferred revenue and recognized ratably through income over the duration of the research program to which the subsidy relates.

A public subsidy that is to be received either as compensation for expenses or for losses already incurred, or for immediate financial support of the Company without associated future costs, is recognized as operating income when there exists reasonable assurance that the subsidies will be received.

##### Revenues from licenses or other contracts

For each of its partnership agreements, the Company determines if it acts as a principal or as an agent in accordance with IFRS 15 *Revenue from contracts with customers* ("IFRS 15").

##### Partnership with Orphan Europe NOPHO clinical trial

Within the context of this agreement, Orphan Europe agreed to finance the NOPHO study for a total amount of €600 thousand. This Income is recognized in "other income" in the statement of income (loss).

##### License agreement with SQZ Biotechnologies ("SQZ")

Under the term of the agreement, the Company has granted SQZ Biotechnologies an exclusive worldwide license to develop antigen specific immune modulating therapies employing red blood cell-based approaches. In accordance with IFRS15, this agreement grants to SQZ Biotechnologies a right to use the underlying intellectual property ("static license"). Consequently, the income linked to the upfront payment (€1 million) was recognized in June 2019 when SQZ Biotechnologies could begin to use the licensed intellectual property.

The Company does not generate any revenue from the sale of its products considering its stage of development.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Research Tax Credit	3,430	3,669	1,486
Subsidies and extinguishment of conditional advance (1)	42	383	4,968
Income from licenses or other contracts	246	128	194
Net gain on disposal of tangible assets			24,351
<b>Total</b>	<b>3,718</b>	<b>4,180</b>	<b>30,998</b>

(1) The extinguishment of BPI conditional advance on TEDAC research program for €4,895 thousand is discussed in note 4.8.2.

The reduction in the research tax credit is related to the end of the TRYbeCA1 clinical trial.

The net gain from the disposal of fixed assets is related to the sale of the Princeton plant to Catalent and breaks down as follows :

- Proceeds from the sale of €40,676 thousand (\$44,500 thousand);
- The net book value of tangible fixed assets of €15,673 thousand (\$17,146 thousand);
- The net book value of intangible fixed assets of €4 thousand (\$4 thousand)
- The net book value of the rights of use for €3,022 thousand (\$3,307 thousand);
- The cancellation of the lease obligation for €5,419 thousand (\$5,928 thousand);
- Transaction costs of €3,046 thousand (\$3,333 thousand)

### 3.2 Operating expenses by nature

#### 3.2.1 Research and development expenses

For the year ended December 31, 2020 (amounts in thousands of euros)	R&D	Clinical studies	Total
Consumables	54	6,732	6,786
IT costs and maintenance	117	1,162	1,279
Services, subcontracting and fees	1,099	28,487	29,586
Personnel expenses	2,268	13,361	15,629
Depreciation and amortization	283	3,951	4,234
Other	25	41	66
<b>Total</b>	<b>3,846</b>	<b>53,734</b>	<b>57,580</b>

For the year ended December 31, 2021 (amounts in thousands of euros)	R&D	Clinical studies	Total
Consumables	151	4,849	5,000
IT costs and maintenance	116	1,366	1,482
Services, subcontracting and fees	589	17,480	18,069
Personnel expenses	1,960	13,633	15,593
Depreciation and amortization	353	4,531	4,884
Other	17	55	72
<b>Total</b>	<b>3,186</b>	<b>41,914</b>	<b>45,100</b>

For the year ended December 31, 2022 (amounts in thousands of euros)	R&D	Clinical studies	Total
Consumables	165	1,019	1,184
IT costs and maintenance	45	949	994
Services, subcontracting and fees	395	1,287	1,682
Personnel expenses	1,883	9,576	11,459
Depreciation, amortization & impairment	444	3,548	3,992
Other	82	514	596
<b>Total</b>	<b>3,014</b>	<b>16,893</b>	<b>19,907</b>

The €25.2 million significant decrease in research and development expenses between 2022 and 2021 can be explained by:

- a decrease of €16.4 million of services and subcontracting expenses:
  - TRYbeCA-1 study cost decreased by \$14.5 million, of which patient cost for €5.3 million, CRO cost for €5.9 million, Graspera production cost for €1.5 million and other clinical vendors for €1.8 million, following the negative result of the study at the end of 2021 .
  - TRYbeCA-2 cost decreased by €0.9 million (including €0.6 million for patient cost) and NOPHO cost decreased by €0.3 million.
- a decrease in consumable of €3.8 million, as no additional purchase of Eryaspase were made in 2022.
- a decrease of €4.1 million of personnel expenses, with the transfer to Catalent of Princeton manufacturing facility employees in April 2022 and the restructuring plan in Lyon completed in the fourth quarter 2022. The average number of full-time employees allocated to our research and development workforce decreased from 152 in 2021 to 93 in 2022. The personnel expense in 2022 includes a Lyon (France) restructuring charge of €1.3 million (refer to note 1 and 4.6).
- a net decrease in depreciation and amortization expenses of €- 0.9 million in 2022, mainly related to:
  - the decrease in depreciation of the Princeton Manufacturing facility sold to Catalent for €2.0 million
  - the decrease in amortization and impairment of intangible assets of €0.6 million in 2022 (due to impairment loss recorded in 2021 on the Troy project)
  - an impairment charge of €1.7 million in 2022 for the facilities, fixtures, equipment and rights of use of the Adenine production unit in France (refer to notes 4.1.3 and 4.2).

The €12.5 million decrease in research and development expenses between 2021 and 2020 can be explained by:

- the decrease of €11.5 million in external services mainly linked to decrease in clinical study expenses (Clinical Research Organization vendor and Patients site cost).
- the decrease of €1.8 million in consumables, mainly related to reduction of purchase of Asparagynase (Graspera production key component used in clinical trial for patient treatment)

### 3.2.2. General and administrative expenses

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Consumables	224	226	93
IT Costs and maintenance	1,070	1,129	1,048
Services, subcontracting and fees	5,962	6,684	6,477
Personnel expenses	6,573	6,174	5,013
Depreciation and amortization	686	494	627
Other	455	888	630
<b>Total</b>	<b>14,970</b>	<b>15,595</b>	<b>13,887</b>

The 0.6 million euro increase of general and administrative expenses between 2020 and 2021 is explained mostly by insurance premium increase of €1,323 thousand and personnel expenses decrease €399 thousand.

The €1.71 million decrease of general and administrative expenses between 2021 and 2022 is explained mostly by personnel expenses reductions. G&A personnel expenses decreased by €1.2 million in 2022, with the combined effects of employees resignations and a restructuring plan in Lyon . The average number of full-time employees allocated to our G&A workforce decreased from 42 in 2021 to 26 in 2022. The personnel expense in 2022 includes a Lyon (France) restructuring charge of €0.4 million (refer to note 1 and 4.6).

### 3.3 Personnel expenses

### 3.3.1. Research and development expenses

For the year ended December 31, 2020 (amounts in thousands of euros)	R&D	Clinical studies	Total
Wages and salaries	1,579	9,886	11,465
Share-based payments (employees and executive management)	24	507	531
Social security expenses	665	2,968	3,633
<b>Total personnel expenses</b>	<b>2,268</b>	<b>13,361</b>	<b>15,629</b>

For the year ended December 31, 2021 (amounts in thousands of euros)	R&D	Clinical studies	Total
Wages and salaries	1,318	10,106	11,424
Share-based payments (employees and executive management)	110	570	680
Social security expenses	532	2,957	3,489
<b>Total personnel expenses</b>	<b>1,960</b>	<b>13,633</b>	<b>15,593</b>

For the year ended December 31, 2022 (amounts in thousands of euros)	R&D	Clinical studies	Total
Wages and salaries	1,348	7,748	9,096
Share-based payments (employees and executives)	0	(44)	(44)
Social security expenses	535	1,872	2,407
<b>Total personnel expenses</b>	<b>1,883</b>	<b>9,576</b>	<b>11,459</b>

The weighted average full-time employees (FTE) was 166 in 2020, 152 in 2021 and 93 in 2022.

### 3.3.2. General and administrative expenses

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Wages and salaries	4,393	4,032	3,399
Share-based payments (employees and executive management)	532	561	442
Social security expenses	1,648	1,581	1,172
<b>Total personnel expenses</b>	<b>6,573</b>	<b>6,174</b>	<b>5,013</b>

The weighted average full-time employees (FTE) was 41 in 2020, 42 in 2021 and 26 in 2022.

### 3.3.3. Share-based payments (IFRS 2)

#### Accounting policies

The Company has applied IFRS 2 *Share-based payment* (“IFRS 2”) to all equity instruments e.g. free shares (“AGA”), stock options (“SO”), share subscription warrants (“BSA”) and founder subscription warrants (“BSPCE”) granted since inception to its employees, members of the Board of Directors or other individuals. Pursuant to IFRS 2, the cost of the remuneration granted with equity instruments is recognized as an expense in exchange for an increase in the shareholders’ equity for the vesting period during which the rights to be enjoyed from the equity instruments are acquired. As such, changes in value subsequent to the grant date have no effect on this initial measurement.

Fair value is estimated using the Black & Scholes valuation model (for BSA, SO and BSPCE valuation) and Monte-Carlo valuation model (for AGA valuation). These models allow the Company to take into account the characteristics of the plan (exercise price, vesting period), the market data at the grant date (volatility, expected dividends, repo margin), possible performance conditions attached to warrants and recipient behavior assumptions.

The Company has no legal or constructive obligation to repurchase or settle any of these equity instruments in cash.

**Founder subscription warrants (“BSPCE”) plan**

<b>Types of securities</b>	<b>BSPCE2012</b>	<b>BSPCE2014</b>
Maturity	May 20, 2020	January 22, 2024

In the event of a beneficiary departure from the Company for any reason whatsoever, this beneficiary shall retain the BSPCE<sub>2014</sub> to which he subscribed prior to his departure. However, in the event of a beneficiary departure from the Company, for any reason whatsoever, prior to subscription of the BSPCE<sub>2014</sub> to which the beneficiary has a right, the BSPCE<sub>2014</sub> will be forfeited. In this situation, the BSPCE<sub>2014</sub> not subscribed may be re-allocated to other beneficiaries within the same category and/or replacing the person who left the Company.

**Share subscription warrants (“BSA”) plan**

<b>Types of securities</b>	<b>BSA2014</b>	<b>BSA2016</b>	<b>BSA2017</b>	<b>BSA2019</b>	<b>BSA2021</b>
Vesting period	NA	Tranche 1 : 1 year Tranche 2 : 2 years	Tranche 1 : 1 year Tranche 2 : 2 years Tranche 3 : 3 years	2 years	1 year
Maturity	January-2024	Depending of the grant date October-2021 January-2022	Depending of the grant date June-2022 January-2023	October-2022	October 2024

The main assumptions used to determine the fair value of the plans granted in 2021. The Company did not grant new BSA in 2020 and 2022.

	<u>Grant in July 2021</u>
Number of warrants	75,250
Plan	BSA <sub>2021</sub>
Exercise price	€3.82
Price of the underlying share	€3.55
Expected dividends	— %
Volatility (1)	55.16 %
Expected term	2.5 years
Fair value of the plan (in thousands of euros) (2)	82

(1) based on the historical volatility observed on the ERYP index on Euronext

(2) The acquisition price of the BSA granted in July 2021 was equal to the grant date fair value of the instrument. Therefore, no expense was recognized under IFRS 2.

**Stock options (“SO”) plan**

Types of securities	SO2016	SO2017	SO2018	SO2019	SO2020	SO2021
Vesting period (identical for all plans)	Tranche 1: 2 years Tranche 2: 3 years					
Maturity	Depending of the grant date October-2026 January-2027 June-2027 October-2027	Depending of the grant date June-2027 January-2028	Depending of the grant date September-2028 January-2029 April-2029	Depending of the grant date July-2029 October-2029 February-2030	Depending of the grant date July-2030 November-2030 June-2031	Depending of the grant date July-2031 December-2031

The main assumptions used to determine the fair value of the plans granted in 2020 and 2021 are presented in the tables below. The Company did not grant any SO in 2022.

	<u>Grant in February 2020</u>	<u>Grant in July 2020</u>
Number of options	41,950	374,000
Plan	SO2019	SO2020
Exercise price	€ 5.87	€ 6.88
Price of the underlying share	€ 5.51	€ 6.56
Expected dividends	0.00 %	0.00 %
Volatility (1)	41.35 %	43.41 %
Expected term	T1: 6 years T2: 6.5 years	
Fair value of the plan (in thousands of euros)	84	951

	Grant in November 2020		Grant in June 2021		Grant in July 2021		Grant in December 2021	
Number of options	75,000		57,000		377,550		149,000	
Plan	SO2020		SO2020		SO2021		SO2021	
Exercise price	€	6.14	€	4.78	€	3.71	€	2.14
Price of the underlying share	€	6.37	€	4.37	€	3.55	€	2.10
Expected dividends	0.00 %		0.00 %		0.00 %		0.00 %	
Volatility (1)	44.32 %		44.30 %		44.25 %		45.82 %	
Expected term			T1: 6 years T2: 6.5 years					
Fair value of the plan (in thousands of euros)	199		96		533		131	

(1) based on the historical volatility observed on the ERYP index on Euronext

### Free shares ("AGA") plan

Types of securities	AGA2017	AGA2018	AGA2019	AGA2020	AGA2021
Vesting period	Tranche 1: 1 year Tranche 2: 2 years Tranche 3: 3 years			Tranche 1: 1 year Tranche 2: 2 years Tranche 3: 3 years Tranche 4: 4 years Tranche 5: 5 years	

The main assumptions used to determine the fair value of the plans granted in 2020 and 2021 are presented in the table below. The Company did not grant new AGA in 2022.

	Grant in February 2020		Grant in July 2020	
Number of shares	50,037		250,012	
Plan	AGA 2019		AGA 2020	
Price of the underlying share	€	5.51	€6.56	
Expected dividends	0.00 %		0.00 %	
Volatility (1)	38.55 %		42.23 %	
Maturity	5 years		5 years	
Performance criteria	(2)		(2)	
ERYP	€	5.87	€	6.88
Performance multiple ("PM")	2		2	
Fair value of the plan (in thousands of euros)	133		877	

	Grant in June 2021	Grant in July 2021	Grant in December 2021
Number of shares	50,831	231,000	93,331
Plan	AGA 2020	AGA 2021	AGA 2021
Price of the underlying share	€ 4.37	€ 3.55	€ 2.10
Expected dividends	0.00 %	0.00 %	0.00 %
Volatility (1)	44.79 %	44.72 %	47.56 %
Maturity	5 years	5 years	5 years
Performance criteria	(2)	(2)	(2)
ERYP	€ 4.78	€ 3.71	€ 2.14
Performance multiple ("PM")	2	2	2
Fair value of the plan (in thousands of euros)	121	465	133

(1) based on the historical volatility observed on the ERYP index on Euronext

(2) performance criteria: progression of the quoted market share price between the grant date and the tranche acquisition date

- $TR_i = (ERYP_i - ERYP) / (ERYP \times (PM - 1))$  with  $ERYP_i$ :
  - average price of the 40-quoted market share price days before the acquisition date for grants until April 2019 ;
  - maximum between the share price at the acquisition date and the average price of the 20-quoted market share price days before the grant date discounted by 5% for grants from October 2019.
- If  $TR_i \leq 0\%$  no shares granted are acquired
- If  $TR_i > 100\%$  all the shares granted are acquired
- If  $0\% < TR_i < 100\%$  shares granted are acquired following the  $TR_i$  percentage

#### Breakdown of expenses per financial year

Plan name	Amount in P&L in euros thousands as of December 31, 2020	of which employees	of which executive officers and executive committee	of which board members
AGA	537	298	239	—
BSA	43	—	—	43
SO	599	189	410	—
<b>Total</b>	<b>1,179</b>	<b>487</b>	<b>649</b>	<b>43</b>

Plan name	Amount in P&L in euros thousands as of December 31, 2021	of which employees	of which executive officers and executive committee	of which board members
AGA	616	306	311	—
BSA	1	—	—	1
SO	706	193	432	82
<b>Total</b>	<b>1,323</b>	<b>499</b>	<b>743</b>	<b>83</b>

<b>Plan name</b>	<b>Amount in P&amp;L in euros thousands as of December 31, 2022</b>	<b>of which employees</b>	<b>of which executive officers and executive committee</b>	<b>of which board members</b>
AGA	246	(51)	297	—
BSA	—	—	—	—
SO	201	(22)	174	49
<b>Total</b>	<b>447</b>	<b>(73)</b>	<b>471</b>	<b>49</b>

There were no new instruments attributed in 2022. Due to the significant departures of the year, share based expenses in 2022 included a true up to account for actual forfeitures, which resulted in a net reversal for employees.

#### Summary of outstanding instruments

*Number of outstanding warrants (BSA) and founder's warrants (BSPCE) with a ratio of 1 option = 10 shares*

	<b>Number of BSA and BSPCE</b>	<b>Weighted-average exercise price</b>
<b>Outstanding at December 31, 2019</b>	<b>40,804</b>	<b>€ 97.34</b>
<b>Exercisable at December 31, 2019</b>	<b>40,804</b>	<b>€ 97.34</b>
Granted	—	€ —
Forfeited	(19,386)	€ 73.60
Exercised	(1,608)	€ 73.60
<b>Outstanding at December 31, 2020</b>	<b>19,810</b>	<b>€ 122.50</b>
<b>Exercisable at December 31, 2020</b>	<b>19,810</b>	<b>€ 122.50</b>
Granted		
Forfeited		
Exercised		
<b>Outstanding at December 31, 2021</b>	<b>19,810</b>	<b>€ 122.50</b>
<b>Exercisable at December 31, 2021</b>	<b>19,810</b>	<b>€ 122.50</b>
Granted		
Forfeited		
Exercised		
<b>Outstanding at December 31, 2022</b>	<b>19,810</b>	<b>€ 122.50</b>
<b>Exercisable at December 31, 2022</b>	<b>19,810</b>	<b>€ 122.50</b>

<i>Number of outstanding stock-options and warrants (BSA) with a ratio of 1 option = 1 share</i>	<b>Number of stock-options and BSA</b>	<b>Weighted-average exercise price</b>
<b>Outstanding at December 31, 2019</b>	<b>897,246</b>	<b>€ 10.26</b>
<b>Exercisable at December 31, 2019</b>	<b>173,899</b>	<b>€ 21.46</b>
Granted	505,950	€ 6.69
Forfeited	(111,860)	€ 9.53
Exercised	—	€ —
<b>Outstanding at December 31, 2020</b>	<b>1,291,336</b>	<b>€ 8.91</b>
<b>Exercisable at December 31, 2020</b>	<b>236,525</b>	<b>€ 21.28</b>
Granted	658,800	€ 3.46
Forfeited	(45,925)	€ 5.74
Exercised	—	€ —
<b>Outstanding at December 31, 2021</b>	<b>1,904,211</b>	<b>€ 7.09</b>
<b>Exercisable at December 31, 2021</b>	<b>636,376</b>	<b>€ 11.47</b>
Granted		
Forfeited	(881,264)	€ 7.83
Exercised		
<b>Outstanding at December 31, 2022</b>	<b>1,022,947</b>	<b>€ 6.45</b>
<b>Exercisable at December 31, 2022</b>	<b>549,097</b>	<b>€ 11.56</b>

<i>Number of outstanding free shares (AGA) with a ratio of 1 option = 1 share</i>	<b>Number of outstanding free shares</b>
<b>Outstanding at December 31, 2019</b>	<b>648,345</b>
Granted	300,049
Forfeited	(181,146)
Acquired	(6,743)
<b>Outstanding at December 31, 2020</b>	<b>760,505</b>
Granted	375,162
Forfeited	(144,047)
Acquired	(22,539)
<b>Outstanding at December 31, 2021</b>	<b>969,081</b>
Granted	
Forfeited	(385,360)
Acquired	
<b>Outstanding at December 31, 2022</b>	<b>583,721</b>

As of December 31, 2022, the outstanding equity instruments could lead to the issuance of 1,804,768 potential shares.

### 3.4. Depreciation, amortization and impairment

<b>(amounts in thousands of euros)</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	<b>12/31/2022</b>
Amortization and impairment of intangible assets	16	571	7
Depreciation of property, plant and equipment	3,457	3,455	2,168
Impairment of property, plant and equipment			983
Depreciation of the right of use	1,518	1,351	733
Impairment of the right of use			728
<b>Total amortization and depreciation</b>	<b>4,991</b>	<b>5,377</b>	<b>4,619</b>

The decrease in depreciation in 2022, is primary related to the sale of the Princeton facility to Catalent in April 2022 for €1,896 thousand and to the impairment of the intangible production process for €560 thousand in 2021 . The impairment charge

increase in 2022 mainly concerns Adenine (Lyon, France) production site, with €983 thousand for the equipments and €728 thousand for the right of use (see note 4.1.2 and 4.2).

### 3.5. Financial income (loss)

#### Accounting policies

Financial income (loss) includes mainly:

- Amortized costs of convertibles notes and change in fair value of embedded derivatives;
- Interest expenses incurred on financial liabilities and lease liabilities;
- Income received from cash and cash equivalents;
- Gains and losses on exchange rate variations on financial and investing transactions.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Income from short term deposits	12	13	58
Change in fair value of derivative liabilities	652	1,175	0
Other financial income	225	4,234	4,395
<b>Financial income</b>	<b>889</b>	<b>5,422</b>	<b>4,453</b>
Amortized cost of convertible notes	(1,684)	(1,566)	
Financial expenses on lease liability	(336)	(305)	(138)
Interest expense related to borrowings	(142)	(267)	(181)
Other financial expenses	(3,192)	(564)	(1,045)
<b>Financial expenses</b>	<b>(5,354)</b>	<b>(2,702)</b>	<b>(1,364)</b>
<b>Financial income (loss)</b>	<b>(4,465)</b>	<b>2,720</b>	<b>3,089</b>

Other financial income and expenses are mainly comprised of:

- Net Foreign currency gains and (losses) of €(3,028) thousand in 2020, €3,570 thousand in 2021 and €2,891 thousand in 2022;
- A net expense of €390 thousand in 2021 related to the accounting of OCABSA contract, in accordance with IFRS 9 (no corresponding expense in 2020 and 2022).
- In 2022 we recorded €386 thousand related to the extinguishment of BPI conditional advance accrued interest (see note 4.8.2).

### 3.6 Income tax

#### Accounting policies

##### Current taxes

The Parent Company, as an entity incorporated in France, is subject to the corporate value-added contribution "cotisation sur la valeur ajoutée des entreprises—CVAE". To enter within the scope of IAS 12 *Income Taxes* ("IAS 12"), a tax must be calculated based on a net amount of income and expenses, and this net amount can be different from the net book results. The Company has judged that the corporate value-added contribution satisfies the characteristics outlined in this conclusion, insofar as the value added constitutes the intermediate level of income that systematically serves as the basis, according to French tax law, for determining the amount owing in relation to the corporate value-added contribution.

##### Deferred taxes

Except in specific cases, deferred taxes are calculated for the temporary differences between the carrying value of an asset or a liability and its tax value. Changes in the tax rates are recorded in the results of the financial year during which the rate change is decided. Deferred tax assets resulting from temporary differences or tax losses carried forward are limited to the deferred tax liabilities with the same maturity, except where their allocation on future taxable income is probable. Deferred taxes are calculated based on the most recent tax rates adopted at the date of each financial year-end. Deferred tax assets and liabilities are not discounted.

### Tax rate and tax loss carryforwards

As of December 31, 2022, the amount of accumulated tax loss carryforwards were:

- €364.2 million in France, with no expiration date. The proposed merger with PHERECYDES (refer to note 2.9) may limit the Company's ability to use all or part of the tax loss carryforward.
- €12.2 million (\$13.0 million) in the United States with no expiration date.

The standard corporate tax rate in France was 25% for 2022.

### Reconciliation of the effective tax rate

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
<b>Net loss</b>	<b>(73,300)</b>	<b>(53,797)</b>	<b>(228)</b>
Current Income tax (1)	(3)	(2)	(521)
<b>Profit / Loss before tax</b>	<b>(73,297)</b>	<b>(53,795)</b>	<b>293</b>
Tax rate	28 %	26.50 %	25.00 %
<b>Theoretical tax expense or income</b>	<b>20,522</b>	<b>14,256</b>	<b>(73)</b>
Current year loss not capitalized	(20,803)	(15,766)	(585)
Research tax credits	960	972	371
Tax rate differences	—	—	(58)
Share based compensation expense	(330)	(351)	(112)
Other differences	(354)	887	(64)
<b>Effective tax (loss) / income</b>	<b>(3)</b>	<b>(2)</b>	<b>(521)</b>

### Nature of deferred taxes

The deferred tax related to loss carryforwards of Erytech Pharma S.A are computed using a rate of 25%.

<sup>(1)</sup> Considering the level of tax loss of the Company, no current tax expense were recognized in 2020 and 2021. In 2022 following the sales of the Princeton facility by our US subsidiary and the recognition of a net gain of €24.3 millions (see note 3.1), the Company performed a tax analysis to determine the extent of prior year federal and state tax losses which could be carried forward to offset the current year gain. As a result of this analysis, the company recorded a current income tax expense of €0.5 million for the year ended December 31, 2022.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Loss carryforward	76,978	91,775	94,466
Tax credit carryforward	79	178	158
Temporary differences	484	953	410
Unrecognized deferred tax assets	(77,541)	(92,906)	(95,035)
<b>Net amount</b>	<b>—</b>	<b>—</b>	<b>—</b>

The Company did not recognized any deferred tax expense or income in 2020, 2021, 2022.

### 3.7 Basic earnings (loss) per share and diluted earnings (loss) per share

#### Accounting policies

The basic earnings per share are calculated by dividing the Company's net income (loss) by the weighted average number of shares in circulation during the corresponding period.

The diluted earnings per share are calculated by dividing the results by the weighted average number of common shares in circulation, increased by all dilutive potential common shares. The dilutive potential common shares include, equity instruments granted to employees, members of the Board of Directors or other individuals as detailed in note 3.3.3 and convertibles notes and warrants issued as part of the financing agreement with financing agreement with Luxembourg-based European High Growth Opportunities Securitization Fund as detailed in note 4.8.1.

Dilution is defined as a reduction of earnings per share or an increase of loss per share. When the exercise of outstanding share options and warrants decreases loss per share, they are considered to be anti-dilutive and excluded from the calculation of diluted loss per share. Thus, basic and diluted loss per share are equal as all equity instruments issued have been considered anti-dilutive.

	12/31/2020	12/31/2021	12/31/2022
Net loss (in thousands of euros)	(73,300)	(53,797)	(228)
Weighted number of shares for the period (1)	18,386,587	23,692,457	31,016,053
<b>Basic loss per share (€/share)</b>	<b>(3.99)</b>	<b>(2.27)</b>	<b>(0.01)</b>
<b>Diluted loss per share (€/share)</b>	<b>(3.99)</b>	<b>(2.27)</b>	<b>(0.01)</b>
	12/31/2020	12/31/2021	12/31/2022
<b>Number of shares as of January 1 (1)</b>	<b>17,937,535</b>	<b>18,386,587</b>	<b>31,016,053</b>
<i>Number of shares issued during the year (prorata temporis)</i>			
Share capital increase	—	3,591,634	
Conversion of convertible notes ("OCA")	437,128	1,705,162	
Exercise of warrants	10,391	—	
Free shares acquired	1,533	9,074	
<b>Weighted number of shares for the period</b>	<b>18,386,587</b>	<b>23,692,457</b>	<b>31,016,053</b>

(1) after deduction of treasury shares (2,500 shares are held by the Company as treasury shares and recognized as a deduction of shareholders' equity).

As of December 31, 2020, 2021 and 2022, the potential shares that could be issued (see Note 3.3.3 and Note 4.9.1) were not taken into consideration in the calculation of the diluted earnings, as their effect would be anti-dilutive.

#### 4. NOTES RELATED TO THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

##### 4.1 Fixed assets

##### 4.1.1 Intangible assets

###### Accounting policies

###### Internally generated intangible assets – Research and development costs

In accordance with IAS 38 *Intangible Assets* (“IAS 38”), research expenditures are expensed in the period during which they are incurred.

An internally generated intangible asset relating to a development project is recorded as an asset if, and only if, the following criteria are met:

- (a) it is technically feasible to complete the development project;
- (b) intention on the part of the Company to complete the project and to utilize it;
- (c) capacity to utilize the intangible asset;
- (d) proof of the probability of future economic benefits associated with the asset;
- (e) availability of the technical, financial, and other resources for completing the project; and
- (f) reliable evaluation of the development expenses.

The initial measurement of the asset is the sum of expenses incurred starting on the date on which the development project meets the above criteria.

Because of the risks and uncertainties related to regulatory authorizations and to the research and development process, the Company believes that the six criteria stipulated by IAS 38 have not been fulfilled to date and the application of this principle has resulted in all development costs being expensed as incurred in all periods presented.

###### Other intangible assets

Other intangible assets are recorded at their acquisition cost plus costs directly attributable to the preparation of the asset for its intended use.

Other intangible assets mainly comprised costs of modeling studies of a new production process and costs of acquisition of software licenses.

Intangible assets with a finite life are amortized on the basis of the straight-line method over their estimated useful life.

<u>Intangible assets Item</u>	<u>Amortization period</u>
Software	1 to 5 years

(amounts in thousands of euros)	Other intangible assets	Intangible assets in progress	TOTAL
<b>GROSS VALUE</b>			
<b>As of As of December 31, 2019</b>	<b>1,876</b>	<b>—</b>	<b>1,876</b>
Increase	—	2	2
Decrease	—	—	—
FX rate impact	(1)	—	(1)
Reclassification	—	—	—
<b>As of As of December 31, 2020</b>	<b>1,875</b>	<b>2</b>	<b>1,877</b>
Increase	—	—	—
Decrease	(201)	—	(201)
FX rate impact	1	—	1
Reclassification	(2)	—	(2)
<b>As of As of December 31, 2021</b>	<b>1,673</b>	<b>2</b>	<b>1,675</b>
Increase	—	—	—
Decrease	(7)	—	(7)
FX rate impact	—	—	—
Reclassification	2	(2)	—
<b>As of As of December 31, 2022</b>	<b>1,668</b>	<b>—</b>	<b>1,668</b>
<b>ACCUMULATED AMORTIZATION AND IMPAIRMENT</b>			
<b>As of As of December 31, 2019</b>	<b>(1,273)</b>	<b>—</b>	<b>(1,273)</b>
Increase	(16)	—	(16)
Decrease	—	—	—
FX rate impact	1	—	1
<b>As of As of December 31, 2020</b>	<b>(1,288)</b>	<b>—</b>	<b>(1,288)</b>
Increase	(571)	—	(571)
Decrease	199	—	199
FX rate impact	—	—	—
<b>As of As of December 31, 2021</b>	<b>(1,660)</b>	<b>—</b>	<b>(1,660)</b>
Increase	(7)	—	(7)
Decrease	4	—	4
FX rate impact	—	—	—
<b>As of As of December 31, 2022</b>	<b>(1,663)</b>	<b>—</b>	<b>(1,663)</b>
<b>NET VALUE</b>			
<b>As of December 31, 2019</b>	<b>603</b>	<b>—</b>	<b>603</b>
<b>As of December 31, 2020</b>	<b>587</b>	<b>2</b>	<b>589</b>
<b>As of December 31, 2021</b>	<b>13</b>	<b>2</b>	<b>15</b>
<b>As of December 31, 2022</b>	<b>5</b>	<b>—</b>	<b>5</b>

After performing an impairment test at the end of 2019, the Company determined that €1,036 thousand of the intangible asset will no longer be used in the intended production process. The remaining amount has been impaired totally in 2021 for €560 thousand.

#### 4.1.2 Property, plant and equipment

##### Accounting policies

Property, plant and equipment are recorded at their acquisition cost, comprised of their purchase price and all the direct costs incurred to bring the asset to the location and working condition for its use as intended by the company's management.

Property, plant, and equipment are depreciated on the basis of the straight-line method over their estimated useful life. The non-reusable fixtures of property rented are depreciated over the term of their own lifetime or of the term of the rental agreement, whichever is shorter.

The depreciation periods used are the following:

Property, plant and equipment items	Depreciation period
Industrial equipment	1 to 5 years
Fixtures and improvements in structures	3 to 10 years
Office equipment and computers	3 to 5 years

The useful lives of property, plant and equipment as well as any residual values are reviewed at each year end and, in the event of a significant change, result in a prospective revision of the depreciation pattern.

According to IAS 36 *Impairment of Assets* ("IAS 36"), a loss in value must be recognized where the carrying value of an asset, or the cash generating unit to which the asset belongs (if it is not possible to estimate the recoverable amount of the individual asset), is higher than its recoverable value. The recoverable value of an asset corresponds to its fair value less costs to sell or its value in use, whichever is higher.

The property, plant, and equipment and intangible assets that have a finite life are subject to an impairment test when the recoverability of their carrying value is called into question by the existence of indications of impairment.

The intangible assets that are not amortized are tested for impairment at the end of the period in which they are acquired, subsequently annually and whenever there is an indication that the intangible asset may be impaired.

An impairment is recognized up to the amount of the excess of the value over the recoverable value of the asset.

(amounts in thousands of euros)	General equipment, fixtures and fittings	Plant, equipment and tooling	Office equipment and computers	Assets under construction	TOTAL
<b>GROSS VALUE</b>					
<b>As of December 31, 2019</b>	<b>22,385</b>	<b>4,806</b>	<b>1,171</b>	<b>1,079</b>	<b>29,441</b>
Increase	30	301	37	78	446
Decrease	(83)	(69)	—	(26)	(178)
FX rate impact	(1,644)	(247)	(36)	(13)	(1,940)
Reclassification	13	996	32	(1,041)	—
<b>As of December 31, 2020</b>	<b>20,701</b>	<b>5,787</b>	<b>1,204</b>	<b>77</b>	<b>27,769</b>
Increase	59	27	21	108	215
Decrease	(157)	(144)	(204)	—	(505)
FX rate impact	1,487	234	31	3	1,755
Reclassification	—	12	65	(76)	1
<b>As of December 31, 2021</b>	<b>22,090</b>	<b>5,916</b>	<b>1,117</b>	<b>112</b>	<b>29,235</b>
Increase	0	82	0	0	82
Decrease	(19,862)	(3,092)	(383)	(54)	(23,390)
FX rate impact	686	147	14	2	849
Reclassification	0	58	2	(60)	0
<b>As of December 31, 2022</b>	<b>2,914</b>	<b>3,111</b>	<b>750</b>	<b>0</b>	<b>6,775</b>
<b>ACCUMULATED DEPRECIATION AND IMPAIRMENT</b>					
<b>As of December 31, 2019</b>	<b>(2,121)</b>	<b>(1,220)</b>	<b>(469)</b>	<b>—</b>	<b>(3,810)</b>
Increase	(2,232)	(993)	(232)	—	(3,457)
Decrease	8	69	—	—	77
FX rate impact	218	52	13	—	283
Reclassification	—	—	—	—	—
<b>As of December 31, 2020</b>	<b>(4,127)</b>	<b>(2,092)</b>	<b>(688)</b>	<b>—</b>	<b>(6,907)</b>
Increase	(2,170)	(1,072)	(213)	—	(3,455)
Decrease	151	142	196	—	489
FX rate impact	(308)	(80)	(14)	—	(402)
Reclassification	—	—	—	—	—
<b>As of December 31, 2021</b>	<b>(6,454)</b>	<b>(3,102)</b>	<b>(719)</b>	<b>—</b>	<b>(10,275)</b>
Depreciation	(1,466)	(604)	(99)	—	(2,169)
Impairment	(65)	(795)	(123)	—	(983)
Decrease	5,437	1,601	222	—	7,261
FX rate impact	(154)	(57)	(6)	—	(218)
Reclassification	—	—	—	—	—
<b>As of December 31, 2022</b>	<b>(2,701)</b>	<b>(2,957)</b>	<b>(725)</b>	<b>—</b>	<b>(6,383)</b>
<b>NET VALUE</b>					
<b>As of December 31, 2019</b>	<b>20,264</b>	<b>3,586</b>	<b>702</b>	<b>1,079</b>	<b>25,631</b>
<b>As of December 31, 2020</b>	<b>16,574</b>	<b>3,695</b>	<b>516</b>	<b>77</b>	<b>20,862</b>
<b>As of December 31, 2021</b>	<b>15,636</b>	<b>2,814</b>	<b>398</b>	<b>112</b>	<b>18,960</b>
<b>As of December 31, 2022</b>	<b>213</b>	<b>154</b>	<b>25</b>	<b>0</b>	<b>393</b>

The decrease of the gross value is primary related to the sale of the Princeton facility to Catalent in April 2022 (refer to note 3.1). The gross value of the manufacturing facility was €22,346 thousand (\$24,447 thousand), of which general equipment fixtures of €19,862 thousand, fittings and plant equipments and tooling of €2,070 thousand, Office equipment and computers of €361 thousand, and assets under construction of €54 thousand.

The Company further disposed of plant equipments and tooling with a gross value of €1,022 thousand.

The decrease of accumulated depreciation of €7,261 thousand in 2022 is mainly related to the depreciation of the property, plant and equipment transferred to Catalent, which represents €6,673 thousand (\$7,301 thousand). The remaining decrease of depreciation is related to plant equipment and tooling disposal for €565k.

The net book value of the property, plant and equipment sold to Catalent is €15,673 thousand (\$17,146 thousand).

The €983k impairment loss recorded in 2022 mainly concerns the equipment of the Adenine (Lyon, France) production site. The equipment was tested for impairment further to the Company's decision to engage in a restructuring of the Company's activities in France, and in particular the decision to start a collective redundancy procedure (see notes 1 and 4.7) which resulted in substantial changes to the Company clinical manufacturing capacities. These measures were required after the unsuccessful end of the TRYbeCA1 and TRYbeCA2 clinical trials and the subsequent termination of the Eryaspase development program (Eryaspase was produced at Adenine). The impairment loss was included in research and development expenses (see note 3.2.1) and in general and administrative expenses (see note 3.2.2).

The Company estimated the recoverable amount of the Company's assets based on their fair values less costs of disposal using a depreciated replacement cost method and after considering the specialized nature of the assets. The fair value measurement was categorized as a Level 3 fair value based on the inputs in the valuation technique used.

## 4.2 Right of use

### Accounting policies

In accordance with IFRS 16 *Leases* (“IFRS 16”), applicable since January 1, 2019, the right of use is recognized on the lessee's balance sheet when the asset linked to the lease agreement become available.

The right of use asset is measured at cost and comprises:

- the amount of the initial measurement of the lease liability (see note 4.10),
- lease incentives, payments at or prior to commencement date,
- incremental costs which would not have been incurred if the contract had not been concluded.

The right of use is subsequently measured at cost less depreciation and any accumulated impairment loss. The amount can be adjusted based on certain revaluations of the lease liability. The right of use are tested for impairment whenever there is an indicator that such asset may be impaired.

(amounts in thousands of euros)	Buildings	Plant, equipment and tooling	Transport equipment	Office equipment and computers	TOTAL
<b>GROSS VALUE</b>					
As of December 31, 2019	11,237	954	80	118	12,389
Increase	92	—	7	—	99
Decrease	—	—	(14)	—	(14)
FX rate impact	(483)	—	—	—	(483)
Reclassification	—	—	—	—	—
As of December 31, 2020	10,846	954	73	118	11,991
First application of IFRS 16					
Increase	—	383	33	—	416
Decrease	(1,763)	—	—	—	(1,763)
FX rate impact	—	13	—	—	375
Reclassification	—	0	—	0	0
As of December 31, 2021	9,445	1,350	106	118	11,019
Increase	75	—	13	—	88
Decrease	(4,045)	(396)	—	—	(4,441)
FX rate impact	198	—	—	—	198
Reclassification	—	—	—	—	—
As of December 31, 2022	5,673	954	119	118	6,864
<b>ACCUMULATED DEPRECIATION AND IMPAIRMENT</b>					
As of December 31, 2019	(1,285)	(954)	(23)	(118)	(2,380)
Increase	(1,489)	—	(29)	—	(1,518)
Decrease	0	0	10	—	10
FX rate impact	125	—	—	—	125
Reclassification	—	—	—	—	—
As of December 31, 2020	(2,649)	(954)	(42)	(118)	(3,763)
Increase	(1,252)	(76)	(23)	—	(1,351)
Decrease	1,070	0	—	—	1,070
FX rate impact	(103)	(3)	—	—	(106)
Reclassification	—	—	—	—	—
As of December 31, 2021	(2,934)	(1,033)	(65)	(118)	(4,150)
Increase	(706)	—	(27)	—	(733)
Impairment	(728)	—	—	—	(728)
Decrease	1,339	79	—	—	1,418
FX rate impact	(89)	—	—	—	(89)
Reclassification	—	—	—	—	—
As of December 31, 2022	(3,116)	(954)	(92)	(118)	(4,280)
<b>NET VALUE</b>					
As of December 31, 2020	8,197	—	31	—	8,228
As of December 31, 2021	6,511	317	41	—	6,869
As of December 31, 2022	2,557	—	27	—	2,584

The remaining right of use net book value of €2,584 thousand is mainly related to Bioserra building lease in Lyon (France) for €2,557 thousand.

- The decrease in 2022 of the building and equipments rights of use, with a gross amount of \$4,441 thousand, accumulated depreciation of €1,418 thousand and a net book value of €3,022 thousand (\$3,307 thousand) is related to the Princeton Plant sale to Catalent;
- The increase of building right of use impairment loss of €728 thousand in 2022 (see note 3.4) is mainly the result of the impairment test conducted on the Adenine (Lyon, France) building right of use after the site has been idled, following 2022 adverse events (mostly clinical study result and restructuring plan). The Adenine right of use was written down to zero given the specialized nature of the site, its current rent compared to market rents and the low prospects of sub-letting the site before its lease term (end of June 2024).
- The Company also performed an impairment test on the remaining material right-of-use asset which relates to the Bioserra (Lyon, France) building as of December 31, 2022. The Company estimated the recoverable amount of this asset based on its fair value less costs of disposal using a discounted cash flow model with assumptions such as the term of the lease (June 2029), market rents and average rate of return for similar buildings. The fair value measurement was categorized as a Level 3 fair value based on the inputs in the valuation technique used. An immaterial impairment charge was recognized on this asset after conducting the test.

### 4.3. Other non current assets

#### Accounting policies

Other financial assets are composed of receivables initially recognized at their fair value and then at the amortized cost calculated with the effective interest rate (“EIR”) method.

Financial assets with a maturity of more than one year are classified in “other non-current financial assets” in accordance with IAS 1.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Deposits related to leased premises	454	476	193
Advance payments to suppliers	620	342	0
Other	17	58	2
<b>Total other non-current assets</b>	<b>1,091</b>	<b>876</b>	<b>195</b>

Advance payments comprised payments made to service providers, especially Contract Research Organizations (“CROs”), involved with the conduct of the clinical trials in the solid tumors indication (TRYbeCA-1 and TRYbeCA-2 study).

### 4.4 Trade receivables and other current assets

#### Accounting policies

Other current assets are initially recognized at their fair value and then at the amortized cost calculated with the effective interest rate (“EIR”) method.

#### Trade receivables

Trade receivables are initially recognized in accordance with IFRS 15 and then at the amortized cost calculated with the effective interest rate (“EIR”) method. The Company recognizes loss allowances for expected credit losses (“ECL”), which, for trade receivables and contract assets, are measured at an amount equal to lifetime ECLs that result from all possible default events over their expected life. Loss allowances are deducted from the gross amounts of the assets.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Trade and other receivables	4	12	76
<b>Total current trade receivables</b>	<b>4</b>	<b>12</b>	<b>76</b>
Research Tax Credit	3,432	3,549	1,484
Other receivables (including tax and social receivables)	898	669	973
Net investment in a sublease	0	479	43
Deposits related to leased premises	8	7	121
Advance payments and deposits to suppliers	51	377	342
Prepaid expenses	793	1,256	805
<b>Total other current assets</b>	<b>5,182</b>	<b>6,337</b>	<b>3,769</b>

### Research Tax Credit

The Company benefits from the provisions in Articles 244 *quater* B and 49 *septies* F of the French Tax Code related to the Research Tax Credit.

As of December 31, 2020, December 31, 2021 and December 31, 2022, the CIR receivables included Research Tax Credit of the year.

### Tax and social receivables and other receivables

Tax and social receivables and other receivables mainly related to VAT receivables (€635 thousand as of December 31, 2020, €610 thousand as of December 31, 2021 and €899 thousand as of December 31, 2022).

### Prepaid expenses

As of December 31, 2022 and December 31, 2021, prepaid expenses are mainly related to insurance expense..

## 4.5 Cash and cash equivalents

### Accounting policies

The item “cash and cash equivalents” includes bank accounts and highly liquid securities. They are readily convertible into a known amount of cash and are subject to a negligible risk of change in value.

The cash equivalents classification is made if the following criteria are fulfilled:

- held for the purpose of meeting short term cash commitments rather than for investment or other purposes.
- exit options exist:
  - exercisable at any time at least every three months;
  - initially included in the contract and this exit option is always provided in the initial contract; and
  - exercisable without exit penalty and without significant risk of change in the amount received as cash reimbursement.
- there is no value risk related to the level of minimum compensation acquired (i.e. that obtained in the event of early exit) because over the entire duration and at each moment this remuneration will be identical to that obtained from an investment of no more than three months that meets the definition of a cash equivalent. This can be the case when the rate is variable or revisable.

They are recorded as assets in cash equivalents, measured at their fair value, and the changes in value are recognized in financial income (loss).

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Current account	34,348	24,593	26,676
Term deposits	10,098	9,106	12,113
<b>Total cash and cash equivalents as reported in statement of financial position</b>	<b>44,446</b>	<b>33,699</b>	<b>38,789</b>
Bank overdrafts	—	—	—
<b>Total cash and cash equivalents as reported in statement of cash flow</b>	<b>44,446</b>	<b>33,699</b>	<b>38,789</b>

As of December 31, 2020, term deposits included a term deposit of €10.0 million with a maturity of one month and deposits of €0.1 million convertible into cash immediately.

As of December 31, 2021, term deposits included a term deposit of €9.0 million with a maturity of one month and deposits of €0.1 million convertible into cash immediately.

As of December 31, 2022, term deposits included a term deposit of €12.0 million with a maturity of one month and deposits of €0.1 million convertible into cash immediately.

#### 4.6. Shareholders' equity

##### Accounting policies

Common shares are classified under shareholders' equity. The costs of share capital transactions that are directly attributable to the issue of new shares or options are recognized in shareholders' equity as a deduction from the proceeds from the issue, net of tax.

As of December 31, 2022, the capital of the Parent Company consisted of 31,018,553 shares, fully paid up, with a nominal value of 0.10 euro.

	<b>Number of shares</b>
<b>As of December 31, 2019</b>	<b>17,940,035</b>
Conversion of convertible notes ("OCA")	2,094,704
Exercise of warrants	16,080
Free shares acquired	6,743
<b>As of December 31, 2020</b>	<b>20,057,562</b>
Shares issued as part of the April Registered Direct Offering	4,137,932
Shares sold under the at-the-market ("ATM") program	744,186
Shares issued as part of the December Registered Direct Offering	3,078,432
Conversion of convertible notes ("OCA")	2,977,887
Free shares acquired	22,554
<b>As of December 31, 2021</b>	<b>31,018,553</b>
Shares issued as part of the April Registered Direct Offering	—
Shares sold under the at-the-market ("ATM") program	—
Shares issued as part of the December Registered Direct Offering	—
Conversion of convertible notes ("OCA")	—
Free shares acquired	—
<b>As of December 31, 2022</b>	<b>31,018,553</b>

##### Capital management

The capital is managed to ensure that the Company will be able to continue as a going concern while maximizing the return to shareholders through the optimization of the debt and equity balance. The Company is not subject to any externally imposed capital requirements. For additional information on capital and premium increase see: 2.9 Events after the close of the reporting period

The number of shares presented does not include the warrants issued in connection with the registered offerings in 2021.

- For the registered offering of April 2021: 3,103,449 Warrants, giving the right to subscribe to one share of the company. The Warrants have an exercise price of 7.5 euros per share, will be immediately exercisable upon issuance and will expire two years from the issuance date.
- For the registered offering of December 2021: 2,308,824 Warrants, giving the right to subscribe to one share of the company. The Warrants have an exercise price of 2.83 euros per share, will be immediately exercisable upon issuance and will expire two years from the issuance date.

## 4.7 Provisions

### Accounting policies

A provision is recognized when the Company has a current or implicit legal obligation resulting from a past event, where the obligation can be reliably estimated, and where it is probable that an outflow of resources representing economic benefits will be necessary to settle the obligation. The portion of a provision that become due in less than one year is recorded under current liabilities, and the balance under non-current liabilities. The provisions are discounted when the impact is material.

Disclosure is made on any contingent assets and liabilities where the impact is expected to be material, except where the probability of occurrence is low.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Provision for retirement indemnities	652	524	318
Other provision			101
<b>Provisions - non-current portion</b>	<b>652</b>	<b>524</b>	<b>419</b>
Restructuring provision	—	—	166
Other provision			148
<b>Provisions - current portion</b>	<b>—</b>	<b>—</b>	<b>314</b>

## Provision for retirement indemnities - defined benefit plans

### Accounting policies

The French employees of the Company receive the retirement benefits stipulated by law in France:

- a compensation paid by the Company to employees upon their retirement (defined-benefit plan); and
- a payment of retirement pensions by the social security agencies, which are financed by the contributions made by companies and employees (defined contribution plans in France).

The French Company pension commitments are not covered by plan assets. The American employees do not receive defined-benefit plan.

For the defined-benefit plans, the costs of the retirement benefits are estimated using the projected credit unit method.

The consolidated financial statements have been prepared applying the IFRS Interpretations Committee (IFRIC) agenda decision dated May 24, 2021 “Attributing Benefit to Periods of Service (IAS 19 Employee Benefits. The Company applies the Pharmaceutical Industry” collective agreement (“Convention collective nationale de l’industrie pharmaceutique”), which caps the pension rights after 30 years of employment.

Through its agenda decision, IFRIC considers that, as long as, on the one hand, no rights are acquired in the event of departure before retirement age and, on the other hand, rights are capped after a certain number of years of service, the retirement benefits should be spread over the last 30 years before the retirement date that give rights to those benefits. The retirement benefit commitments are valued at the current value of the future payments estimated using, for discounting, the market rate for high quality corporate bonds with a term that corresponds to the estimated term for the payment of the benefits.

The difference between the amount of the provision at the beginning of a period and at the close of that period is recognized through profit or loss for the portion representing the costs of services rendered and the net interest costs, and through other comprehensive income for the portion representing the actuarial gains and losses.

The Company’s payments for the defined-contribution plans are recognized as expenses on the statement of income (loss) of the period in which they become payable.

As part of the estimate of the retirement commitments, the following assumptions were used for all categories of employees:

	12/31/2020	12/31/2021	12/31/2022
Discount rate	0.34 %	0.79 %	3.16 %
Wage increase	2 %	2 %	2 %
Social welfare contribution rate			
- non executive employees	39 %	39 %	39 %
- executive employees	51 %	51 %	51 %
- executive management	49 %	49 %	49 %
Expected staff turnover			
- non executive and executive employees	High	High	High
- executive management	Low	Low	Low
Age of retirement	65 - 67 years	65 - 67 years	65 - 67 years
Mortality table	INSEE 2019	TGH05 TGF05	TGH05 TGF05

The change in the provision for retirement indemnities is as follows:

(amounts in thousands of euros)

<b>As of December 31, 2019</b>	<b>506</b>
Service costs	123
Financial costs	4
Actuarial gains and losses	19
<b>As of December 31, 2020</b>	<b>652</b>
Service costs	(63)
Financial costs	3
Actuarial gains and losses	(68)
<b>As of December 31, 2021</b>	<b>524</b>
Curtailment Gain - restructuring plan 2022 (PSE)	(63)
Service costs	82
Financial costs	9
Actuarial gains and losses	(235)
<b>As of December 31, 2022</b>	<b>318</b>

The final IFRS IC agenda decision of May 24, 2021 regarding the attribution of benefits to periods of service did not have a significant impact in 2021.

As of December 31, 2022, the impact regarding the restructuring plan (PSE) is €(63) thousand.

#### 4.8 Financial liabilities

##### Accounting policies

Unless otherwise stated, financial liabilities are initially recognized at fair value less transaction costs and subsequently measured at amortized cost using the effective interest rate method.

Financial liabilities with a maturity of more than one year are classified in “Financial liabilities – non-current portion” in accordance with IAS 1.

The Company derecognises a financial liability when its contractual obligations are discharged or cancelled, or expire.

On derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid (including any non-cash assets transferred or liabilities assumed), if any, is recognised in profit or loss.

(amounts in thousands of euros)	Convertible notes	Conditional advances	Bank loans	Other	Total
<b>As of December 31, 2019</b>	—	<b>1,321</b>	<b>61</b>	<b>38</b>	<b>1,420</b>
Collection	14,155	2,979	10,000	—	27,134
Fair value of embedded derivatives	(1,070)	—	—	—	(1,070)
Amortized cost	1,684	121	20	—	1,825
Conversion	(12,600)	—	—	—	(12,600)
Repayment	—	—	(62)	—	(62)
Reclassification	—	—	—	—	—
FX rate impact	—	—	—	(3)	(3)
<b>As of December 31, 2020</b>	<b>2,169</b>	<b>4,421</b>	<b>10,019</b>	<b>35</b>	<b>16,644</b>
Collection	11,423	734	—	—	12,157
Fair value of embedded derivatives	(758)	—	—	—	(758)
Amortized cost	1,566	126	58	—	1,750
Conversion	(14,400)	—	—	—	(14,400)
Repayment	—	—	—	—	—
FX rate impact	—	—	—	3	3
<b>As of December 31, 2021</b>	—	<b>5,281</b>	<b>10,077</b>	<b>38</b>	<b>15,396</b>
Increase	—	—	—	3,081	3,081
Fair value of embedded derivatives	—	—	—	—	—
Amortized cost	—	—	(6)	—	(6)
Conversion	—	—	—	—	—
Extinguishment of conditional advance	—	(5,281)	—	—	(5,281)
Repayment	—	—	—	(3,081)	(3,081)
FX rate impact	—	—	—	3	3
<b>As of December 31, 2022</b>	—	—	<b>10,071</b>	<b>41</b>	<b>10,112</b>

During the first half of 2022, the Company entered into a new financing agreement with Société Générale secured by the Company's 2021 CIR receivable of which €3,081k was received at June 30, 2022, and fully reimbursed in October 2022.

#### Financial liabilities by maturity

December 31, 2020 (in thousands of euros)	Less than one year	One to three years	Three to five years	More than five years	Total
Convertible notes	2,169	—	—	—	<b>2,169</b>
Conditional advances	—	—	—	4,421	<b>4,421</b>
Bank loans	96	3,768	4,069	2,086	<b>10,019</b>
Other	—	35	—	—	<b>35</b>
<b>Total financial liabilities</b>	<b>2,265</b>	<b>3,803</b>	<b>4,069</b>	<b>6,507</b>	<b>16,644</b>

December 31, 2021 (in thousands of euros)	Less than one year	One to three years	Three to five years	More than five years	Total
Convertible notes	—	—	—	—	—
Conditional advances	—	—	—	5,281	<b>5,281</b>
Bank loans	164	5,014	4,424	475	<b>10,077</b>
Other	—	38	—	—	<b>38</b>
<b>Total financial liabilities</b>	<b>164</b>	<b>5,052</b>	<b>4,424</b>	<b>5,756</b>	<b>15,396</b>

December 31, 2022 (in thousands of euros)	Less than one year	One to three years	Three to five years	More than five years	Total
Convertible notes					—
Conditional advances					—
Bank loans	2,565	4,972	2,535		10,072
Other		40			40
<b>Total financial liabilities</b>	<b>2,565</b>	<b>5,012</b>	<b>2,535</b>	<b>—</b>	<b>10,112</b>

#### 4.8.1. Convertible notes

##### Accounting policies

In accordance with IFRS 9, a financial instrument with all three of the following characteristics is a derivative:

- its value changes in response to changes in the so-called “underlying”
- it requires no initial net investment,
- it is settled at a future date.

Derivatives are initially recognized at their fair value and subsequent changes are recognized in financial income (loss).

In accordance with IAS 32, a derivative is qualified as an equity instrument only if it will be necessarily settled by exchanging a fixed amount of cash for a fixed amount of equity instruments of the issuer. Equity instruments are initially recognized at their fair value and are not subsequently remeasured.

Generally, convertible notes are qualified as compound instruments as they have both a financial liability and an equity component.

Because the conversion option is a derivative, if the conversion option does not meet the “fixed-for-fixed” condition, the conversion option is classified as a financial derivative liability. In that case, convertible notes are qualified as hybrid instrument in accordance with IFRS 9 comprising a financial liability for the host contract plus an embedded derivative instrument for the conversion option.

The initial bifurcation of a separable embedded derivative does not result in any gain or loss being recognized.

Because the embedded derivative component is measured at fair value on initial recognition, the carrying amount of the host contract on initial recognition is the difference between the carrying amount of the hybrid instrument and the fair value of the embedded derivative.

On June 24, 2020, the Company signed a financing agreement with Luxembourg-based European High Growth Opportunities Securitization Fund in the form of convertible notes with share subscription warrants attached (“OCABSA”).

The Company issued 1,200 note warrants for free that may be exercised in tranches for the same number of convertible notes at the Company request until June 25, 2022. European High Growth Opportunities Securitization Fund could have requested the issuance of two tranches.

Each tranche gave rise to the issuance of 60 convertible notes with 33,670 warrants attached (or of 30 convertible notes with 16,835 warrants if the Company's market capitalization is lower to €50 million during 20 consecutive trading days).

The convertible notes (“OCA”) have the following characteristics:

- Nominal value: €50 thousand
- Subscription price: 98% of the nominal value
- Maturity: 12 months
- The notes will not bear interests
- Conversion ratio:  $N = V_n / P$  where
  - N is the number of Shares that can be subscribed
  - $V_n$  is the nominal value of a convertible note
  - P is the higher of (i) 95% of the volume weighted average trading price of the Company's shares on Euronext Paris during the 3 consecutive trading days preceding the conversion date, (ii) the nominal value of the share and (iii) the minimum issuance price of a share as provided in the 25th resolution of the Shareholder's Meeting held on June 21, 2019 (or any resolution that may succeed it), i.e., to date 80% of the volume-weighted average (in the central order book and excluding off-market block trades) of the Company's share price on Euronext Paris during the 3 trading sessions prior to the pricing of the issue price, it being specified that the theoretical

value of the warrants will be taken into account and that the Shareholder's Meeting has set at 10 million the maximum number of shares that may be issued.

The share subscription warrants ("BSA") have the following characteristics:

- Maturity: 5 years
- Each warrant give the right to subscribe one share
- Exercise price: 120% of the lowest volume-weighted average price of the Company's share observed over the fifteen trading days preceding the request for exercise of the first tranche (ie €8.91).

At the end of 2022, the Company has issued nine tranches of €3.0 million each on July 6, 2020, August 24, 2020, November 17, 2020, December 7, 2020, December 22, 2020, March 2, 2021, May 19, 2021, July 22, 2021 and August 24, 2021 respectively (of which two tranches were issued on European High Growth Opportunities Securitization Fund request), representing a total amount of €27.0 million. Consequently, 540 OCA were issued with 303,030 BSA attached, all the OCA were converted into the Company common shares at the end of 2021 (see note 4.6).

As of December 31, 2022, 0 OCA and 303,030 BSA are outstanding.

Derivative liabilities fall under category 3 defined by IFRS 13.

If the convertible notes are converted before the estimated maturity date, any difference between the fair value of the shares issued and the cumulative amount of the financial liability and the derivative liability at the date of conversion is recognized in financial income (loss).

Fair value of the conversion option is estimated with a Monte-Carlo valuation model using the following main assumptions:

	12/31/2020	12/31/2021	12/31/2022
Number of convertible notes	48	0	0
Estimated conversion price	€ 6.75	€ —	€ —
Expected term	30 days	0	0
Fair value (in thousands of euros)	129	—	—

Fair value of the warrants is estimated with a Black & Scholes valuation model using the following main assumptions:

	12/31/2020	12/31/2021	12/31/2022
Number of warrants	168,350	303,030	303,030
Price of the underlying share	€ 7.11	€ 2.12	€ 0.37
Expected dividends	— %	— %	— %
Volatility	58.11 %	47.33 %	73.04 %
Expected term	2 years	1 year	3 years to 4 years
Fair value (in thousands of euros)	288	0	0

#### 4.8.2. *Conditional advances*

##### **Accounting policies**

Funds received from Bpifrance in the form of conditional advances are recognized as financial liabilities, as the Company has a contractual obligation to reimburse Bpifrance for such conditional advances in cash based on a repayment schedule provided the conditions are complied with.

Receipts or reimbursements of conditional advances are reflected as financing transactions in the statement of cash flows.

The amount resulting from the benefit of conditional advances that do not bear interest at market rates is considered a subsidy. This benefit is determined by applying a discount rate equal to the rate the Company would have to pay for a bank borrowing over a similar maturity.

The implicit interest rate resulting from taking into account all the repayments plus the additional payments due in case of commercial success is used to determine the amount recognized annually as a finance expense.

In the event of a change in payment schedule of the stipulated repayments of the conditional advances, the Company recalculates the net book value of the debt resulting from the discounting of the anticipated new future cash flows at the initial effective interest rate. The adjustment that results therefrom is recognized in the consolidated statement of income (loss) for the period during which the modification is recognized.

Since our inception, we have received non-refundable subsidies from Bpifrance in the amount of €2.7 million in connection with our preclinical research programs.

We have also received €4,895 thousand in three conditional advances from Bpifrance related to TEDAC research program.

Within the scope of the TEDAC project, Bpifrance granted to the Company a conditional advances for a total amount of €4,895 thousand. The accrued interest of this conditional advances amounted to €386 thousand as of December 31, 2022. This conditional advance was paid upon completion of the following key milestones:

- €63 thousand upon signature of the agreement (received in 2012)
- €1,119 thousand upon the milestone n°4 (received in 2016)
- €2,979 thousand upon the milestone n°6 (received in 2020)
- €734 thousand upon the milestone n°7 (received in 2021)

The TEDAC research program, which is funded by non-refundable subsidies and conditional advances from Bpifrance, was funded according to a specified schedule set forth in the contract, subject to completion of milestones. The final research report was provided to BPI in 2021. Subsidies and conditional advance were received with the last milestone in 2021, for a total amount of €7.0 million.

The conditional advance reimbursement in cash is initiated upon achieving cumulative sales of €10 millions on Graspas solid tumor product. Following the negative results of the Trybeca 1 clinical trial and the unsuccessful completion of the Trybeca 2 clinical trial in 2022, the Company has no possibility left any more to market and sell Graspas in the treatment of solid tumors. As a consequence in 2022 the extinguishment of the conditional advance has been recorded as subsidy income for €4,895 thousand (see note 3.1) and as financial income for €386 thousand (see note 3.5).

#### 4.8.3. *Bank loans*

In 2017, the Company received a bank loan amounting to €1.9 million with Société Générale with a 0.4% interest rate and 36 monthly repayment terms to finance its investments. This bank loan is fully repaid as of December 31, 2020.

In November 2020, the Company received two loans of €5.0 million each, in the form of State-Guaranteed Loan (Prêt Garanti par l'Etat, or PGE in France), with Bpifrance and Société Générale. The loans bear interest at fixed rates of 1.67% and 0.25% per annum respectively, with an initial term of one year and an option to spread over five-year including one year of deferred payment and four years of reimbursement. The Company used the deferral options, reimbursement will start in 2023. The Proposed Merger could trigger

a request from BPI of early repayment. The two loans are recorded at amortized cost and classified in “Financial liabilities – current portion” for €2.6 million and in “Financial liabilities – non-current portion” for €7.5 million.

#### 4.9 Lease liabilities

##### Accounting policies

In accordance with IFRS 16 *Leases* (“**IFRS 16**”), applicable since January 1, 2019, the lease liability is recognized on the lessee’s balance sheet when the asset linked to the lease agreement become available.

The lease liability is recognized for an amount equal to the present value of the lease payments over the lease term. The lease liability is then increased by the interest expense and decreased by the rents paid.

The lease liability may be remeasured in the following situations:

- Modification related to the assessment of the exercise of an option to purchase or the extension or the non-exercise of a termination option (which become reasonably certain);
- Rent adjustments based on rates and indices provided in the contracts.

The duration corresponds to the firm period of the commitment and takes into account the optional periods that are reasonably certain to be exercised.

The Company has applied exemptions set out in IFRS 16 regarding:

- Contracts with a lease term of 12 months. These contracts have resulted in an expense of approximately €— thousand in 2020, €824 thousand in 2021 and €654 thousand in 2022.
- Contracts for low value assets. These contracts have resulted in an expense of approximately €31 thousand in 2020, €30 thousand in 2021 and €20 thousand in 2022.

<i>(in thousands of euros)</i>	<b>Lease liabilities</b>
<b>As of December 31, 2019</b>	<b>12,703</b>
First application of IFRS 16	—
Allowance received from a lessor	188
Increase without cash impact	98
Repayment	(1,615)
Decrease without cash impact	—
FX rate impact	(570)
Capitalized interests	—
Reclassification	—
<b>As of December 31, 2020</b>	<b>10,804</b>
Increase without cash impact	399
Repayment	(1,702)
Decrease without cash impact	—
FX rate impact	478
Capitalized interests	0
Reclassification	0
<b>As of December 31, 2021</b>	<b>9,979</b>
Increase without cash impact	88
Repayment	(1,545)
Decrease without cash impact (1)	(5,296)
FX rate impact	229
Capitalized interests	—
Reclassification	0
<b>As of December 31, 2022</b>	<b>3,455</b>

(1) Decrease of Princeton lease liability in connection with the sale of the Princeton manufacturing facility in April 2022 (see note 1 and 3.1).

#### Lease liabilities by maturity

<i>(in thousands of euros)</i>	Less than one year	One to three years	Three to five years	More than five years	Total
<b>As of December 31, 2020</b>	<b>1,607</b>	<b>2,949</b>	<b>2,202</b>	<b>4,046</b>	<b>10,804</b>
<b>As of December 31, 2021</b>	<b>1,817</b>	<b>2,548</b>	<b>2,255</b>	<b>3,359</b>	<b>9,979</b>
<b>As of December 31, 2022</b>	<b>775</b>	<b>1,048</b>	<b>920</b>	<b>712</b>	<b>3,455</b>

#### 4.10 Trade payables and other current liabilities

## Accounting policies

Trade payables and other current liabilities are initially measured at their fair value less transaction costs directly attributable, and then at the amortized cost, calculated using the EIR method. Given the due date, the amortized cost is equal to the initial fair value.

Costs are recognized when incurred. The excess of costs incurred over invoices received is recorded in "Vendors - accruals".

### *Estimation of the hospital costs at December 31, 2020 and 2021*

As of 2020 and 2021, the hospital costs related to clinical trials sponsored by the Company are measured based on two allocation keys: (i) site activation for fixed costs which are recognized in full when sites are activated and (ii) patient randomization for variable patient costs (including chemotherapy costs) which are spread over the estimated time of treatment of the patient as planned in the clinical protocol. These allocation keys are applied to the estimated expenses of the clinical trial. The excess of estimated costs incurred over invoices received is recorded in "Vendors - accruals".

### *Estimation of the hospital costs as of December 31, 2022*

Although our TRYbeCA-1 Phase 3 clinical trial in second-line advanced pancreatic cancer was completed in 2021 (see note 1), there is a significant lag between the period the clinical services are rendered by hospitals (i.e. patient treatments, including chemotherapy) and the period the Company receives invoices from such hospitals. The Company therefore continued to use estimates and judgement to measure the remaining hospital costs to be accrued for this trial as of 12/31/22.

The hospital costs accrual related to this trial is still measured as the excess of estimated costs incurred over invoices received. The Company however reestimated the costs incurred using actual costs and the identification by the Company's clinical department of sites that have completed their invoicing process. The actual costs were derived from invoices received from hospitals or costs reported by them in the Medidata database which is used by the Company to track all costs incurred by hospitals. A revised average cost per patient in France and in Spain was derived from this analysis, and then applied to other sites for which there is no evidence of a completed invoicing process.

(amounts in thousands of euros)	12/31/2020	12/31/2021	12/31/2022
Vendors	4,706	2,485	1,562
Vendors - accruals	16,204	11,669	3,553
<b>Total trade and other payables</b>	<b>20,910</b>	<b>14,154</b>	<b>5,115</b>
Social liabilities, taxation and social security	4,149	3,716	2,799
Fixed assets payables	86	2	0
Deferred revenue	148	93	51
Other payables	53	59	59
<b>Total other current liabilities</b>	<b>4,436</b>	<b>3,870</b>	<b>2,909</b>

Hospital costs accruals amounted to €10,770 thousand as of December 31, 2020, €9,289 thousand as of December 31, 2021 and €2,355 thousand as of December 31, 2022 and mainly related to our TRYbeCA-1 phase 3 clinical trial". The decrease in hospital cost accrual between 2021 and 2022 is due to the utilization of the accrual for €3,882 thousand and to a change in estimate booked as a reduction of R&D expenses for €3,053 thousand.

#### 4.11 Financial instruments recognized in the consolidated statement of financial position and effect on net income (loss)

##### Accounting policies

The valuation and the accounting treatment of the financial assets and liabilities are defined by IFRS 9 *Financial Instruments* (“IFRS 9”).

##### *Financial assets at the amortized cost*

These instruments are initially recognized at their fair value and then at the amortized cost calculated with the effective interest rate (“EIR”) method.

##### *Financial liabilities at the amortized cost*

Loans and other financial liabilities are initially measured at their fair value less transaction costs directly attributable, and then at the amortized cost, calculated using the EIR method.

##### *Financial assets and financial liabilities measured at fair value*

In accordance with IFRS 13 *Fair Value Measurement* (“IFRS 13”), financial instruments are presented in three categories based on a hierarchical method used to determine their fair value:

- Level 1: fair value calculated using quoted prices in an active market for identical assets and liabilities;
- Level 2: fair value calculated using valuation techniques based on observable market data such as prices of similar assets and liabilities or parameters quoted in an active market;
- Level 3: fair value calculated using valuation techniques based wholly or partly on unobservable inputs such as prices in an inactive market or a valuation based on multiples for unlisted securities.

As of December 31, 2020 (amounts in thousands of euros)	Carrying amount on the statement of financial position (1)	Fair value through profit and loss	Fair value through other comprehensive income	Financial assets at amortized cost	Financial liabilities at amortized cost	Fair value
Other non-current financial assets	1,091			1,091		1,091
Other current financial assets	59			59		59
Trade and other receivables	4			4		4
Other current assets	4,389			4,389		4,389
Cash and cash equivalents (2)	44,446	44,446				44,446
<b>Total financial assets</b>	<b>48,898</b>	<b>44,446</b>	<b>—</b>	<b>4,452</b>	<b>—</b>	<b>48,898</b>
Financial liabilities - non current portion (3)	14,379				14,379	14,379
Derivative liabilities - non current portion (5)	288	288				288
Lease liabilities - non current portion (4)	9,197				9,197	9,197
Financial liabilities - current portion (3)	2,265				2,265	2,265
Derivative liabilities - current portion (5)	129	129				129
Lease liabilities - current portion (4)	1,607				1,607	1,607
Trade and other payables	20,910				20,910	20,910
Other current liabilities (6)	4,288				4,288	4,288
<b>Total financial liabilities</b>	<b>53,063</b>	<b>417</b>	<b>—</b>	<b>—</b>	<b>52,646</b>	<b>53,063</b>

As of December 31, 2021 (amounts in thousands of euros)	Carrying amount on the statement of financial position (1)	Fair value through profit and loss	Fair value through other comprehensive income	Financial assets at amortized cost	Financial liabilities at amortized cost	Fair value
Other non-current financial assets	876			876		876
Other current financial assets	384			384		384
Trade and other receivables	12			12		12
Other current assets	4,218			4,218		4,218
Cash and cash equivalents (2)	33,699	33,699				33,699
<b>Total financial assets</b>	<b>38,313</b>	<b>33,699</b>	<b>—</b>	<b>4,614</b>	<b>—</b>	<b>38,313</b>
Financial liabilities - non current portion (3)	15,232				15,232	15,232
Lease liabilities - non current portion (4)	8,162				8,162	8,162
Financial liabilities - current portion (3)	164				164	164
Lease liabilities - current portion (4)	1,817				1,817	1,817
Trade and other payables	14,154				14,154	14,154
Other current liabilities (6)	3,777				3,777	3,777
<b>Total financial liabilities</b>	<b>43,306</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>43,306</b>	<b>43,306</b>

As of December 31, 2022 (amounts in thousands of euros)	Carrying amount on the statement of financial position (1)	Fair value through profit and loss	Fair value through other comprehensive income	Financial assets at amortized cost	Financial liabilities at amortized cost	Fair value
Other non-current financial assets	195			195		195
Other current financial assets	464			464		464
Trade and other receivables	76			76		76
Other current assets	2,457			2,457		2,457
Cash and cash equivalents (2)	38,789	38,789				38,789
<b>Total financial assets</b>	<b>41,322</b>	<b>38,789</b>	<b>—</b>	<b>2,533</b>	<b>—</b>	<b>41,322</b>
Financial liabilities - non current portion (3)	7,547				7,547	7,547
Lease liabilities - non current portion (4)	2,680				2,680	2,680
Financial liabilities - current portion (3)	2,565				2,565	2,565
Lease liabilities - current portion (4)	775				775	775
Trade and other payables	5,115				5,115	5,115
Other current liabilities (6)	2,858				2,858	2,858
<b>Total financial liabilities</b>	<b>21,540</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>21,540</b>	<b>21,540</b>

(1) The carrying amount of these assets and liabilities is a reasonable approximation of their fair value.

(2) Cash and cash equivalents are comprised of money market funds and time deposit accounts, which are measured using level 1 measurements.

(3) The fair value of financial liabilities is determined using level 2 measurements.

(4) The fair value of lease liabilities is determined using level 2 measurements.

(5) The fair value of derivative liabilities is determined using level 3 measurements.

(6) Excluding current liabilities accruals

## 5. RELATED PARTIES

The Company's related parties include the Chairman of the Board of Directors (Jean-Paul Kress), the Chief Executive Officer (Gil Beyen), the two Deputy General Managers (Jérôme Bailly and Eric Soyer), members of the Board of Directors and members of the

executive committee. As a result of a termination or change of duties, the Chief Executive Officer and the two Deputy General Managers, could receive a compensation equal to their remuneration during the last 12 months, as well as non-competition indemnities of up to 18 months' salary.

The remuneration of directors and members of the executive committee was as set forth in the table below.

(amounts in thousands of euros)	12/31/2020			12/31/2021			12/31/2022		
	Salary / fees	Retirement benefits	Share based payments	Salary / fees	Retirement benefits	Share based payments	Salary / fees	Retirement benefits	Share based payments
Executive officers / VP and qualified person	1,242	22	448	1,148	22	522	1,170	22	430
Executive committee	1,374	25	201	1,457	24	302	1,139	15	199
Board of directors	300	—	43	306	—	1	306	—	—
<b>Total</b>	<b>2,915</b>	<b>47</b>	<b>692</b>	<b>2,911</b>	<b>46</b>	<b>825</b>	<b>2,615</b>	<b>38</b>	<b>629</b>

The Company has no other related parties.

## 6. MANAGEMENT OF FINANCIAL RISKS

The purpose of the financial instruments held by the Company is to finance its activities. It is not the Company's policy to invest in financial instruments for speculative purposes.

The principal risks to which the Company is exposed are liquidity risk, equity risk, foreign currency exchange risk, interest rate risk and credit risk.

### Liquidity risk

The Company has been structurally loss-generating since its creation. The net cash flows used by the Company's operating activities were respectively €51.7 million, €56.8 million and €31.8 million for the years ended December 31, 2020, December 31, 2021 and December 31, 2022, respectively.

At the date the consolidated financial statements were authorized, the Board of Directors and management believes that the Company will be able to fund its operations beyond the next twelve month following the closing of the accounts (see note 2.1).

As of December 31, 2020 (amounts in thousands of euros)	Less than one year	One to five years	More than five years	Total
Convertible notes	2,400	—	—	2,400
Conditional advances	—	—	4,421	4,421
Bank loans	98	7,929	2,071	10,098
Other financial liabilities	—	35	—	35
Lease liabilities	1,607	5,151	4,046	10,804
Trade and fixed assets payables	4,792	—	—	4,792
<b>Total</b>	<b>8,897</b>	<b>13,115</b>	<b>10,538</b>	<b>32,550</b>

As of December 31, 2021 (amounts in thousands of euros)	Less than one year	One to five years	More than five years	Total
Convertible notes	—	—	—	—
Conditional advances	—	—	5,281	5,281
Bank loans	164	9,438	475	10,077
Other financial liabilities	—	38	—	38
Lease liabilities	1,817	4,803	3,359	9,979
Trade and fixed assets payables	2,487	—	—	2,487
<b>Total</b>	<b>4,468</b>	<b>14,279</b>	<b>9,115</b>	<b>27,862</b>

As of December 31, 2022 (amounts in thousands of euros)	Less than one year	One to five years	More than five years	Total
Convertible notes				—
Conditional advances			—	—
Bank loans	2,565	7,508	—	10,073
Other financial liabilities		40		40
Lease liabilities	775	1,968	712	3,455
Trade and fixed assets payables	1,562			1,562
<b>Total</b>	<b>4,902</b>	<b>9,516</b>	<b>712</b>	<b>15,130</b>

#### Foreign currency exchange risk

The Company's functional currency is the euro. However, a significant portion of its expenses, financial assets and liabilities are denominated in U.S. dollars. A deterioration of the U.S. dollars versus the 1.0666 closing rate at December 31, 2022 could impact the financial assets and liabilities as follows:

(in thousands)	As of December 31, 2022		Sensitivity		
	USD	EUR	+ 1 %	+ 5 %	+ 10 %
<b>Financial assets</b>	<b>16,971</b>	<b>15,912</b>	<b>(158)</b>	<b>(758)</b>	<b>(1,447)</b>
<i>of which cash and cash equivalents</i>	<i>16,399</i>	<i>15,375</i>	<i>(152)</i>	<i>(732)</i>	<i>(1,398)</i>
<b>Financial liabilities</b>	<b>1,848</b>	<b>1,732</b>	<b>(17)</b>	<b>(82)</b>	<b>(157)</b>

#### Interest rate risk

The Company has very low exposure to interest rate risk. Such exposure primarily involves money market funds and time deposit accounts. Changes in interest rates have a direct impact on the rate of return on these investments and the cash flows generated.

The outstanding bank loans bear interest at a fixed rate, and therefore the company is not subject to interest rate risk with respect to these loans.

#### Credit risk

The credit risk related to the Company's cash and cash equivalents is not significant in light of the quality of the co-contracting financial institutions.

### 7. OFF-BALANCE SHEET COMMITMENTS

#### Collaborative arrangements

##### *Agreement with the Teva Group*

In March 2011, the Company entered into an exclusive distribution agreement with the Teva Group (through Abic Marketing Limited), or Teva, to distribute GRASPA® in Israel. Under the terms of the agreement, Teva will submit the request for approval of GRASPA® for ALL in Israel and is responsible for the marketing and distribution of GRASPA® in Israel. The agreement provides that Teva will pay milestone payments to the Company and will share net earnings on product sales in Israel with the Company. In connection with the decision to halt further development with GRASPA® in November 2022 (see note 1), the Company no longer expects to receive any income under this agreement."

##### *Agreement with SQZ Biotechnologies*

On June 24, 2019, the Company entered into a collaboration agreement with SQZ Biotechnologies, a cell therapy company developing novel treatments in multiple therapeutic areas, to advance novel red blood cell-based therapeutics for immune modulation. Under the terms of the agreement, the Company has granted to SQZ Biotechnologies an exclusive worldwide license to develop antigen specific immune modulating therapies employing red blood cell-based approaches. Combining SQZ Biotechnologies' proprietary and versatile

cell engineering platform with the intellectual property of the Company related to red blood cell-based therapeutics is intended to allow for the rapid development of a broad pipeline of novel immunomodulatory products addressing multiple indications.

The agreement provides for:

- An upfront payment of \$1 million, equivalent to €0.9 million when recognized in 2019;
- Potential development, regulatory and commercial milestone payments up to \$56 million for the first product successfully developed by SQZ Biotechnologies under this agreement;
- The Company could also receive progressive royalties based on future sales.

### Financing agreements

#### *Financing agreement with Alpha Blue Ocean and European High Growth Opportunities Securitization Fund in the form of convertible notes with share subscription warrants attached (“OCABSA”)*

On June 24, 2020, the Company signed a financing agreement with Luxembourg-based European High Growth Opportunities Securitization Fund in the form of convertible notes with share subscription warrants attached (“OCABSA”), allowing a potential fundraising up to a maximum of €60 million, subject to the regulatory limit of 20% dilution.

The Company issued 1,200 note warrants for free that may be exercised in tranches at the Company request until June 25, 2022. Only 540 note warrant were exercised in 9 tranches for a total fundraising of €27 million.

The possibility for the Company to issue additional tranches has expired as the OCABSA Agreement provides that the BEOCABSA may be exercised in tranches over a period of 24 months from June 25, 2020, i.e. until June 25, 2022.

#### *Financing facility with the implementation of an at-the-market (“ATM”) program on Nasdaq with Cowen*

On September 21, 2020, the Company entered into a sales agreement with Cowen with respect to an ATM offering program pursuant to which the Company may issue and sell, from time to time at its sole discretion, ordinary shares in the form of American Depositary Shares (“ADSs”) to eligible investors at market prices, with aggregate gross sales proceeds of up to \$30 million, subject to the regulatory limit of 20% dilution. The ATM program will be effective until September 21, 2023, unless terminated prior to such date in accordance with the sales agreement or the maximum number of ADSs to be sold thereunder has been reached.

At the date the consolidated financial statements were authorized, \$22.0 million remained available for issuance until September 2023, subject to the regulatory limit of 20% dilution.

### Lease agreements

#### *Sublease in the United-States*

In July 2019 and June 2021, the Company signed two sublease agreements for its premises located in Cambridge.

(amounts in thousands of euros)

As of December 31, 2022	Income from sublease in 2022	Sublease to be received			
		Total	Less than one year	One to five years	More than five years
Sublease in US	526	44	44	—	—
<b>Total</b>	<b>526</b>	<b>44</b>	<b>44</b>	<b>—</b>	<b>—</b>

The sublease in US will end at the end of January 2023.

The sublease contracts are classified as finance leases: the right of use was derecognized and the Company recorded a net investment in a sublease in other current assets (see note 4.4). The income from the sublease are recognized in the statement of income (loss) over the term of the sublease contract.

**DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

The following description of the ordinary shares, the American Depositary Shares and the bylaws of Erytech Pharma S.A. (“Erytech” or the “Company”) is a summary and does not purport to be complete. This summary is subject to and qualified in its entirety by reference to the complete text of the Company’s bylaws, which are incorporated by reference as Exhibit 1.1 of the Company’s Annual Report on Form 20-F to which this description is also an exhibit. The Company encourages you to read the Company’s bylaws carefully.

As of December 31, 2022, Erytech has the following series of securities registered pursuant to Section 12(b) of the Exchange Act:

<b>Title of Each Class</b>	<b>Trading Symbol</b>	<b>Name of Each Exchange on Which Registered</b>
American Depositary Shares, each representing one ordinary share, nominal value €0.10 per share	ERYP	The Nasdaq Global Select Market
Ordinary shares, nominal value €0.10 per share*	*	The Nasdaq Global Select Market*

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

**ORDINARY SHARES**

As of December 31, 2022, our outstanding share capital consisted of a total of 31,018,553 issued ordinary shares, fully paid and with a nominal value €0.10 per share. The Company has no preferred shares outstanding.

**Preemptive rights**

Under French law, in the event of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a pro rata basis unless such rights are waived by a two-thirds majority of the votes held by the shareholders present at the extraordinary meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights are not waived by the extraordinary general meeting, each stockholder may individually exercise, assign or not exercise its preferential rights.

**Types and class of securities**

**Form of Shares.** The shares are in registered form, until their full payment. When they are fully paid up, they may be in registered form or bearer, at the option of the shareholders.

Further, in accordance with applicable laws, the Company may request at any time from the central depository responsible for holding the Company’s shares, or directly from one or several intermediaries listed in Article L. 211-3 of the French Monetary and Financial Code, the information concerning the owners of the Company’s shares and securities conferring immediate or long-term voting rights at the Company’s general meetings of shareholders as referred to in Article L. 228-2 of the French Commercial Code.

**Holding of Shares.** In accordance with French law concerning the “dematerialization” of securities, the ownership rights of shareholders are represented by book entries instead of share certificates. Shares issued are registered in individual accounts opened by the Company or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions.

**Ownership of Shares by Non-French Persons.** Neither French law nor the Company’s bylaws limit the right of non-residents of France or non-French persons to own or, where applicable, to vote the Company’s securities. However, non-residents of France may have to file an administrative notice with the French authorities in connection with certain direct or indirect investments in the Company, including through ownership of ADSs. In addition, acquisitions of 10% of the share capital or voting rights of a French resident company or a non-French resident company by a non-French resident or by a French resident, respectively, are subject to statistical reporting requirements to the French National Bank.

Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health and telecommunications. etc., pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590). The French government has adapted this foreign investment control procedure in France within the context of the ongoing COVID-19 pandemic in two ways: (i) the inclusion, by a Ministerial order (arrêté) of April 27, 2020, of biotechnologies in the list of critical technologies and (ii) the addition, by a Decree (décret) of July 22, 2020 as amended by Decree n°2020-1729 of December 28, 2020, of the threshold of 10% of voting rights of a company subject to French law whose securities are listed on a stock exchange as triggering the control procedure. The Decree of July 22, 2020, as extended by the Decree n° 2021-1758 of December 22, 2021, currently provides that this new 10% threshold will be effective until December 31, 2022 and a fast-track review procedure for foreign investments exceeding this threshold.

See “Limitations Affecting Shareholders of a French Company—Ownership of ADSs or Shares by Non-French Residents.”

**Assignment and Transfer of Shares.** Shares are freely negotiable, subject to applicable legal and regulatory provisions. French law notably provides for standstill obligations and prohibition of insider trading

#### **Memorandum and articles of association**

##### ***Corporate Purpose (Article 3 of the Bylaws)***

The Company's corporate purpose in France and abroad includes the research, manufacturing, importation, distribution and marketing of investigational drugs, devices and medical equipment, and the provision of advisory services associated with these activities. The Company is authorized to engage in all financial, commercial, industrial, civil, property or security-related transactions that directly or indirectly relate to accomplishing the purposes stated above.

The Company may act directly or indirectly and do all these operations in all countries, for or on behalf of third parties, either alone or with partnership with third parties, association, group or creation of new companies, contribution, sponsorship, subscription, purchase of shares or rights, mergers, alliances, undeclared partnership or taking or giving in lease or in management of all property and rights or otherwise.

##### ***Directors (Articles 17-22 of the Bylaws)***

**Duties of the Board.** Except for powers given to the Company's shareholders by law and within the limit of the corporate purpose, the Company's board of directors is responsible for all matters relating to the successful operations of the Company, including but not limited to, social and environmental issues associated with the Company's activities, and, through its resolutions, governs matters involving the company.

**Appointment and Term.** The Company's board of directors must be composed of at least three members, but may not exceed 18 members, subject to the dispensation established by law in the event of merger. In appointing and electing directors, the Company seeks a balanced representation of women and men. The term of a director is 3 years, and directors may be re-elected at the Company's annual ordinary share meetings; however, a director over the age of 75 may not be appointed if such appointment would result in the number of directors over the age of 75 constituting more than one-third of the board. The number of directors who are also the Company's employees cannot exceed one-third of the board. Directors may be natural persons or legal entities except for the chairman of the board who must be a natural person. Legal entities appointed to the board must designate a permanent representative. If a director dies or resigns between annual meetings, the board may appoint a temporary director to fill the vacancy, subject to ratification at the next ordinary general meeting, or, if such vacancy results in a number of directors below three, the board must call an ordinary general meeting to fill the vacancy. If a director is absent at more than four consecutive meetings or placed with guardians, he or she will be deemed to have automatically resigned.

**Organization.** The board must elect a chairman from among the board members. The chairman must be a natural person, age 75 or younger, and may be removed by the board at any time. The board may also elect a natural person as vice president to preside in the chairman's absence and may designate up to two non-voting board observers.

**Deliberations.** At least half of the number of directors in office must be present to constitute a quorum. Decisions are made by a majority of the directors present or represented and, if there is a tie, the vote of the chairman will carry the decision. Meetings may be held as often as required; however, the chairman is required to call a meeting with a determined agenda upon the request of at least

one-third of the directors if the board has not met for more than two months. French law and the Company's charter and bylaws allow directors to attend meetings in person or, to the extent permitted by applicable law and with specified exceptions in the Company's bylaws, by videoconference or other telecommunications arrangements. The board of directors can also make decisions by way of written consultation under the conditions provided by law.

**Directors' Voting Powers on Proposal, Arrangement or Contract in which any Director is Materially Interested.** Under French law, any agreement entered into, directly or through an intermediary, between the Company and any director that is not entered into in the ordinary course of the Company's business and upon standard market terms is subject to the prior authorization of the board of directors. The interested director cannot vote on such decision. The same provision applies to agreements between the Company and another company, except where such company is the Company's wholly owned subsidiary, if one of the Company's directors is the owner or a general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the Company's directors has an indirect interest.

**Directors' Compensation.** Director compensation for attendance at board meetings is determined at the annual ordinary general meeting. The general meeting may allocate an annual fixed sum and the board of directors allocates this sum among its members as it sees fit. In addition, the board of directors may allocate exceptional compensation (rémunération exceptionnelle) for missions or mandates entrusted to its members, for example as member or chair of one or more board committees, this remuneration is subject to the provisions regarding related-parties agreements. At the Company's combined general meetings of shareholders held on June 26, 2020, shareholders set the total annual attendance fees to be distributed among non-employee directors at €425 thousand for 2020, as well as to subsequent financial years until a new decision is made.

**Board of Directors' Borrowing Powers.** There are currently no limits imposed on the amounts of loans or borrowings that the board of directors may approve.

**Directors' Share Ownership Requirements.** The Company's directors are not required to own any of the Company's shares.

## Shareholder rights

### **Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 9, 16, 30, 33 and 34 of the Bylaws)**

**Dividends.** The Company may only distribute dividends out of the Company's distributable profits, plus any amounts held in the Company's reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.

**"Distributable Profits"** consist of the Company's statutory net profit in each fiscal year, calculated in accordance with accounting standards applicable in France, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to French law.

**Legal Reserve.** Pursuant to French law, the Company must allocate 5% of the Company's statutory net profit for each year to the Company's legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital.

**Approval of Dividends.** Pursuant to French law, the Company's board of directors may propose a dividend for approval by the shareholders at the annual ordinary general meeting.

Upon recommendation of the Company's board of directors, the Company's shareholders may decide to allocate all or part of any distributable profits to special or general reserves, to carry them forward to the next fiscal year as retained earnings or to allocate them to the shareholders as dividends. However, dividends may not be distributed when the Company's net assets are or would become as a result of such distribution lower than the amount of the share capital plus the amount of the legal reserves which, under French law, may not be distributed to shareholders. The amount of the Company's share capital plus the amount of the Company's legal reserves which may not be distributed was equal to €3,101,855.30 at June 24, 2022.

The Company's board of directors may distribute interim dividends after the end of the fiscal year but before the approval of the financial statements for the relevant fiscal year when the interim balance sheet, established during such year and certified by an auditor, reflects that the Company has earned distributable profits since the close of the last financial year, after recognizing the

necessary depreciation and provisions and after deducting prior losses, if any, and the sums to be allocated to reserves, as required by law or the bylaws, and including any retained earnings. The amount of such interim dividends may not exceed the amount of the profit so defined.

**Distribution of Dividends.** Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by the Company's board of directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by the Company's board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Shareholders may be granted an option to receive dividends in cash or in shares, in accordance with legal conditions. The conditions for payment of dividends in cash shall be set at the shareholders' meeting or, failing this, by the board of directors.

**Timing of Payment.** Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

**Voting Rights.** Each share shall entitle its holder to vote and be represented in the shareholders' meetings in accordance with the provisions of French law and of the Company's bylaws. Ownership of one share implies, ipso jure, adherence to the Company's bylaws and the decisions of the shareholders' meeting.

In general, each shareholder is entitled to one vote per share at any general shareholders' meeting. Pursuant to the Company's bylaws, however, 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. Under French law, ordinary bearer shares are not eligible for double voting rights. Purchasers of ADSs or of ordinary shares deposited with the depository to receive ADSs, will be unlikely to meet the requirements to have double voting rights.

Under French law, treasury shares or shares held by entities controlled by the Company are not entitled to voting rights and do not count for quorum purposes.

**Rights to Share in the Company's Profit.** Each share entitles its holder to a portion of the corporate profits and assets proportional to the amount of share capital represented thereby.

**Rights to Share in the Surplus in the Event of Liquidation.** If the Company is liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of the Company's shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the number of shares respectively held by them, taking into account, where applicable, of the rights attached to shares of different classes.

**Repurchase and Redemption of Shares.** Under French law, the Company may acquire its own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, Regulation (EU) No. 596/2014 of April 16, 2014 provides for safe harbor exemptions when the acquisition is made for one of the following purposes:

- to decrease the Company's share capital, provided that such a decision is not driven by losses and that a purchase offer is made to all shareholders on a *pro rata* basis, with the approval of the shareholders at an extraordinary general meeting; in this case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;
- to meet obligations arising from debt securities that are exchangeable into equity instruments;
- to provide shares for distribution to employees or managers under a profit-sharing, free share or share option plan; in this case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or
- the Company benefit from a simple exemption when the acquisition is made under a liquidity contract complying with the general regulations of, and market practices accepted by the French Financial Markets Authority (AMF).

All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L. 20-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.

Under the Market Abuse Regulation 596/2014 of August 16, 2014 (MAR) and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading value on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of shares may result in the Company holding, directly or through a person acting on the Company's behalf, more than 10% of the Company's issued share capital. Shares repurchased by the Company continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as the Company holds them directly or indirectly, and the Company may not exercise the preemptive rights attached to them.

***Sinking Fund Provisions.*** The Company's bylaws do not provide for any sinking fund provisions.

***Liability to Further Capital Calls.*** Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

***Requirements for Holdings Exceeding Certain Percentages.*** None, except as described below under the sections of this exhibit titled "Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws)" and "Form, Holding and Transfer of Shares (Articles 13 and 15 of the Bylaws)—Ownership of Shares by Non-French Persons."

#### ***Actions Necessary to Modify Shareholders' Rights***

Shareholders' rights may be modified as allowed by French law. Only the extraordinary shareholders' meeting is authorized to amend any and all provisions of the Company's bylaws. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

#### ***Special Voting Rights of Warrant Holders***

Under French law, the holders of warrants of the same class (i.e., warrants that were issued at the same time and with the same rights), including founder's warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

#### ***Rules for Admission to and Calling Annual Shareholders' Meetings and Extraordinary Shareholders' Meetings (Section IV of the Bylaws)***

***Access to, Participation in and Voting Rights at Shareholders' Meetings.*** Shareholders' meetings are composed of all shareholders, regardless of the number of shares they hold. Each shareholder has the right to attend the meetings and participate in the discussions (1) personally; (2) by granting proxy to any individual or legal entity of his choosing; (3) by sending a proxy to the Company without indication of the mandate; (4) by voting by correspondence; or (5) at the option of the board of directors at the time the meeting is called, by videoconference or another means of telecommunication, including internet, in accordance with applicable laws that allow identification. The board of directors organizes, in accordance with legal and regulatory requirements, the participation and vote of these shareholders at the meeting, assuring, in particular, the effectiveness of the means of identification.

Participation in shareholders' general meetings, in any form whatsoever, is subject to registration or registration of shares under the conditions and time limits provided for applicable laws.

The final date for returning voting ballots by correspondence is set by the board of directors and disclosed in the notice of meeting published in the French Journal of Mandatory Statutory Notices, or BALO (*Bulletin des Annonces Légales Obligatoires*). This date cannot be earlier than three days prior to the meeting unless otherwise provided in the bylaws. The Company's bylaws provide that the board of directors has the option to accept the voting ballots by correspondence beyond the limit set by applicable laws.

A shareholder who has voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which the Company sends to such shareholder either at the shareholder's request or at the Company's initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.

A shareholder may vote by correspondence by means of a voting form, which the Company sends to such shareholder either at the shareholder's request or at the Company's initiative, or which the Company includes in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on the Company's website at least 21 days before the date of the meeting. The voting form must be recorded by the Company three days prior to the shareholders' meeting, in order to be taken into consideration. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

To better understand the voting rights of the ADSs, ADS holders should carefully read the section in this exhibit titled "II. American Depositary Shares—Voting Rights."

**Notice of Annual Shareholders' Meetings.** Shareholders' meetings are convened by the Company's board of directors, or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances. Meetings are held at the Company's registered offices or at any other location indicated in the meeting announcement (*avis de réunion*). A meeting announcement is published in the BALO at least 35 days prior to a meeting, as well as on the Company's website at least 21 days prior to the meeting. In addition to the particulars relative to the Company, it indicates, notably, the meeting's agenda and the draft resolutions that will be presented. The requests for recording of issues or draft resolutions on the agenda must be addressed to the Company under the conditions provided for in the current legislation.

Subject to special legal provisions, the convening notice (*avis de convocation*) is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the BALO. Further, the holders of registered shares for at least a month at the time of the latest of the insertions of the convening notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. The latter may at any time expressly request by registered letter to the Company with acknowledgment of receipt that the aforementioned means of telecommunication should be replaced in the future by a mailing.

The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.

The convening notice may be addressed, where appropriate, with a proxy form and a voting by correspondence form, under the conditions specified in the Company's bylaws, or with a voting by correspondence form alone, under the conditions specified in the Company's bylaws. When the shareholders' meeting cannot deliberate due to the lack of the required quorum, the second meeting must be called at least ten days in advance in the same manner as used for the first notice.

**Agenda and Conduct of Annual Shareholders' Meetings.** The agenda of the shareholders' meeting shall appear in the convening notice of the meeting and is set by the author of the notice. The shareholders' meeting may only deliberate on the items on the agenda except for the removal of directors and the appointment of their successors which may be put to vote by any shareholder during any shareholders' meeting. Pursuant to French law and the Company's current share capital, one or more shareholders representing 5% of the Company's share capital may request the inclusion of items or proposed resolutions on the agenda. Such request must be received at the latest on the 25<sup>th</sup> day preceding the date of the shareholders' meeting, and in any event no later than the 20<sup>th</sup> day following the date of the shareholders' meeting announcement.

Shareholders' meetings shall be chaired by the Chairman of the board of directors or, in his or her absence, by a Deputy Chairman or by a director elected for this purpose. Failing that, the meeting itself shall elect a Chairman. Vote counting shall be performed by the two members of the meeting who are present and accept such duties, who represent, either on their own behalf or as proxies, the greatest number of votes.

**Ordinary Shareholders' Meeting.** Ordinary shareholders' meetings are those meetings called to make any and all decisions that do not amend the Company's bylaws. An ordinary meeting shall be convened at least once a year within six months of the end of each fiscal year in order to approve the annual and consolidated accounts for the relevant fiscal year or, in case of postponement, within the period established by court order. Upon first notice, the meeting may validly deliberate only if the shareholders present or represented by proxy or voting by mail represent at least one-fifth of the shares entitled to vote. Upon second notice, no quorum is required. Decisions are made by a majority of the votes cast by the shareholders present, or represented by proxy, or voting by mail. Abstentions will have the same effect of a "no" vote. In addition, pursuant to a recent AMF recommendation, French listed companies may be required to conduct a consultation of the ordinary shareholders meeting prior to the disposal of the majority of their assets, under certain circumstances.

**Extraordinary Shareholders' Meeting.** The Company's bylaws may only be amended by approval at an extraordinary shareholders' meeting. The Company's bylaws may not, however, be amended to increase shareholder commitments without the approval of each shareholder. Subject to the legal provisions governing share capital increases from reserves, profits or share premiums, the resolutions of the extraordinary meeting shall be valid only if the shareholders present, represented by proxy or voting by mail represent at least one-fourth of all shares entitled to vote upon first notice, or one-fifth upon second notice. If the latter quorum is not reached, the second meeting may be postponed to a date no later than two months after the date for which it was initially called. Decisions are made by a two-thirds majority of the votes cast by the shareholders present, represented by proxy, or voting by mail. The votes cast do not include the votes attached to shares for which the shareholder has not taken part in the vote, has abstained or has voted blank or naked.

## Limitations

### Ownership of ADSs or Shares by Non-French Residents

Neither the French Commercial Code nor the Company's bylaws presently impose any restrictions on the right of non-French residents or non-French shareholders to own and vote shares. However, non-French residents must file a declaration for statistical purposes with the Bank of France (*Banque de France*) within twenty working days following the date of certain direct foreign investments in the Company, including any purchase of the Company's 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 the share capital or voting rights or cross such 10% threshold. Violation of this filing requirement may be sanctioned by five years' imprisonment and a fine up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity. Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health and telecommunications. etc., pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590). The French government has adapted this foreign investment control procedure in France within the context of the ongoing COVID-19 pandemic in two ways: (i) the inclusion, by a Ministerial order (arrêté) of April 27, 2020, of biotechnologies in the list of critical technologies and (ii) the addition, by a Decree (décret) of July 22, 2020 as amended by Decree n°2020-1729 of December 28, 2020, of the threshold of 10% of voting rights of a company subject to French law whose securities are listed on a stock exchange as triggering the control procedure. The Decree of July 22, 2020, as extended by the Decree n° 2022-1622 of December 23, 2022, currently provides that this new 10% threshold will be effective until December 31, 2023 and a fast-track review procedure for foreign investments exceeding this threshold.

### Foreign Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that the Company 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.

### Availability of Preferential Subscription Rights

The Company's shareholders will have the preferential subscription rights described under "Ordinary Shares—Changes in Share Capital—Preferential Subscription Right." Under French law, shareholders have preferential rights to subscribe for cash issues of new shares or other securities giving rights to acquire additional shares on a pro rata basis. Holders of the Company's securities in the

United States (which may be represented by ADSs) will not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. The Company may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, holders of the Company's securities in the United States will be unable to exercise any preferential subscription rights and their interests will be diluted. The Company is under no obligation to file any registration statement in connection with any issuance of new shares or other securities. The Company intends to evaluate at the time of any rights offering the costs and potential liabilities associated with registering the rights, as well as the indirect benefits to the Company of enabling the exercise by holders of shares in the United States and ADS holders of the subscription rights, and any other factors the Company considers appropriate at the time, and then to make a decision as to whether to register the rights. The Company cannot guarantee that it will file a registration statement.

For holders of the Company's ordinary shares represented by ADSs, the depository may make these rights or other distributions available to ADS holders. If the depository does not make the rights available to ADS holders and determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, ADS holders will receive no value for them. The section herein titled "II. American Depositary Shares—Dividends and Other Distributions" explains in detail the depository's responsibility in connection with a rights offering. See also "*Risk Factors—The right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to the holders of our ADSs*" in the Company's Annual Report on Form 20-F to which this description is filed as an exhibit.

### ***Provisions Having the Effect of Delaying, Deferring or Preventing a Change in Control of the Company***

Provisions contained in the Company's bylaws and French corporate law could make it more difficult for a third-party to acquire the Company, even if doing so might be beneficial to the Company's shareholders. These provisions include the following:

- under French law, the owner of 90% of the share capital or 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 the Company, including any purchase of the Company's 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 the Company's share capital or voting rights or cross such 10% threshold. See "Limitations Affecting Shareholders of a French Company;"
- under French law, certain investments in a French company relating to certain strategic industries, including biotechnologies, by individuals or entities not residents in a Member State of the European Union are subject to prior authorization of the Ministry of Economy pursuant to Law n°2019-486 (and as from April 1, 2020 pursuant to the decree n°2019-1590 of December 31, 2019, as amended by decree (arrêté) of April 27, 2020). See "Limitations Affecting Shareholders of a French Company;"
- a merger (i.e., in a French law context, a share for share exchange following which the Company's company would be dissolved into the acquiring entity and the Company's shareholders would become shareholders of the acquiring entity) of the Company's company into a company incorporated in the European Union would require the approval of the Company's board of directors as well as a two-thirds majority of the votes cast by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of the Company's company into a company incorporated outside of the European Union would require 100% of the Company's 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;
- the Company's shareholders have granted and may grant in the future the Company's board of directors broad authorizations to increase the Company's share capital or to issue additional ordinary shares or other securities, such as warrants, to the

Company's shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for the Company's shares;

- the Company's shareholders have preferential subscription rights on a pro rata basis on the issuance by the Company 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 the Company's shareholders or on an individual basis by each shareholder;
- the Company's board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director for the remaining duration of such directors' 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 the Company's board of directors ;
- the Company's board of directors can be convened by its chairman or its managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one third of the total number of directors;
- the Company's board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;
- the Company's shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice;
- approval of at least a majority of the votes cast by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- 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 director can be proposed at any shareholders' meeting without notice;
- the Company's bylaws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the section of this exhibit titled "Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws);"
- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of the bylaws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by two-thirds of the votes of the Company's shareholders present, represented by a proxy or voting by mail at the meeting.

#### **Disclosure of shareholdings**

##### ***Declaration of Crossing of Ownership Thresholds (Article 9 of the Bylaws)***

Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code coming to directly or indirectly own, or cease to own, alone or in concert, a number of shares representing a fraction of the Company's capital or voting rights greater or equal to 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% and 95% shall inform the Company as well as the French Financial Market Authority (AMF) of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds.

This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In the event of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code.

In addition, any shareholder, alone or acting in concert, crossing the 10%, 15%, 20% or 25% threshold shall file a declaration with the AMF pursuant to which it shall expose its intention over the following 6 months, including notably whether it intends to continue acquiring shares of the Company, it intends to acquire control over the Company, its intended strategy for the Company.

Further, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 30% threshold shall file a mandatory public tender offer with the AMF. Also, any shareholder holding directly or indirectly a number between 30% and 50% of the capital or voting rights and who, in less than 12 consecutive months, increases his/her/its holding of capital or voting rights by at least 1% company's capital or voting rights, shall file a mandatory public tender offer.

### Differences in Corporate Law

*The Company is a société anonyme, or S.A., incorporated under the laws of France. The laws applicable to French sociétés anonymes differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to the Company and the Delaware General Corporation Law relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and French law.*

	FRANCE	DELAWARE
Number of Directors	Under French law, a société anonyme must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the bylaws. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied will be null and void.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the chairman of the board), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors as well as the deliberations taken by the board member irregularly appointed.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.
Removal of Directors	Under French law, directors may be removed from office, with or without cause, at any shareholders' meeting without notice or justification, by a simple majority vote.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death or a resignation, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification by the shareholders by the next shareholders' meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors.

	FRANCE	DELAWARE
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months after the close of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing that, by the statutory auditors, or by a court appointed agent (mandataire ad hoc) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

	FRANCE	DELAWARE
Notice of General Meetings	<p>A meeting announcement is published in the French Journal of Mandatory Statutory Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the meeting. Subject to limited exceptions provided by French law, additional convening notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the French Journal of Mandatory Statutory Notices (BALO). Further, shareholders holding registered shares for at least a month at the time latest insertions of the notices shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice to registered shareholders may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. When the shareholders' meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice.</p> <p>The convening notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Commerce and Companies, the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail and, as the case may be, the email address to which they may send written questions. The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail and conditions in which they can obtain voting forms by mail.</p>	<p>Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.</p>

	FRANCE	DELAWARE
Proxy	Each shareholder has the right to attend the meetings and participate in the discussions (i) personally, or (ii) by granting proxy to his/her spouse, his/her partner with whom he/she has entered into a civil union or to another shareholder or to any individual or legal entity of his choosing; or (iii) by sending a proxy to the company without indication of the mandate (in this case, such proxy shall be cast in favor of the resolutions supported by the board of directors), or (iv) by voting by correspondence, or (v) by videoconference or another means of telecommunication in accordance with applicable laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period.
Shareholder Action by Written Consent	Under French law, shareholders' action by written consent is not permitted in a société anonyme.	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.

	FRANCE	DELAWARE
Preemptive Rights	<p>Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a pro rata basis unless such rights are waived by a two-thirds majority of the votes cast by the shareholders present at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights have not been waived by the extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period shall not be less than five trading days. Preferential subscription rights are transferable during a period equivalent to the subscription period but starting two business days prior to the opening of the subscription period and ending two business days prior to the closing of the subscription period.</p>	<p>Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.</p>
Sources of Dividends	<p>Under French law, dividends may only be paid by a French société anonyme out of "distributable profits," plus any distributable reserves and "distributable premium" that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.</p> <p>"Distributable profits" consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years.</p> <p>"Distributable premium" refers to the contribution paid by the stockholders in addition to the par value of their shares for their subscription that the stockholders decide to make available for distribution.</p> <p>Except in case of a share capital reduction, no distribution can be made to the stockholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the bylaws.</p>	<p>Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus or (2) in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.</p>

	FRANCE	DELAWARE
Repurchase of Shares	<p>Under French law, a corporation may acquire its own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes:</p> <ul style="list-style-type: none"> <li>• to decrease its share capital with the approval of the shareholders at the extraordinary general meeting;</li> <li>• to meet obligations arising from debt securities, that are exchangeable into equity instruments; or</li> <li>• with a view to distributing the relevant shares to employees or managers under a profit-sharing, free share or share option plan.</li> </ul> <p>All other purposes, and especially share buy-backs for external growth operations by virtue of Article L. 20-10-62 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.</p> <p>Under the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) and in accordance with the General Regulations of the French Financial Markets Authority, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.</p> <p>No such repurchase of ordinary shares may result in the company holding, directly or through a person acting on its behalf, more than 10% of its issued share capital.</p>	<p>Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.</p>

	FRANCE	DELAWARE
Liability of Directors and Officers	Under French law, the bylaws may not include any provisions limiting the liability of directors. Civil liability of the directors may be sought for (1) an infringement of laws and regulations applicable to the company, (2) breach of the bylaws and (3) management failure.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: <ul style="list-style-type: none"> <li>• any breach of the director's duty of loyalty to the corporation or its stockholders;</li> <li>• acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;</li> <li>• intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or redemptions; or any transaction from which the director derives an improper personal benefit</li> </ul>
Voting Rights	French law provides that, unless otherwise provided in the bylaws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder. As from April 2016, double voting rights are automatically granted to the shares being registered since more than two years, unless the bylaws are modified in order to provide otherwise.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.
Shareholder Vote on Certain Transactions	Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: <ul style="list-style-type: none"> <li>• the approval of the board of directors; and</li> <li>• approval by a two-thirds majority of the votes cast by the shareholders present, represented by proxy or voting by mail at the relevant meeting or, in the case of a merger with a non-EU company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the board authority to decide a merger-absorption or to determine the terms and conditions of the merger plan).</li> </ul>	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: <ul style="list-style-type: none"> <li>• the approval of the board of directors; and</li> <li>• approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.</li> </ul>

	FRANCE	DELAWARE
Dissent or Dissenters' Appraisal Rights	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	<p>Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock. Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of merger or consolidation requires the holders to accept for their shares anything other than:</p> <ul style="list-style-type: none"> <li>• shares of stock of the surviving corporation;</li> <li>• shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders;</li> <li>• cash in lieu of fractional shares of the stock described in the two preceding bullet points; or</li> <li>• any combination of the above.</li> </ul> <p>In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.</p>
Standard of Conduct for Directors	French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest (intérêt social). In addition, directors shall take into account social and environmental issues arising out of the company's activity.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

	FRANCE	DELAWARE
Shareholder Suits	<p>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.</p> <p>The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.</p>	<p>Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:</p> <ul style="list-style-type: none"> <li>• state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and</li> <li>• allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or</li> <li>• state the reasons for not making the effort.</li> </ul> <p>Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.</p>
Amendment of Bylaws	<p>Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws. However, the board of directors is authorized to (i) modify the bylaws as a result of a decision to move the company's registered office and (ii) to bring to the bylaws any modification rendered necessary by an amendment to an applicable law or regulation if the board of directors has been prior authorized by the extraordinary shareholders meeting for this purpose, and subject, in both cases, to ratification by the next extraordinary shareholders' meeting.</p>	<p>Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal the bylaws of the corporation. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors.</p>

### Changes in Share Capital

**Increases in Share Capital (Article 10 of the Bylaws).** Pursuant to French law, the Company's share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of the Company's board of directors. The shareholders may delegate to the Company's board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

Increases in the Company's share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; and
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; and
- subject to certain conditions, by way of offset against debt incurred by the Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings.

**Reduction in Share Capital.** Pursuant to French law, any reduction in the Company's share capital requires shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of the Company's board of directors. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

**Preferential Subscription Right.** According to French law, if the Company issues additional securities for cash, current shareholders will have preferential subscription rights to these securities on a *pro rata* basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe *pro rata* based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, the Company's share capital by means of a cash payment or a set-off of cash debts. The preferential subscription rights are transferable during the subscription period relating to a particular offering.

The preferential subscription rights will be transferable during a period starting two days prior to the opening of the subscription period and ending two days prior to the closing of the subscription period.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of the Company's shareholders or individually by each shareholder. The Company's board of directors and its independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

In the future, to the extent permitted under French law, the Company may seek shareholder approval to waive preferential subscription rights at an extraordinary general shareholders' meeting in order to authorize the board of directors to issue additional shares and/or other securities convertible or exchangeable into shares.

## II. AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon acts as the depository for the American Depositary Shares. The Bank of New York Mellon's depository offices are located at 240 Greenwich Street, New York, New York 10286. American Depositary Shares are frequently referred to as ADSs and represent ownership interests in securities that are on deposit with the depository. ADSs may be evidenced by certificates that are commonly known as American Depositary Receipts, or ADRs. The depository typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Société Générale. The Company has appointed The Bank of New York Mellon as depository pursuant to an amended and restated deposit agreement. A copy of the amended and restated deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-3. ADS holders may obtain a copy of the amended and

restated deposit agreement from the SEC's website ([www.sec.gov](http://www.sec.gov)) and should refer to Registration Number 333-259690 when retrieving such copy.

An owner of ADSs may hold its ADSs either (1) directly (a) by having an ADR, which is a certificate evidencing a specific number of ADSs, registered in such owner's name, or (b) by having uncertificated ADSs registered in the owner's name in the Direct Registration System, or DRS, or (2) indirectly by holding a security entitlement in ADSs through the owner's broker or other financial institution that is a direct or indirect participant in the Depository Trust Company, or DTC. If an owner of ADSs decides to hold its ADSs directly, such owner is a registered ADS holder, also referred to as an ADS holder. This description assumes all owners are an ADS holder. If an owner of ADSs decides to hold the ADSs indirectly, such owner must rely on the procedures of its broker or other financial institution to assert the rights of ADS holders described in this section. Such indirect holder should consult with its broker or financial institution to find out what those procedures are. DRS is a system administered by DTC pursuant to which the depository may register the ownership of uncertificated ADSs, which ownership is confirmed by periodic statements sent by the depository to the registered holders of uncertificated ADSs.

An ADS holder will not be treated as one of the Company's shareholders and such ADS holder will not have shareholder rights. French law governs shareholder rights. The depository will be the holder of the ordinary shares underlying each owner's ADSs. A holder of ADSs will have ADS holder rights. An amended and restated deposit agreement among the Company, the depository and all persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depository. New York law governs the amended and restated deposit agreement and the ADRs. In the event of any discrepancy between the ADRs and the amended and restated deposit agreement, the amended and restated deposit agreement governs. The following is a summary of the material provisions of the amended and restated deposit agreement. More complete information is contained in the amended and restated deposit agreement and the form of ADR. Members of the public may obtain copies of those documents from the SEC's website at [www.sec.gov](http://www.sec.gov). A copy of the amended and restated deposit agreement is also filed as an exhibit to the Company's Annual Report on Form 20-F to which this description is also an exhibit.

## **Dividends and Other Distributions**

### ***How will ADS holders receive dividends and other distributions on the ordinary shares?***

The depository has agreed to pay or distribute to owners of ADSs the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after deducting its fees and expenses. Owners of ADSs will receive these distributions in proportion to the number of ordinary shares such owner's ADSs represent.

**Cash.** The Company does not expect to declare or pay any cash dividends or cash distributions on the Company's ordinary shares for the foreseeable future. The depository will convert any cash dividend or other cash distribution the Company pays on the ordinary shares or any net proceeds from the sale of any ordinary shares, rights, securities or other entitlements into U.S. dollars if it can do so on a reasonable basis, and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the amended and restated deposit agreement allows the depository to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. Before making a distribution, any withholding taxes or other governmental charges, together with fees and expenses of the depository that must be paid, will be deducted. See the section titled "Taxation" in the Company's Annual Report on Form 20-F to which this description is filed as an exhibit. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depository cannot convert the foreign currency, ADS holders may lose some or all of the value of the distribution.*

**Ordinary Shares.** The depository may distribute additional ADSs representing any ordinary shares the Company distributes as a dividend or free distribution. The depository will only distribute whole ADSs. It will sell ordinary shares which would require it to deliver a fractional ADS, or ADSs representing those ordinary shares, and distribute the net proceeds in the same way as it does with cash. If the depository does not distribute additional ADSs, the outstanding ADSs will also represent the new ordinary shares. The depository may sell a portion of the distributed ordinary shares, or ADSs representing those shares, sufficient to pay its fees and expenses in connection with that distribution.

***Rights to Purchase Additional Ordinary Shares.*** If the Company offers holders of its securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse unexercised. *In that case, owners of ADSs will receive no value for them.*

The depositary will exercise or distribute rights only if the Company asks it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary makes rights available to ADSs holders, it will exercise the rights and purchase the ordinary shares on such holders' behalf and in accordance with such holders' instructions. The depositary will then deposit the ordinary shares and deliver ADSs to such ADS holders. It will only exercise rights if such ADS holder pays it the exercise price and any other charges the rights require such holders to pay and comply with other applicable instructions. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

***Other Distributions.*** The depositary will send to ADS holders anything else the Company distributes on deposited securities by any means it determines is legal, fair and practical. If it cannot make the distribution in that way, the depositary may adopt another method. It may decide to sell what the Company distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what the Company distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from the Company that it is legal to make that distribution. In addition, the depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

Neither the Company nor the depositary are responsible for any failure to determine that it may be lawful or feasible to make a distribution available to any ADS holders. The Company has no obligation to register ADSs, ordinary shares, rights or other securities under the Securities Act. The Company also has no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that ADS holders may not receive the distributions the Company makes on its ordinary shares or any value for them if it is illegal or impractical for the Company to make them available to such ADS holder.*

## **Deposit, Withdrawal and Cancellation**

### ***How are ADSs issued?***

The depositary will deliver ADSs if a shareholder or their broker deposits ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names such shareholder requests and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

### ***How can ADS holders withdraw the deposited securities?***

An ADS holder may surrender its ADSs at the depositary's office. Upon payment of its fees and expenses and of any taxes or governmental charges payable in connection with such surrender or withdrawal, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to such holder or a person designated by such holder at the office of the custodian or through a book-entry delivery. Alternatively, at the holder's request, risk and expense, the depositary will, if feasible, deliver the amount of deposited securities represented by the surrendered ADSs for delivery at the depositary's office or to another address such holder may specify. The depositary may charge the holder a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

### ***How can ADS holders interchange between certificated ADSs and uncertificated ADSs?***

An ADS holder may surrender its ADRs to the depositary for the purpose of exchanging its ADRs for uncertificated ADSs. The depositary will cancel the ADRs and will send such holder a statement confirming that the holder is the owner of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the

exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to such holder an ADR evidencing those ADSs.

## **Voting Rights**

### ***How do ADS holders vote?***

An ADS holder may instruct the depositary to vote the number of whole deposited ordinary shares such holder's ADSs represent. If the Company requests the depositary to solicit the holder's voting instructions (and the Company is not required to do so), the depositary will notify such holder of shareholders' meetings or other solicitations of consents and arrange to deliver the Company's voting materials to such holder. Those materials will describe the matters to be voted on and explain how the holder may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

If the depositary timely receives voting instructions for the ADS holder, it will endeavor, in so far as practicable, to vote or cause to be voted the amount of deposited ordinary shares represented by those ADSs in accordance with such voting instructions set forth in such holder's request. If the Company does not request the depositary to solicit the holder's voting instructions, such holder can still send voting instructions, and, in that case, the depositary may try to vote as the holder instructs, but it is not required to do so. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If the Company timely asked the depositary to solicit the ADS holder's instructions but the depositary does not receive voting instructions from such holder by the specified date and the Company confirms to the depositary that (1) the Company wishes to receive a proxy, (2) as of the instruction cutoff date the Company reasonably does not know of any substantial shareholder opposition to the particular question, and (3) the particular question would not be materially adverse to the interests of the Company's shareholders, then the depositary will consider ADS holders to have authorized and directed it to give a proxy to a person designated by the Company to vote the number of deposited securities represented by such holder's ADSs in favor of that question, but only if the question was endorsed by the Company's board of directors.

The Company cannot assure ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ordinary shares. 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 ADS holders may not be able to exercise their right to vote and there may be nothing such holders can do if their ordinary shares are not voted as requested.*

In order to give ADS holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if the Company requests the depositary to act, the Company will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date except where under French law the notice period for such meeting is less than 30 days.

*Except as described above, ADS holders will not be able to exercise their right to vote unless they withdraw the ordinary shares. However, ADS holders may not know about the shareholder meeting enough in advance to withdraw the ordinary shares.*

## **Fees and Expenses**

### ***What fees and expenses will ADS holders be responsible for paying?***

Pursuant to the terms of the amended and restated deposit agreement, the holders of ADSs will be required to pay the following fees:

<p>Persons depositing or withdrawing ordinary shares or ADSs must pay:</p> <p>\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)</p>	<p>For:</p> <ul style="list-style-type: none"> <li>• Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights</li> <li>• Cancellation of ADSs for the purpose of withdrawal, including if the amended and restated deposit agreement terminates</li> </ul>
<p>\$0.05 (or less) per ADS</p>	<ul style="list-style-type: none"> <li>• Any cash distribution to an ADS holder</li> </ul>
<p>A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been ordinary shares and the shares had been deposited for issuances of ADSs</p>	<ul style="list-style-type: none"> <li>• Distribution of securities distributed to holders of deposited securities which are distributed by the depository to an ADS holder</li> </ul>
<p>\$0.05 (or less) per ADS per calendar year</p>	<ul style="list-style-type: none"> <li>• Depository services</li> </ul>
<p>Registration or transfer fees</p>	<ul style="list-style-type: none"> <li>• Transfer and registration of ordinary shares on the Company's share register to or from the name of the depository or its agent when an ADS holder deposits or withdraws shares</li> </ul>
<p>Expenses of the depository</p>	<ul style="list-style-type: none"> <li>• Cable (including SWIFT) and facsimile transmissions as expressly provided in the amended and restated deposit agreement</li> <li>• Converting foreign currency to U.S. dollars</li> </ul>
<p>Taxes and other governmental charges the depository or the custodian have to pay on any ADS or share underlying an ADS, for example, share transfer taxes, stamp duty or withholding taxes</p>	<ul style="list-style-type: none"> <li>• As necessary</li> </ul>
<p>Any charges payable by the depository, custodian or their agents in connection with the servicing of deposited securities</p>	<ul style="list-style-type: none"> <li>• As necessary</li> </ul>

The depository collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depository may collect its annual fee for depository services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depository may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depository may generally refuse to provide for-fee services until its fees for those services are paid.

From time to time, the depository may make payments to the Company to reimburse or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the amended and restated deposit agreement, the depository may use brokers, dealers, foreign currency or other service providers that are affiliates of the depository and that may earn or share fees, spreads or commissions.

The depository may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the

exchange rate assigned to the currency conversion made under the amended and restated deposit agreement and the rate that the depository or its affiliate receives when buying or selling foreign currency for its own account. The depository makes no representation that the exchange rate used or obtained in any currency conversion under the amended and restated deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to holders of ADSs, subject to the depository's obligations under the amended and restated deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

### **Payment of Taxes**

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of such holder's ADSs. The depository may refuse to register any transfer of a holder's ADSs or allow them to withdraw the deposited securities represented by such holder's ADSs until such taxes or other charges are paid. It may apply payments owed to ADS holders or sell deposited securities represented by such holder's ADSs to pay any taxes owed and such holder will remain liable for any deficiency. If the depository sells deposited securities, it will, if appropriate, reduce the number of ADSs registered in the ADS holder's name to reflect the sale and pay to such holder any net proceeds, or send such holder any property, remaining after it has paid the taxes. An ADS holder's obligation to pay taxes and indemnify the Company and the depository against any tax claims will survive the transfer or surrender of such holder's ADSs, the withdrawal of the deposited ordinary shares as well as the termination of the amended and restated deposit agreement.

### **Reclassifications, Recapitalizations and Mergers**

#### ***If the Company:***

- Changes the nominal value of the Company's ordinary shares
- Reclassifies, splits up or consolidates any of the deposited securities
- Distributes securities on the ordinary shares that are not distributed to ADSs holders

#### ***If the Company:***

- Recapitalizes, reorganizes, merges, liquidates, sells all or substantially all of the Company's assets, or takes any similar action

#### ***Then:***

The cash, ordinary shares or other securities received by the depository will become deposited securities.

Each ADS will automatically represent its equal share of the new deposited securities.

The depository may also deliver new ADSs or ask ADS holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities. The depository may also sell the new deposited securities and distribute the net proceeds if the Company is unable to assure the depository that the distribution (a) does not require registration under the Securities Act or (b) is exempt from registration under the Securities Act.

#### ***Then:***

Any replacement securities received by the depository shall be treated as newly deposited securities and either the existing ADSs or, if necessary, replacement ADSs distributed by the depository will represent the replacement securities. The depository may also sell the replacement securities and distribute the net proceeds if the replacement securities may not be lawfully distributed to all ADS holders.

### **Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depository will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depository may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depository as a holder of deposited securities, the depository will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depository receives new securities in exchange for or in lieu of the old deposited securities, the depository will hold those replacement securities as deposited securities under the deposit agreement. However, if the depository decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depository may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depository will continue to hold the replacement securities, the depository may distribute new ADSs representing the new deposited securities or ask the ADS holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depository may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

### **Amendment and Termination**

#### ***How may the amended and restated deposit agreement be amended?***

The Company may agree with the depository to amend the amended and restated deposit agreement and the ADRs without ADS holders' consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges, registration fees, facsimile costs, delivery costs or other such expenses, or that would otherwise prejudice a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depository notifies ADS holders of the amendment. *At the time an amendment becomes effective, ADS holders are considered, by continuing to hold their ADSs, to agree to the amendment and to be bound by the ADRs and the amended and restated deposit agreement as further amended.*

#### ***How may the amended and restated deposit agreement be terminated?***

The depository will terminate the amended and restated deposit agreement if the Company asks it to do so, in which case the depository will give notice to ADS holders at least 90 days prior to termination. The depository may also terminate the amended and restated deposit agreement if the depository has told the Company that it would like to resign and the Company has not appointed a new depository within 60 days. In such case, the depository must notify ADS holders at least 90 days before termination. In addition, the depository may initiate termination of the amended and restated deposit agreement if (i) the Company delists its shares from an exchange on which they the Company is listed and does not list the shares on another exchange; (ii) the Company appears to be insolvent or enter insolvency proceedings; (iii) all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities; (iv) there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or (v) there has been a replacement of deposited securities.

After termination, the depository and its agents will do the following under the amended and restated deposit agreement but nothing else: collect dividends and other distributions on the deposited securities, sell rights and other property, and deliver ordinary shares and other deposited securities upon cancellation of ADSs. At any time after the termination date, the depository may sell the deposited securities. After that, the depository will hold the money it received on the sale, as well as any other cash it is holding under the amended and restated deposit agreement, unsegregated and without liability for interest, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. Normally, the depository will sell as soon as practicable after the termination date.

After the termination date and before the depository sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depository may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depository may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depository will continue to collect distributions on deposited securities, but, after the termination date, the depository is not required to register any transfer of ADSs or distribute any dividends or other

distributions on deposited securities to the ADS holder (until they surrender their ADSs) or give any notices or perform any other duties under the amended and restated deposit agreement except as described in this paragraph.

#### **Limitations on Obligations and Liability**

The amended and restated deposit agreement expressly limits the Company's obligations and the obligations of the depository. It also limits the Company's liability and the liability of the depository to ADS holders. The Company and the depository:

- are only obligated to take the actions specifically set forth in the amended and restated deposit agreement without negligence or bad faith;
- are not liable if either the Company or depository is prevented or delayed by law or circumstances beyond the Company's control from performing the Company's obligations under the amended and restated deposit agreement;
- are not liable if either the Company or depository exercises, or fails to exercise, discretion permitted under the amended and restated deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the amended and restated deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the amended and restated deposit agreement;
- are not liable for any tax consequences to any holders of ADSs on account of their ownership of ADSs;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the amended and restated deposit agreement on ADS holders' behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents the Company believes in good faith to be genuine and to have been signed or presented by the proper person.

In the amended and restated deposit agreement, the Company and the depository agree to indemnify each other under certain circumstances.

#### **Requirements for Depository Actions**

Before the depository will deliver or register a transfer of an ADS, make a distribution on an ADS, or permit withdrawal of ordinary shares, the depository may require:

- payment of any tax or other governmental charges and any stock transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the amended and restated deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs generally when the transfer books of the depository or the Company's transfer books are closed or at any time if the depository or the Company think it advisable to do so.

#### **ADS Holders' Right to Receive the Ordinary Shares Underlying Their ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depository has closed its transfer books or the Company has closed its transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting; or (3) the Company pays a dividend on its ordinary shares;
- when ADS holders owe money to pay fees, taxes and similar charges; and
- when it is necessary to prohibit withdrawals in order to comply with any U.S. or foreign laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

This right of withdrawal is not limited by any other provision of the amended and restated deposit agreement.

### **Direct Registration System**

In the amended and restated deposit agreement, all parties to the amended and restated deposit agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC under which the depository may register the ownership of uncertificated ADSs and such ownership will be evidenced by periodic statements sent by the depository to the registered holders of uncertificated ADSs. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the amended and restated deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the amended and restated deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile System and in accordance with the amended and restated deposit agreement will not constitute negligence or bad faith on the part of the depository.

### **Shareholder Communications; Inspection of Register of Holders of ADSs; ADS Holder Information**

The depository will make available for an ADS holders inspection at its office all communications that it receives from the Company as a holder of deposited securities that the Company makes generally available to holders of deposited securities. The depository will send ADS holders copies of those communications or otherwise make those communications available to such holder if the Company asks it to. ADS holders have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to the Company's business or the ADSs.

Each holder of ADSs will be required to provide certain information, including proof of taxpayer status, residence and beneficial ownership (as applicable), from time to time and in a timely manner as the Company, the depository or the custodian may deem necessary or proper to fulfill obligations under applicable law.

### **Jury Trial Waiver**

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against the Company or the depository arising out of or relating to the Company's ordinary shares, the ADSs or the amended and restated deposit agreement, including any claim under the U.S. federal securities laws. If the Company or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, ADS holders will not be agreeing to the terms of the deposit agreement, be deemed to have waived the Company's or the depository's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

**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**

I, Gil Beyen, certify that:

1. I have reviewed this annual report on Form 20-F of ERYTECH Pharma S.A. (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 28, 2023

/s/ Gil Beyen

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Name: Gil Beyen

Title: Chief Executive Officer  
*(Principal Executive Officer)*

**CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a - 14(a)  
AND 15(d)-14(a) as ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Eric Soyer, certify that:

1. I have reviewed this annual report on Form 20-F of ERYTECH Pharma S.A. (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 28, 2023

/s/ Eric Soyer

Name: Eric Soyer

Title:

Chief Financial Officer, Chief Operating Officer and  
Deputy General Manager (*Principal Financial  
Officer*)

**CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gil Beyen, Chief Executive Officer of ERYTECH Pharma S.A. (the “Company”), and Eric Soyer, Chief Financial Officer, Chief Operating Officer and Deputy General Manager of the Company, each hereby certifies that, to the best of his knowledge:

- (1) The Company’s Annual Report on Form 20-F for the year ended December 31, 2022, to which this Certification is attached as Exhibit 13.1 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 28<sup>th</sup> day of March, 2023.

/s/ Gil Beyen

\_\_\_\_\_  
Name: Gil Beyen

Title: Chief Executive Officer  
(Principal Executive Officer)

/s/ Eric Soyer

\_\_\_\_\_  
Name: Eric Soyer

Title: Chief Financial Officer, Chief Operating Officer and Deputy General  
Manager  
(Principal Financial Officer)

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of ERYTECH Pharma S.A. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements Nos. 333-265927, 333-255900, 333-239429, 333-232670, and 333-222673 on Form S-8 and Nos. 333-248953 and 333-259690 on Form F-3 of our reports dated March 28, 2023, with respect to the consolidated financial statements of Erytech Pharma S.A and the effectiveness of internal control over financial reporting.

Lyon, March 28, 2023  
KPMG S.A.

Stéphane Gabriel Devin  
*Partner*