

Item 3. Key Information

A. [Reserved]

Not applicable.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to our Financial Position and Need for Additional Capital

We are a clinical-stage company with a limited operating history and no approved products and no product revenues, which makes it difficult to assess our future prospects and financial results.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which we evaluate our business and prospects. We were incorporated as a Delaware limited liability company on December 4, 2013 and, to date, we have focused primarily on organizing and staffing our corporate affairs, planning, raising capital, identifying, acquiring and in-licensing our drug candidates, establishing a property portfolio, conducting research, preclinical studies and clinical trials, establishing relationships with parties for the manufacture of our drug candidates and related raw materials and providing general and administrative support for these operations. Investment in product development in the healthcare industry of biopharmaceutical products, is highly speculative because it entails substantial upfront costs and a significant risk that any potential drug candidate will fail to demonstrate adequate effect or safety, gain regulatory approval or become commercially viable. As a result, our ability to achieve consistent profitability from product sales is unproven, and we may never sustain profitability from products approved for commercial sale and have not generated any revenue from product sales to date.

Our ability to generate revenue from product sales and achieve and maintain profitability depends on our ability, alone or with any future collaborators, to successfully complete the development of, obtain regulatory approvals necessary to commercialize, our lead drug candidate, obefazimod. Our ability to finance our operations and generate revenue from product sales, therefore will depend on the successful development and commercialization of obefazimod, as other programs in our preclinical portfolio are in the early stages of development. Since our inception in 2013, the majority of our operating income has resulted from research collaborations unrelated to obefazimod, and we do not anticipate generating significant product sales for the next several years, if ever. Our ability to generate revenue from product sales depends on our or any future collaborators' success in:

- timely and successful completion of clinical development of obefazimod, our lead drug candidate;
- obtaining and maintaining regulatory and marketing approval for obefazimod and any other drug candidates for which we successfully complete clinical trials;
- launching and commercializing any drug candidates for which we obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure or by collaborating with a commercialization partner;

- obtaining coverage and adequate reimbursement from government and third-party payors for our current or any future drug candidates, if approved, both in the United States and in foreign markets, and reaching acceptable agreements with foreign government and third-party payors on pricing and reimbursement;
- developing, validating and maintaining a commercially viable, sustainable, scalable and transferable manufacturing process for obefazimod or any future drug candidates that complies with current good manufacturing practices;
- establishing and maintaining supply and manufacturing relationships with third parties to ensure an adequate amount and quality of drugs and services to support our planned clinical trials as well as the market demand for obefazimod and any future drug candidates, if approved;
- obtaining market acceptance, if and when approved, of obefazimod or any future drug candidate as a viable treatment option by physicians, patients, third-party payors and others in the medical community;
- effectively addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements in the future, and performing our obligations pursuant to such arrangements;

- maintaining, protecting and expanding our portfolio of intellectual property rights trade secrets and know-how;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We have incurred considerable losses historically, which we anticipate will continue and may future.

Since our inception, we have incurred net losses. For the years ended December 31, 2023, 2022 and 2021, we reported net losses of €14.7 million, €60.7 million and €42.5 million. As of December 31, 2023, we carried forward accumulated losses of €145.0 million.

We have devoted most of our financial resources to research and development, including our preclinical development activities. Even if we obtain regulatory approval to market a drug candidate, our revenues will depend upon the size of any markets in which our drug candidates have received regulatory approval and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and access to commercial markets for our drug candidates in those markets. There can be no assurance that we will ever earn revenues sufficient to offset past, current and future losses or achieve profitability, which would impact our operations. Moreover, even if we achieve profitability, such profitability may not be sufficient to generate sustained profits could have a material adverse effect on our business, prospects, financial position and cash flows and results of operations.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate achieving profitability in the future unless we obtain the regulatory approvals needed for the commercialization of obefazimod and any additional drug candidates that we may pursue in the future. We anticipate that our operating losses will increase substantially if, and as, we:

- timely and successfully complete clinical development of obefazimod, our clinical-stage drug candidate;
- seek and maintain regulatory and marketing approvals for obefazimod and any future drug candidates for which we successfully complete clinical trials;
- continue the preclinical and clinical development of our drug candidates;
- expand the scope of our current clinical trials for our drug candidates;
- begin new clinical trials for our drug candidates;
- develop, scale and validate our commercial manufacturing capabilities for our drug candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any drug candidates for which we may obtain marketing approval for which we have not entered into a collaboration with a third party;
- seek to discover, identify and validate additional drug candidates;

- acquire or in-license other drug candidates and technologies;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- obtain, maintain, protect, enforce and expand our intellectual property portfolio;
- attract new and retain existing skilled personnel; and
- create additional infrastructure to support our operations as a U.S. public company.

In addition, following the issuance of royalty certificates in September 2022 and other similar arrangements, the payment of royalties in the event of commercial sales of obefazimod will result in a decrease in cash flows generated by sales of the product, which could have an unfavorable impact on our financial position, particularly at the beginning of the commercial sales period.

The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. A comparison of our results of operations may not be a good indication of our results in any particular period or periods, our operating results could be below the expectations of some investors, which could cause the price of the ordinary shares (which may be in the form of ADRs) to decline. An increase in operational losses would have a material adverse effect on our business, financial position and growth and outlook.

We will require substantial additional funding, which may not be available on acceptable terms, and a failure to obtain this necessary capital may force us to delay, limit or terminate our product development or other operations.

Our operations have consumed substantial amounts of cash since inception. We are currently developing obefazimod through clinical development and conducting preclinical studies with respect to other drug candidates. Developing drug candidates is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we seek regulatory approval toward commercialization. If our clinical trials are successful and we obtain regulatory approval to commercialize the drug candidates that we develop, we will incur commercialization expenses before these drug candidates are marketed.

Based on (a) our existing cash and cash equivalents and other short-term investments of €25.0 million as of December 31, 2023, (b) the drawdown of the second tranche of the Kreos / Claret Financing, €25.0 million in gross proceeds received on March 28, 2024, and (c) the expected reimbursement of our research and development expenses in 2023 in the second half of 2024 amounting to €4.5 million, we expect to be able to fund our future operations through the fourth quarter of 2025. Under these assumptions and based on our current cash requirements, we would have sufficient funds to finance our operations through the announcement of our top-line results from the 3 ABTECT-1 and ABTECT-2 induction trials for UC.

This takes into account our assumption that R&D expenditure will be substantially increased by the progression of the Phase 3 clinical trials of obefazimod in UC and the initiation of the Phase 1 clinical trials of other drug candidates in 2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our capital resources sooner than we expect. However, there is no guarantee that we would be able to meet our capital requirements or that we would be able to draw down on the remaining tranche of the Kreos / Claret Financing in a timely manner.

Financial statements. We cannot assure that the consolidated financial statements prepared by us will accurately reflect our financial condition or results of operations or our financing need projections.

Until we can generate sufficient product or royalty revenue to finance our cash requirements, we may never do, we may seek additional financing in the form of public or private equity or debt financing, other third-party funding, marketing and distribution arrangements and collaborations, strategic licensing arrangements or a combination of these sources.

The amount and timing of our funding needs will depend on factors that are largely outside our control, such as:

- higher costs and slower-than-expected progress on our research and development programs and clinical trials;
- costs related to preparing, filing, enforcing and maintaining our patents and other intellectual property rights;

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- the scope of the research required and time needed to sign licensing agreements with third parties;
- the expenses needed to respond to technological and market developments;
- higher costs and longer-than-expected lead times obtaining regulatory authorization for preparing application dossiers for the relevant authorities; and
- new opportunities for developing new products or acquiring technologies, products or services.

Any additional fundraising efforts may divert our management from their day-to-day activities and may adversely affect our ability to develop and, if approved, commercialize our drug candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us. Under French law, our share capital may be increased only with shareholders' approval at an extraordinary shareholders' meeting on the basis of a report from the board of directors. In addition, the law imposes certain limitations on our ability to price certain offerings of our share capital without the approval of the *commissaire aux apports*. Such limitations may prevent us from successfully completing any such offering. To the extent that we raise additional capital, the terms of any such financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock (which may be in the form of ADSs) to decline. The sale of additional equity or convertible securities may dilute our shareholders' ownership interest. The incurrence of indebtedness would result in increased fixed obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur debt, limitations on our ability to acquire, sell or license intellectual property rights and other assets, and that could adversely impact our ability to conduct our business. To the extent that we raise additional capital through arrangements with research and development partners or otherwise, we may be required to relinquish or share technologies, drug candidates or revenue streams, license our technologies or drug candidates to such partners or otherwise agree to terms unfavorable for us. If we are unable to obtain adequate financing, we may be required to delay, reduce or eliminate the number or scope of our projects and drug candidates (including pre-clinical and clinical trial programs). In order to obtain financing, we may be required to relinquish or share technologies or drug candidates or otherwise agree to terms unfavorable to us. If we are unable to obtain financing on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs or the commercialization of any drug candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could impair our prospects for future growth.

Our financial statements contain a footnote describing management's assumption regarding our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms.

For the years ended December 31, 2023 and 2022, we reported net losses of \$1.7 million and \$1.5 million, respectively. As of December 31, 2023, we carried forward a deferred tax asset of \$0.4 million. The loss of losses may cast significant doubt or raise substantial doubt about our ability to continue as a going concern.

There cannot be any assurance that we will be successful in obtaining necessary financing to continue as a going concern or achieve profitability. We expect that we will need to raise additional capital to complete the necessary trials to achieve commercial viability of some or all of our drug candidates. If financing is not available, we may be required to delay, reduce the scope of, or eliminate research or development programs or commercialization efforts with respect to our products. The sale of additional equity may dilute the ownership interest of our shareholders and newly issued shares may contain senior rights and preferences compared to our existing ordinary shares. Issued debt securities may contain covenants and limit our ability to pay dividends or make distributions to our shareholders. If we are unable to obtain such additional financing, future clinical development programs would need to be scaled back or discontinued. These factors may cast significant doubt about our ability to continue as a going concern.

There are material weaknesses in our internal controls over financial reporting and if we are unable to remediate these weaknesses, the accuracy and timeliness of our financial statements could be adversely affected, which could adversely affect our business, investor confidence and the market price of our securities.

Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting for external purposes in accordance with international financial reporting standards. Internal control over financial reporting includes maintaining records that in reasonable detail accurately reflect our transactions; providing reasonable assurance that transactions are recorded as needed to prepare our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized persons do not have access to assets.

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or disposition of our assets that could have a material effect on the financial statements were not detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is designed to provide reasonable assurance but cannot be expected to detect all misstatements. Internal control is intended to provide absolute assurance that a misstatement of our financial statements would be detected.

We must maintain effective internal controls over financial reporting in order to accurately report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act will require, among other things, that we assess the effectiveness of our internal controls over financial reporting at the end of each fiscal year, starting with the end of the first full fiscal year of our initial public offering of our ADSs in the United States. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting so long as we are an "emerging growth company," which may be up to five fiscal years following our initial public offering of our ADSs in the United States. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not.

Our management has not completed an assessment of the effectiveness of our internal controls over financial reporting, and our independent registered public accounting firm has not conducted an audit of our internal controls over financial reporting concurrent with preparing our financial statements as of and for the year ended December 31, 2023 and 2022. Material weaknesses in our internal controls over financial reporting were identified. The material weaknesses related to a lack of risk assessment as well as formal, documented approval and review processes, controls and review procedures, specifically due to a lack of a sufficient number of personnel with an appropriate level of internal control knowledge, training and experience. These material weaknesses could result in a material misstatement to our financial statements included herein, however these material weaknesses could also result in material inaccuracies in our financial statements and impair our ability to comply with applicable reporting requirements and related regulatory filings on a timely basis.

We have developed a remediation plan to address these material weaknesses and strengthen our internal controls in these areas. In this regard, we have started to reorganize our finance and accounting functions, hire experienced employees to provide more review and oversight over our financial processes. While we intend to remediate the material weaknesses as quickly and efficiently as possible, we cannot at this time provide a timeline in connection with implementing our remediation. As of December 31, 2023, we had not completed remediation of these material weaknesses. These remediation measures may be time-consuming and may require significant demands on our financial and operational resources. There is no assurance that the measures we may take in the future will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal control over financial reporting or that they will prevent or avoid future material weaknesses.

The rules governing the standards that will have to be met for our management to assess the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our management design, implement, document, test and regularly update our internal controls over financial reporting. The process of designing, implementing, and testing the internal controls over financial reporting is time-consuming, costly, and complicated. Our management cannot guarantee that we will be able to effectively and timely implement controls and procedures that adequately respond to the increased requirements and reporting requirements that will be applicable to us as a public company listed in the United States. If we fail to staff our accounting and finance function adequately or maintain internal controls over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the United States, our business and reputation may be harmed and the price of our ordinary shares and ADSs may decline. There may be undetected material weaknesses in our internal controls over financial reporting that could lead to errors in our financial statements and require us to incur the expense of remediation. Any of these developments could result in investor perceptions of us being adversely affected, which could cause a decline in the market price of our securities.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our growth will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could result in our inability to report our financial results accurately and timely or to detect and prevent fraud.

Significant impairment of our goodwill could materially impact our financial position and results of operations.

We carry a goodwill balance, which is allocated to obefazimod and ABX196 cash generating units. Goodwill represents the excess of the purchase price over the fair value of identifiable intangible assets. As a result of past business acquisitions, including with respect to obefazimod, we are required to review our goodwill for impairment on an annual basis or more frequently if events or circumstances indicate evidence of impairment. We did not record any goodwill impairment loss for the year ended December 31, 2023. For the year ended December 31, 2022, we recorded a goodwill impairment loss of €18.4 million. The goodwill impairment loss was related to an impairment test conducted with respect to the obefazimod cash-generating unit.

cash-generating unit as a result of significant external changes in the hepatocellular carcinoma treatment landscape (including the development of new, lengthy, heavy and risky internal development process (including compounds). As such, due to the lack of progress made in the negotiation of a development partnership with the decision to freeze the development program for ABX196 in the treatment of hepatocellular carcinoma, we have decided to completely stop our ABX196 development program, which will be reflected in our next financial statements. After full impairment of the goodwill, we will continue to carry a goodwill balance allocated to obefazimod amounting to €18.4 million in our balance sheet as of December 31, 2023. We have not currently identified reasons to impair the goodwill allocated to obefazimod. However, there can be no assurance that, based on the results of our annual goodwill impairment tests, we will be required to identify further goodwill impairment losses, which could have a material adverse effect on our results of operations.

We have significant debt commitments, which require us to meet certain operating covenants, and we may not be able to comply with those covenants. The bondholders would be able to accelerate our repayment obligations if we fail to comply with those covenants. Additionally, the conversion of some or all of our bonds into ordinary shares would dilute the ownership of existing shareholders.

On August 2023, we entered into a framework subscription agreement (the "Framework Subscription Agreement") with entities affiliated with Kreos Capital ("Kreos") and entities affiliated with Growth Capital ("Claret"), as the Secured Lenders (the "Kreos / Claret Financing"). Under this

Subscription Agreement may draw up to €75 million in structured debt financing, in three tranches of €25 million in aggregate principal amount each. The first and second tranches were drawn on August 24, 2023, and March 28, 2024, respectively. The Kreos / Claret Financing provides for certain restrictive covenants (including customary exceptions), which include, among other things, restrictions on the incurrence of debt in default, the distribution of dividends and the grant of security interests. As security for the Kreos / Claret Financing, the Secured Lenders benefit from the grant of first-ranking collateral on our principal tangible assets, including pledges over our ~~business~~ ~~commercial~~ ~~assets~~ ~~as~~ a going concern and intellectual property rights in our lead drug candidate, as well as pledges over our bank accounts and receivables. Such security is provided by the Kreos / Claret Financing.

In addition, on August 20, 2023, we entered into a subscription agreement with entities of Capital Management ("Heights"), and such agreement, the "Heights Subscription Agreement"). Under the Heights Subscription Agreement, we may draw up to €75 million in amortizing senior convertible notes, in three tranches of €25 million, €35 million and €40 million, respectively, as further described below. The first tranche in the Heights Subscription Agreement of €35 million was drawn on August 24, 2023. The terms and conditions of the Heights Subscription Agreement include a negative pledge providing that any security granted in favor of other borrowed debt should also be granted in favor of the Heights Convertible Notes on an equal basis (with the securities issued pursuant to the Kreos / Claret Financing).

In June 2020, we obtained a non-dilutive financing in the form of a State-guaranteed loan from the French government. The loan was structured with an initial maturity of 12 months at 0.25% and a five-year extension option. We exercised the five-year extension option with a one-year deferral of principal repayment, with the following conditions: (i) a revised interest rate of 0.5% and (ii) a State-guaranteed premium of €0.1 million to be paid by installments over the contract term. The loan includes certain customary covenants and prepayment provisions. The negative covenants include an undertaking not to dispose of all or part of our assets for more than 50% of the gross value of the assets.

The loan includes certain customary covenants and prepayment provisions. The negative covenants include an undertaking not to dispose of all or part of our assets for more than 50% of the gross value of the assets.

There is also no guarantee that we will have sufficient cash to pay the bonds issued to the Heights at maturity, which could have a negative impact on our business as security interests in our principal tangible and intangible assets: in particular, on our goodwill, intellectual property rights, lead drug candidates, as well as a pledge of our bank accounts and claims. There is also no guarantee that we will have sufficient cash to make the scheduled payments on the Kreos / Claret Financing, the Heights Subscription Agreement, the State-guaranteed loan, which could have a material adverse effect on our business, financial condition and operations. Any failure to make scheduled payments or trigger for early repayment of the loan could have an adverse effect on our business, financial position, income, growth and outlook. If we breach any of these agreements, it could result in default and trigger an early repayment of the bonds, which could have a material adverse effect on our business, financial condition and operations that we would have the necessary resources to fund an advance repayment of the bonds.

Our principal tangible and intangible assets serve as collateral under the terms of debt agreements. If we default on these debt obligations, the Secured Lenders could foreclose on our assets and we would be unable to continue our business and operations.

In August 2023, we entered into the Kreos / Claret Financing. In connection with the financing, we granted the Secured Lenders with first-ranking collateral on our principal tangible and intangible assets, including pledges over our ~~business~~ ~~commercial~~ ~~assets~~ ~~as~~ a going concern and intellectual property rights in our lead drug candidate, as well as pledges over our bank accounts and receivables until our debt obligations are repaid in full. There can be no assurance that we will not breach the covenants or other terms of, or that we will not occur under, the debt agreements for the Kreos / Claret Financing. If a breach or event of default occurs, there can be no assurance that we will be able to cure the breach within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations could result in an event that causes an acceleration of payment at a time when we do not have sufficient resources to make such payments. If the Secured Lenders foreclose on the collateral, the Secured Lenders would lose our intellectual property rights in our lead drug candidate and be unable to commercialize our lead drug candidate and conduct our business. Any of these consequences would have a material adverse effect on our business, financial condition and share price.

We rely on grants and subsidies, which may not continue to be available and we may be forced to repay conditional advances prematurely if we fail to comply with our contractual obligations under grant agreements.

We have received various grants and conditional advances from Bpifrance under various development programs, in a total of €20.1 million as of December 31, 2023. In the event that we do not comply with the contractual conditions stipulated in the aid agreements we have entered into, we may have to repay the advances early. Such premature repayment could deprive us of the necessary financial resources to fund our research and development projects and we cannot guarantee that we will find necessary additional financing to replace the advanced amounts or the possibility of replacing these financial resources with others. We cannot guarantee that we will have the necessary resources to cope with an early repayment. A material repayment would result in a material adverse effect on our business, operations, financial position, income, growth, and outlook.

In addition, the amount and date of payment of current and future grants and subsidies depend on decisions that are not in our control, including possible non-distribution decisions or the freezing of funding for the achievement of key milestones previously agreed on with Bpifrance. Delays or failure in obtaining these grants and subsidies in the future could have a material adverse effect on our business, financial position, income, growth and outlook.

Current equity agreements and convertible debt instruments may dilute our equity resulting in a loss of control to our shareholders.

Since our incorporation, we have issued and granted founder's share warrants (BCE) and share warrants (BSA) and granted free shares (AGA) to persons linked to us and financing entities. We have also issued convertible debt instruments. See "Item 5.B-Liquidity and Capital Resources."

The theoretical exercise of all the founder's share warrants (BCE) and share warrant (BSA) could result in access to our capital issued and outstanding as of December 31, 2023, excluding securities held by the

would allow for the subscription of 638,643 potential new ordinary shares, resulting in a hypothetical 1.01% based on our existing share capital as of December 31, 2023.

Our general meeting of June 5, 2023 delegated authority to the board of directors (the “Board”) to make one or more capital increases and/or issues of securities giving access to our capital subject to the following limitations:

- a total maximum nominal amount of the capital increases set at €500,000 (or the equivalent amount in the event of an issue in another currency) with a total maximum nominal amount of debt securities that may be issued set at €150,000,000 (or the equivalent value of event of an issue in another currency); and
- the shares that may be issued or allotted in the context of equity incentive plans (share options and/or free shares (AGA)) may not exceed 10% of the share capital on basis recorded as of June 5, 2023.

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Using such delegation, we issued in August 2023 the following securities in connection with the Financing and the Heights Financing:

- 25,000,000 convertible bonds with warrants attached with an individual nominal value of €25,000,000 to KC and Claret, which allow for the subscription of up to 1,178,084 new ordinary shares at a conversion price of €21.22 per ordinary share;
- 214,198 share warrants (BSA) issued to KC and Claret, which allow for the subscription of up to 214,198 new ordinary shares at an exercise price of €18.67 per ordinary share; and
- 350 convertible notes due 2027 with an individual nominal value of €100,000 issued to KC and Claret, which allow for the subscription of up to 1,472,606 new shares at a conversion price of €67.50 per share. In case we opt to repay the principal and accrued interest of such notes entered into, we may issue up to 2,830,201 new ordinary shares in connection with such repayment.

Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may affect our operations and finances.

As a French biopharmaceutical company, we have benefited from certain tax advantages, including, for example, the Research and Development Tax Credit (*crédit d’impôt recherche* (“CIR”)), which is a French tax credit aimed at stimulating research and development. CIR can be offset against French corporate income tax in excess, if any, may be refunded. CIR is calculated based on our claimed amount of development expenditures in France and simplified for 2023. The French tax authorities, with the assistance of the Higher Education and Research Ministry, may audit each research and development project in respect of which a CIR benefit has been claimed and assess whether such program qualifies for the benefit. The French tax authorities may challenge our eligibility for, or our calculation of, CIR benefits, which could result in reductions in respect of our research and development activities and, should the French tax authorities reduce our credits, which would have a negative impact on our results of operations and financial condition. Furthermore, the French Parliament may decide to eliminate, or to reduce the scope or the rate of, the CIR either of which it could decide to do at any time. If we fail to receive future CIR amounts, our financial condition, cash flows or results of operations could be adversely affected.

We may be unable to carry forward existing tax losses.

As of December 31, 2023, we carried forward accumulated tax losses of €459.8 million. In 2014, we acquired the companies Splicos, WittyCell and Zophis by means of a universal transfer of assets and liabilities. We carried forward of the three companies combined (Splicos, WittyCell and Zophis) amounted to €22.1 million at the date of the mergers and transfer of remaining assets. The transfer to us of these losses was approved by the French tax authorities, which approved the transfer of a total amount of €22.1 million. The transfer of these tax losses to us, our tax losses of €208.1 million at the end of 2022. To the extent we have continued conducting the business that led to these losses for a minimum of five years, without making significant changes during this period, the transfer of such tax losses to us in France, the maximum amount of carried forward tax losses that can be written off against the taxable profits of the financial year is limited to €1 million plus 50% of the amount of taxable profits for the first financial year. The outstanding tax losses remain valid and can be carried forward to be written off in subsequent financial years subject to the same limit, for an unlimited period of time (subject to a change of activity” at our level). It cannot be ruled out that regulatory or legislative changes may suppress or limit all or part of the ability to use carried forward tax losses, or limit the amount of tax losses to offset future profits. Changes in corporate taxation regarding the use of carried forward tax losses could have a material adverse effect on our financial position and results of operations.

Risks Related to Product Development, Regulatory Approval and Commercialization

Drug candidates under development must undergo costly, rigorous and highly regulated preclinical and clinical trials, whose time of completion, number and outcomes are uncertain.

The development of a drug candidate is a long and expensive process with an uncertain outcome in several phases, where the objective is to demonstrate the therapeutic benefit provided by a drug for one or more indications. Any failure during the various preclinical and clinical phases for a drug candidate may delay development, production and commercialization of the therapeutic product concerned or even discontinuing its development. Identifying potential drug candidates and conducting preclinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and the data or required results required to obtain regulatory approval and achieve commercialization.

At each phase of clinical development, we must ask for authorization from the relevant authorities in each country, according to our development plan, to conduct clinical trials and then present the results of the trials to these authorities. The authorities may refuse to provide the authorizations necessary for the trials to have additional requirements (for example, relating to study protocols, patient characteristics, etc.). In the post-treatment follow-up, certain differences in interpreting results between local regulatory authorities may require additional studies. Any refusal or decision by health authorities to require additional examinations would be likely to result in the discontinuation or delay of the development of the drug. An absence of or delay in therapeutic response could also result in the delay or even discontinuation of the development of our drug candidates.

We are developing drug candidates for inflammatory diseases. To our knowledge, currently, similar immunological treatments with a mechanism of action based on enhanced expression of a miR-124, with marketing authorization granted by competent regulatory authorities. As a result, it is uncertain for the development and profitability of obefazimod in the area of inflammatory diseases. The acceptance by patients, doctors and paying agencies. Animal testing does not necessarily predict results to be obtained in humans. Positive results for obefazimod during Phase 1, Phase 2b or Phase 3 clinical trials could be for all the products in the portfolio during their research or preclinical phases might not be the same for all phases. Such outcomes could have a material adverse impact on our business, income, financial position and cash flow.

We currently have no drug candidates approved for marketing, and we cannot guarantee that marketable drug candidates. Our ability to generate revenue related to sales, if any, will be entirely on the successful development and regulatory approval of obehazimod. In Europe and the well as in many other countries, access to the drug market is strictly controlled and market a regulatory authority. Most of the time, this registration application is filed with a national authority. However, in the European Union, the marketing authorization application ("MAA") must be filed at the EU-level to the European Medicines Agency ("EMA") for categories of the most innovative drugs in order to obtain a centralized marketing authorization valid for all the European Union territories.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, market. our drug candidates are, and will remain, subject to comprehensive and extensive regulation of the European Union and European Union Member States national authorities in the European Union, the Food and Drug Administration ("FDA") in the United States, the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan, and various regulatory authorities in other countries, with regulations differing from country to country. In order to obtain regulatory approvals in the European Union, the United States, and Japan, we must submit an MAA to the European Commission following EMA's opinion or a New Active Ingredient Application ("NAI") to the FDA or a New Drug Application ("NDA") to the PMDA. Regulatory authorities in other countries may also require regulatory approvals. Regulatory authorities in each jurisdiction have their own procedures for approval of drug candidates. We are not permitted to market our drug candidates in any jurisdiction until we receive approval of an MAA from the European Commission following EMA's opinion or an NAI from the FDA or an NDA from the PMDA. Failure to obtain regulatory approval for our drug candidates in any jurisdiction will prevent us from commercializing and marketing our drug candidates in such jurisdiction. Regulatory authorities may be granted for narrow indications which may significantly reduce the commercial potential of our drug candidates.

Obtaining and maintaining marketing authorization, by country or by geographical area in European Union, presupposes compliance with the mandatory standards imposed by the concerned authorities and submission to the authorities of a great deal of information about the drug (toxicity, dosage, quality, efficacy and safety all over its life cycle. The authorization process and the result of this process remains highly uncertain. We are therefore careful to continue our practices in order not to jeopardize our chances of ultimately obtaining, directly or via our marketing authorization for the products we are developing. Furthermore, obtaining marketing

NDAs, MAAs and similar authorizations must also include significant information regarding manufacturing and controls for the drug. Obtaining approval of a MAA or a NDA and similar authorizations, collecting all required information, proof and data for this process, is a lengthy, expensive, and we may not be successful in obtaining approval. This is further enhanced by the fact that our requirements and procedures for the scientific evaluation or approval of drug candidates. Union Member States national authorities, FDA and PMDA review processes can therefore take years and approval is never guaranteed.

In addition, delays in approvals or rejections of marketing applications in the European States or other countries may be based upon many factors, including regulatory requests for a

reports, data, preclinical studies and clinical trials, regulatory questions regarding different data, and results, changes in regulatory policy during the period of drug development and the emergence of information regarding our drug candidates or other drug candidates. Even if a drug is approved by the FDA or the PMDA, as the case may be, may limit the indications for which the drug may be marketed, require additional warnings on the drug labeling or require expensive and time-consuming post-marketing clinical studies or conditions of approval.

Even if we receive regulatory approval for any drug candidate, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

Even if we receive approval of any of our drug candidates, such regulatory approval may be contingent on such approvals may be contingent on ongoing obligations and continued regulatory review, which may result in significant additional expense. As a general matter, any regulatory approvals that we may receive for our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, advertising, promotion, import, export and recordkeeping for our drug candidates will be subject to ongoing regulatory requirements. These requirements include submissions of safety, efficacy and marketing information and reports, registration, as well as ongoing compliance with current Good Manufacturing Practice ("GMP") and Good Clinical Practice requirements ("GCPs") for any clinical trials that we intend to conduct post-marketing. In addition, manufacturers of drug products and their facilities are subject to review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with GMP regulations and standards.

Additionally, our drug candidates, even if approved, may be subject to restrictions on their use, such as advertising, include limitations related to prescriptions by specialists, use restrictions for certain patient populations, warnings, precautions or contraindications, and may include burdensome post-approval study or surveillance requirements. For example, the FDA may require a risk evaluation and mitigation strategy ("REMS") for approval of our drugs candidates, which could include requirements for a medication guide, patient education and communication plans or additional elements to ensure safe use, such as restricted distribution, registries and other risk minimization tools.

Obtaining and maintaining a Good Manufacturing Practice ("GMP") certificate will be required for us to produce the immunotherapies that we are developing (for clinical trial purposes and during the commercial phase). We cannot guarantee that we will obtain or be able to maintain this certificate, nor can we guarantee that constraints related to this certificate will not be imposed on us in the future. Any failure to obtain or maintain adherence to such GMP 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 a clinical trial, or may delay or prevent filing or approval of marketing applications for our products. Failure to obtain or maintain applicable regulations could also result in the FDA or other applicable regulatory authorities imposing the following:

- 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 or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us or our third-party manufacturers to suspend manufacturing activities or to recall, destroy or export;
- requiring us to communicate with physicians and other customers about concerns relating to the safety, efficacy and other issues involving our products;
- mandating product recalls or withdrawals or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Failure to obtain or maintain authorization for our drug candidates in one or more jurisdictions with respect to our lead drug candidate, odefibrid, would have a material adverse effect on our business, financial position, results and development.

Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent regulatory approval, or, if approval is received, require our drug candidates to be withdrawn from the market or require them to include safety warnings or otherwise limit their sales.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to delay or halt clinical trials, or even discontinuation and could result in a more restrictive regulatory approval by the European Commission, FDA, PMDA or other comparable authorities in other jurisdictions. If severe side effects were to occur, or if one of our drug candidates is shown to have characteristics, we may need to either restrict the use of such product to a smaller population or discontinue development of such drug candidates.

If one or more of our drug candidates received marketing approval, and we or others later discover or learn of side effects caused by such drugs or negative interactions with other products or treatments (as a result of interactions with other products once on the market), a number of potentially adverse consequences could result, including:

- regulatory authorities may withdraw or reduce the scope of approvals of such products;
- regulatory authorities may require additional warnings on the product's label;
- we may be required to create a medication guide outlining the risks of such side effects to patients;
- we could be sued and held liable for harm caused to patients;
- physicians, healthcare payors, patients or the medical community in general may not use our products;
- sales of the product may decrease significantly; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a drug candidate, if approved, and could have a material adverse effect on our business, prospects, financial performance and cash flows or results of operations.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials, as well as data from any interim analysis of ongoing trials are not necessarily predictive of future results. We advance through clinical trials may not have favorable results in later clinical trials.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Clinical failure can occur at any stage of our clinical development. Success in preclinical studies and clinical trials, as well as data from any interim analysis of ongoing trials do not ensure that subsequent trials will generate the same or similar results. A number of companies in the pharmaceuticals industry, including those with greater resources and experience than us, have suffered significant setbacks in the last development of clinical trials, even after seeing promising results in earlier clinical trials, and we could experience similar setbacks. In some instances, there can be significant variation in safety or efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in the protocol, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Any such variation could negatively impact our business, financial condition, results of operation and prospects. The success of our preclinical and clinical trials for obefazimod does not ensure that current or future trials will demonstrate similar safety and/or efficacy results.

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Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy results after having progressed through preclinical studies and earlier clinical trials. In addition to the uncertainties associated with any drug candidate, clinical trial failures may result from a multitude of factors including differences in patient selection, placebo effect and patient enrollment criteria. Based upon negative or inconclusive results, our collaborators may decide, or regulators may require us, to conduct additional clinical trials. Further, data obtained from trials and studies are susceptible to varying interpretation, and we may choose to interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

We cannot guarantee the commercial success or the pricing and reimbursement of the drug candidates we develop.

If we or one or more of our commercial partners succeeds in obtaining marketing authorization to market the therapeutic products developed by us, it may nevertheless take time to gain acceptance from the medical community, health care providers and third-party payors.

The level of market acceptance for each of our products will depend on several factors, including the following:

- prescribers' perception of the product's therapeutic benefit;
- healthcare policies established in each of the countries in which we are considering marketing our products;
- possible occurrence of adverse reactions once marketing authorization has been obtained;
- ease of use of the product, especially relating to its mode of administration;
- cost of treatment;
- reimbursement policies of governments and other third parties;
- effectiveness of sales and marketing efforts;
- effective implementation of a scientific publication strategy;
- willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- prevalence and severity of any side effects;
- development of one or more competing products for the same indication; and
- restrictions on the use of the product together with medications.

Although the products we are developing are intended to provide a therapeutic response to a need that is presently unmet, poor market penetration resulting from one or more of the factors described above could have a negative impact on their commercialization and on our ability to generate profits, which could have a material adverse effect on our business, outlook, financial position, income and growth.

The level of market acceptance and sale of our drug candidates, if approved, will heavily depend on the availability of coverage and adequate reimbursement from third-party payors. The conditions for reimbursement, including price and reimbursement rate for drugs are beyond the control of pharmaceutical companies. They are determined by competent public committees and bodies and by social security or private insurance companies. In the United States, a number of factors. Pricing and reimbursement schemes vary widely from country to country. In the European Union, pricing and reimbursement are determined individually by European Union Member States. In some countries, they may approve a specific price for a product while others may instead allow companies to fix the price of their products but monitor and control company profits. Within the US, as a principle, drug companies set their own prices, which may then be discounted through negotiations with payors. However, as a result of the Inflation Reduction Act of 2022 ("IRA"), the Secretary of Health and Human Services is now authorized to

with pharmaceutical companies for certain drugs covered under Medicare Part D program (i.e., for Americans aged 65 or older and Americans receiving social security disability).

Generally, the downward pressure on health care costs has become intense. As a result, in barriers are being erected to the entry of new products. Delays in the price negotiation process, significant delay in marketing, our product may not obtain an appropriate level of reimbursement. price level and reimbursement rate of the treatments we market may be changed. We are also uncertain that we will succeed in maintaining, over time, the price level of our products or the acceptance

Our future may depend on our most advanced clinical development program, obehazimod, since our candidates are in a less advanced stage of development.

Obehazimod is our most advanced drug candidate. Obehazimod has required, and may continue to require, significant investments of our time and financial resources, as well as the special attention of regulatory authorities. Consequently, if we were unable to obtain conclusive results in ongoing maintenance trials, Phase 1 in UC or Phase 2 of obehazimod in CD, it could have a material adverse effect on our business position, results and development.

We may experience setbacks that could delay or prevent regulatory approval of our drug candidates or our ability to commercialize any products, including:

- negative or inconclusive results from our preclinical studies or clinical trials or results from others for drug candidates similar to ours, leading to a decision or requirement to discontinue preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by subjects in our clinical trials or by individuals using our therapeutics comparable to our drug candidates;
- delays in submitting investigational new drug applications in the United States or other countries, applications or delays or failure in obtaining the necessary approvals from regulatory authorities, review boards ("IRBs") or ethics committees to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- if the FDA or comparable foreign authorities do not accept the earlier preclinical work, then we may need to conduct additional preclinical studies or clinical trials. If we are delayed in our work, we currently have planned and significant preclinical study or clinical trial delay, which may allow any periods during which we may have the exclusive right to commercialize our drug, to expire and allow our competitors to bring products to market before we do and impair our ability to commercialize our drug candidates and may harm our business;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope of our clinical trials;
- delays in contracting with clinical sites or enrolling subjects in clinical trials, including due to the health pandemic and/or other macroeconomic factors;
- delays or interruptions in the supply of materials necessary for the conduct of our clinical trials;
- regulators or IRBs or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may prevent us from initiating our clinical trials with our originally intended trial design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective clinical investigators and prospective contract research organizations ("CROs") which can be the result of extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any drug candidates may be less than we anticipate or subjects may drop out of these clinical trials or fail to return for follow-up visits at a higher rate than we anticipate;
- our CROs for preclinical studies or clinical trials may fail to comply with regulatory requirements, meet their contractual obligations to us in a timely manner, or at all, or may deviate from the trial protocol or take actions that could cause clinical sites or clinical investigators to suspend or terminate the trial, which may require that we add new clinical trial sites or investigators;

- greater than anticipated clinical trial costs, including as a result of delays or interruptions, which may increase the overall costs to finish our clinical trials as our fixed costs are not variable and are incurred during delays;
- we may elect to, or regulators, IRBs or Data Safety Monitoring Boards ("DSMBs") may require us to, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are at an unacceptable health risk;
- we may not have the financial resources available to begin and complete the planned clinical trials of any drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data, such as long term toxicology studies, or impose other requirements before permitting us to commence a clinical trial, including because the FDA has not reviewed our preclinical or clinical data having been developed outside the United States;
- inability to compete with other therapies;
- poor efficacy of our drug candidates during clinical trials;

- We do not have complete control over many of these factors, including certain aspects of and the regulatory submission process, potential threats to our intellectual property rights marketing, distribution and sales efforts or that of any future collaborator.

Patient enrollment is a significant factor in the timing of clinical trials, and the time to enroll patients can depend, in part, on the speed at which we can recruit patients to participate in our trials, required follow-up periods. We may not be able to initiate or continue clinical trials for our products if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. The conclusion as required by applicable regulatory authorities. The eligibility criteria of our clinical trials, if established, may further limit the pool of available trial participants.

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the drug candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate in relation to other available therapies, including any products that may be approved candidates under investigation for, the indications we are investigating;

- Additionally, other pharmaceutical companies targeting these same diseases are recruiting patients from these patient populations, which may make it more difficult to fully enroll any rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely trials and preclinical studies. Though we have entered into agreements governing their service influence over their actual performance. Our inability to enroll a sufficient number of patients would result in significant delays or may require us to abandon one or more clinical trials and delays in our clinical trials may result in increased development costs for our drug candidates' ability to obtain regulatory approval for the sale of our drug candidates. Furthermore, even sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment in our clinical trials.

We are developing certain of our drug candidates in combination with one or more approved therapies. Even if any drug candidate we develop were to receive marketing approval or be combined in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA, PDMA or similar foreign regulatory authorities could revoke approval of the combination with our product or that safety, efficacy, manufacturing or supply issues could arise with existing therapies. If the therapies we use in combination with our drug candidates are replaced for the indications we choose for any of our drug candidates, the EMA, FDA, PDMA or similar regulatory authorities outside may require us to conduct additional clinical trials. The occurrence of these risks could result in our own products, if approved, being removed from the market or being sold commercially.

If the FDA, European Commission or similar foreign regulatory authorities do not approve therapies or revoke their approval of, or if safety, efficacy, manufacturing or supply issues we choose to evaluate in combination with our drug candidates, we may be unable to obtain approval for any such drug candidate.

We may conduct clinical trials for our drug candidates outside of the U.S., and the FDA may not approve our drug candidates based on data from such trials, in which case our development plans may be delayed, which could materially impact our business.

We have in the past conducted clinical trials or a portion of our clinical trials for our drug candidates outside of the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another country by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted. In cases where data from foreign clinical trials are intended to serve as the sole basis for approval of a drug candidate in the U.S., for example, the FDA will generally not approve the application on the basis of foreign data unless: (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were conducted in accordance with the FDA's Good Clinical Practice (GCP) regulations; and (iii) the data were gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we may be required to conduct additional trials, which could be costly and time-consuming, and which may result in our drug candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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accordance with GCP requirements and the FDA is able to validate the data from the study through an on-site inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical trials conducted outside of their respective jurisdictions. In addition, such foreign trials would be subject to the local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we may be required to conduct additional trials, which could be costly and time-consuming, and which may result in our drug candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Interim, "top-line" and preliminary data from our clinical trials and preclinical studies that we may publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials or preclinical studies, which is based on a preliminary analysis of then-available data, and the findings and conclusions are subject to change following a more comprehensive review of the data from the particular study or trial. We also make assumptions, estimations, calculations and conclusions based on the data we have received, and we may not have received or had the opportunity to fully and carefully evaluate the interim, top-line or preliminary results that we report may differ from future results of the study or trial. Different conclusions or considerations may qualify such results, once additional data have been received and evaluated. Top-line and preliminary data also remain subject to audit and verification procedures. The final data being materially different from the top-line or preliminary data we previously reported. Interim, top-line and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further subject to the risk that the final clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, top-line or preliminary data and final data could significantly impact our business prospects. Further, disclosure of such data by us or by our competitors could result in a loss of confidence in our securities.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, calculations, conclusions or analyses or may interpret or weigh the importance of data differently than we do, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate, product and our company in general. In addition, the information we choose to publicly disclose about a particular study or clinical trial is based on what is typically extensive information, and we determine what information is material or otherwise appropriate information to include in our disclosures. Information we determine not to disclose may ultimately be deemed significant with respect to our conclusions, views, activities or otherwise regarding a particular drug candidate or our business. If our interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory agencies, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health crises could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent our products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products is dependent on a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and allocate sufficient resources, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform their routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated significantly over the years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, could delay the time necessary for new drugs or modifications to approved drugs and to be reviewed and/or approved by the necessary government agencies, which would adversely affect our business. For example, over the years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have been placed on furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could prevent the FDA or other regulatory authorities from conducting their reviews, or other regulatory activities, it could significantly impact the ability of the FDA and other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. Regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored educational activities, promotional activities involving the internet and off-label promotion. The FDA grants is limited to those specific diseases and indications for which a product is effective by FDA. While physicians in the United States may choose, and are generally permitted, for uses that are not described in the product's labeling and for uses that differ from those approved by the regulatory authorities, our ability to promote any products will be narrowly limited to indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant federal government has levied large civil and criminal fines against companies for alleged in off-label use and has enjoined several companies from engaging in off-label promotion. The FDA that companies enter into consent decrees or permanent injunctions under which specified promotion changed or curtailed. If we cannot successfully manage the promotion of any drug candidates, we become subject to significant liability, which would materially adversely affect our business.

We may not be able to find industrial partners to pursue the clinical and commercial development of our drug candidates.

We aim to enter into licensing and distribution partnerships with pharmaceutical companies at the completion of the clinical development and marketing preparation of our lead drug candidates. Consequently, we should find partners with sufficient capacity to perform Phase 1, 2 and/or 3 clinical trials on a national or international scale and mass-produce, distribute and market immunotherapies and other treatments such as obefazimod. If we were to enter into such partnerships, the commercialization of our drug candidates would depend, in part, on the clinical, industrial, marketing and commercial development efforts of our partners and the ability of these partners to produce and sell obefazimod. Any failure on the part of our partners could have a material adverse effect on our growth and outlook.

It is also possible that we may not be able to enter into partnerships under economically favorable terms, or at all. This could have a material adverse effect on our business, outlook, financial position and development.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could affect our research and development activities.

Certain laws and regulations relating to drug development require us to test our drug candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of significant adverse publicity. Animal rights groups and other organizations and individuals have attempted to restrict animal testing activities by pressing for legislation and regulation in these areas and by disrupting animal testing activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related to our Operations and Strategic Development

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In order to manage our anticipated development and expansion, including the potential commercialization of our drug candidates in Europe and the United States, we must continue to implement and improve our operational and financial systems, expand our facilities and continue to recruit and train additional personnel. Due to our limited financial resources and the limited experience of our management team, if we expand our company with such expected growth, we may not be able to effectively manage the expansion of our operations, recruit and train additional qualified personnel. The expansion of our operations may lead to increased costs and may divert the attention of our management and business development resources away from day-to-day operations and devote a substantial amount of time to managing internal or external growth. Our inability to manage our growth and unexpected difficulties encountered during expansion could have a material adverse effect on our financial position, growth and outlook.

Our international operations subject us to various risks, and our failure to manage these risks could materially affect our results of operations.

We face significant operational risks as a result of doing business internationally, such as:

- fluctuations in foreign currency exchange rates;
- differing payor reimbursement regimes, governmental payors or patient self-pay system controls;
- potential changes to the accounting standards, which may influence our financial statements;
- becoming subject to the different, complex and changing laws, regulations and court decisions in multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- reduced protection of, or significant difficulties in enforcing, intellectual property rights in foreign countries;
- difficulties in attracting and retaining qualified personnel;
- restrictions imposed by local labor practices and laws on our business and operational flexibility, unilateral cancellation or modification of contracts;
- rapid changes in global government, economic and political policies and conditions, political unrest or instability, terrorism or epidemics and other similar outbreaks or events.

- in confidence of our suppliers or customers due to such changes or events; and
- tariffs, trade protection measures, import or export licensing requirements, trade barriers.

The market opportunities for our drug candidates may be limited to patients who are ineligible for prior treatments and may be small or different from our estimates.

The current IBD treatment approach is influenced by multiple factors, including disease response to treatment, side effects and co-morbidities. The current standard of care for treating mild IBD involves the use of conventional anti-inflammatory therapies. Conventional anti-inflammatory treatments include: aminosalicylates (e.g., 5-ASA), immunosuppressants or immunomodulators (e.g., 6-mercaptopurine ("6-MP"), methotrexate ("MTX")) and corticosteroids that are usually prescribed for short-term treatment of flare-ups. Despite these conventional therapies, patients suffering from mild IBD may evolve to severe forms of IBD requiring the use of advanced therapies. However, available therapies offer efficacy that changes or may wane over time, as patients have the potential to stop responding to all to these treatments and thus require new therapeutic management options.

While we hope to position obefazimod as a potential first-line advanced therapy, there is no guarantee that, even if approved, it would be approved for first-line advanced therapy. This could limit our market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for our advanced therapy.

The estimates of market opportunity and forecasts of market growth included in this Annual Report on Form 20-F may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Market opportunity estimates and growth forecasts included in this Annual Report on Form 20-F are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this Annual Report on Form 20-F relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size and growth forecasts included in this Annual Report on Form 20-F, our business may not grow at similar rates. Our growth is subject to many factors, including our success in implementing our business strategy and to many risks and uncertainties.

Sales of our drug candidates could be adversely impacted by the reluctance of physicians, health care providers, patients or the medical community in general to adopt them and by the availability of competitive products.

Even if we obtain regulatory approval for one or more of our drug candidates, physicians, health care providers, patients or the medical community in general may be reluctant to try a new drug due to the high costs associated with the application of new drugs in the field of human medicine, especially if the new drug is not perceived to be a significant improvement over the currently prevailing medication for a given complaint. We will need to expend significant resources to promote our drug candidates.

market our products to increase the public's awareness within numerous limits set by the regulatory requirements for the promotion of drugs. If our products do not achieve an adequate level of acceptance, we may not be able to generate sufficient revenues to become profitable or the profitability may occur much later.

Competing drug candidates in the chronic inflammatory disease field are being manufactured by other companies, including, but not limited to, AbbVie, Amgen, Janssen, Johnson & Johnson, Pfizer and Takeda. Even if our drug candidates compete with other drugs, particularly any that sell at lower prices, our drug candidates will not necessarily have a competitive advantage. Even if we can overcome physician reluctance to try new drugs, our drug candidates may not compete with products that are currently on the market, our competitors may succeed in developing more accurate or more cost-effective treatments or therapeutic indications that could render our drug candidates non-competitive.

Global economic conditions could materially adversely impact demand for our drug candidates.

Our operations and performance depend significantly on economic conditions. Global financial markets continue to be subject to volatility arising from international geopolitical developments, such as global economic phenomena, as well as general financial market turbulence, natural phenomena and the global health crisis. Uncertainty about global economic conditions could result in:

- third-party suppliers being unable to produce components for our drug candidates in a timely manner or on the same timeline or being unable to deliver such parts and components as quickly as required, which could have a material adverse effect on our production of such production; and
- once our drug candidates are available for sale, customers postponing purchases of our drug candidates in response to tighter credit, unemployment, negative financial news and/or decline in consumer confidence and other macroeconomic factors, which could have a material adverse effect on our sales of our drug candidates,

either of which could, accordingly, have a material adverse effect on our business, results of operations and financial condition.

Access to public financing and credit can be negatively affected by the effect of these conditions on U.S. and global credit markets. The health of the global financing and credit markets may affect our ability to obtain equity or debt financing in the future and the terms at which financing or credit is available. Global financial volatility and market turmoil could adversely affect our operations and the trading price of our common stock.

Changes to trade policy, tariffs, and import/export regulations may have a material adverse effect on our business, financial condition, and results of operations.

Changes in laws and policies governing foreign trade could adversely affect our business and future policy changes, there may be greater restrictions and economic disincentives on imports and exports. Changes have the potential to adversely impact the global and local economies, our industry and our drug candidates and, as a result, could have a material adverse effect on our business, results of operations and financial condition.

Fluctuations in currency exchange rates may significantly impact our results of operations.

Our business is located, and our operations are conducted, in Europe. As a result, we are exposed to exchange rate risk between the U.S. dollar and the Euro. The exchange rates between these currencies have fluctuated significantly and may continue to do so in the future. An appreciation of the U.S. dollar could increase the relative cost of our drug candidates outside of Europe, which could have a negative effect on sales. Conversely, to the extent that we are required to pay for goods or services in Euros, depreciation of the Euro against the U.S. dollar would increase the cost of such goods and services.

We do not hedge our currency exposure and, therefore, we incur currency transaction risk in connection with either a purchase or sale transaction using a currency other than the Euro. Given the volatility of the Euro, we might not be able to effectively manage our currency transaction risks, and volatility in the Euro might have a material adverse effect on our business, financial condition or results of operations.

We rely on a small number of third-party suppliers and manufacturers, and in certain cases a single supplier, and we may be in a position of dependence with respect to these third parties.

We do not own or operate manufacturing facilities and have no current plans to develop our own commercial-scale manufacturing capabilities. We currently rely, and expect to continue to rely, on third-party suppliers, and in certain cases a single-source supplier, for the supply of various chemical products and clinical batches needed for our preclinical studies and clinical trials. For the manufacture of our drug candidates, we rely on single-source suppliers. The supply of specific materials and products required for conducting clinical trials and manufacturing our products cannot be guaranteed.

We are dependent on third parties for the supply of various materials, including chemical products that are necessary to produce drug candidates for our clinical trials and, ultimately, for the manufacture of our drug candidates that may receive approval.

The facilities used by our third-party manufacturers must be approved for the manufacture of our drug candidates by the FDA, the EMA and any comparable foreign regulatory authorities in other jurisdictions. We are required to undergo inspections that will be conducted after we submit an NDA to the FDA, MAA to the EMA, or a comparable marketing application to a comparable regulatory authority. We do not control the process of, and are completely dependent on, third-party manufacturers for compliance with GMP requirements for the manufacture of our drug candidates. If these third-party manufacturers cannot successfully maintain regulatory compliance, we may not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

In addition, we have no control over the ability of third-party manufacturers to maintain regulatory compliance, quality assurance and qualified personnel. If any regulatory authority does not approve the manufacture of our drug candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to obtain regulatory approval for or market our drug candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approval, operating restrictions and criminal prosecutions, any of which could significantly and adversely impact our business.

Our or a third party's failure to execute on our manufacturing requirements on commercial scale, or in compliance with GMP or other regulatory requirements could adversely affect our business operations, including:

- an inability to initiate or complete clinical trials of our drug candidates in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our drug candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our drug candidates; and
- in the event of approval to market and commercialize any drug candidate, an inability to meet commercial demands.

In addition, we do not have any long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our drug candidates or such quantities at an acceptable cost. Any performance failure on the part of our third-party manufacturers or suppliers could delay clinical development or marketing approval, and any remedial measures may be costly or time consuming to implement. We do not currently have second source arrangements for raw materials used in the manufacture of our drug candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to do so on a timely basis or at all, which would have a material adverse impact on our financial position.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. We rely on, and will continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and clinical trials, in each case in accordance with trial protocols and applicable regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and

subsequent collection and analysis of data. Though we expect to carefully manage our relationships with CROs, investigators and other third parties, there can be no assurance that we will not encounter delays in the future, or that these delays or challenges will not have a material adverse impact on our financial condition and prospects. Further, while we have and will have agreements governing our relationships with third-party contractors, we have limited influence over their actual performance. Nevertheless, we are committed to ensuring that each of our clinical trials is conducted in accordance with the applicable regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities.

In addition, we and our CROs are required to comply with stringent standards governing the conduct of preclinical studies and clinical trials, including Good Laboratory Practice ("GLP") and Good Clinical Practice ("GCP") regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, and applicable regulatory requirements in clinical development. Regulatory authorities enforce GCPs through periodic inspections of sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with GLP, GCP or other requirements, the data generated in our clinical trials may be deemed unreliable by comparable foreign regulatory authorities may require us to perform additional clinical trials or submit new marketing applications, if ever. Furthermore, our clinical trials must be conducted with material compliance with GMP regulations. Failure to comply with these regulations may require us to re-submit applications, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote sufficient resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise fails to perform in a standard manner, our clinical trials may be extended, delayed or terminated. In addition, our relationships with whom we contract may also have relationships with other commercial entities, including competitors, with whom they may also be conducting clinical trials or other activities that could harm our competitive position. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors to us from time to time and may receive cash or equity compensation in connection with such service. Such relationships and any related compensation result in perceived or actual conflicts of interest, and that the financial relationship may have affected the interpretation of the study, the integrity of the data, the applicable clinical trial site may be questioned and the utility of the clinical trial itself. Such conflicts could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could result in the delay or rejection by the FDA of any NDA we submit.

In addition, our CROs have the right to terminate their agreements with us in the event of a breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional costs and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our management, scientific and medical personnel whose services are critical to our success. Our success depends greatly on the involvement and expertise of our senior executive and scientific staff. While Dr. Philippe Pouletty, MD, our founder and Chairman of our Board since 2013, resigned from his Chairman position in August 2022, he continues to support our development.

our Board as the representative for Truffle Capital. We do not maintain key person insurance. The permanent unavailability of our management and scientific staff, as well as Dr. Pouletty, could result in the following:

- loss of know-how and weakening of certain activities, especially in the case of transition to new competition; and
- deficiencies in terms of technical skills that could slow down activity and ultimately prevent us from reaching our objectives.

Recruiting and retaining additional qualified management and scientific, clinical, manufacturing and marketing personnel will also be critical to our success, particularly as we expand in order to develop our pipeline. Skills, such as manufacturing, quality assurance and regulatory and medical affairs. The loss of any senior management team or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business plan. Furthermore, replacing executive officers and key employees may be difficult and may take more time because of the limited number of individuals in our industry with the breadth of skills necessary to successfully develop, gain regulatory approval of and commercialize drug candidates. Competition for this limited pool is intense, and we may be unable to hire, train, retain or motivate these individuals on the terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience intense competition for the hiring of scientific and clinical personnel from pharmaceutical companies, universities and research institutions. We may not be able to attract or retain qualified personnel.

scientific competence with the ability to develop and commercialize drugs for inflammatory diseases, of equal or better quality than we do. Our competitors may also provide more diverse and better chances for career advancement. An inability to attract and retain high quality personnel could have an adverse effect on our business, prospects, financial condition, cash flow or results of operations.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, in formulating our research and development and commercialization strategy. Our consultants and advisors are employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain consultants and personnel, the marketing and production of our drugs could be delayed or prevented, which could have a material adverse effect on our business, prospects, financial condition, cash flows or results of operations.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, recklessness or unauthorized activity that violates (i) the laws and regulations of the European Union, the United States and other countries, the European Commission, FDA and other regulatory authorities, including those laws and regulations relating to reporting of true, complete and accurate information to such authorities, (ii) manufacturing, distribution, marketing and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and elsewhere and (iv) laws that require the true, complete and accurate reporting of clinical trial data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other improper practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing, sales, commission, customer incentive programs and other business arrangements. Such misconduct also could include improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials, or misrepresentation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It may be difficult to identify and deter misconduct by employees and other third parties, and the precautions we take to prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws and regulations. Additionally, we are subject to the risk that a person or government could allege or bring a claim of misconduct, even if none occurred. If any such actions are instituted against us and we are unable to successfully defend ourselves or asserting our rights, those actions could result in significant civil, criminal or other penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and other restrictions, and we may be subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, which could have a negative impact on our business, financial condition, results of operations and cash flows.

We have limited infrastructure in market access, sales, marketing and distribution.

We lack infrastructure and resources in the fields of sales, marketing and distribution. We currently have no own marketing and sales capacity, either alone or with partners once marketing authorizations are obtained. As part of setting up our sales and marketing infrastructure, we will need to incur additional costs and hire management resources, implement new skills and take the time necessary to set up the appropriate infrastructure to support the products in accordance with current legislation and, more generally, commercialization efforts. We compete with many companies that currently have extensive, experience in market access, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel and will have to compete with those companies to recruit, hire, train and retain any of our own marketing and sales personnel. If we are unable to expand our sales and marketing team, we may not be able to compete successfully against these more established companies. Alternatively, if we choose to enter the market globally or on a territory-by-territory basis, with third parties that have direct sales force and distribution systems, either to augment our own sales force and distribution systems or in lieu of our own, and distribution systems, we will be required to negotiate and enter into arrangements with such third parties to the proposed collaboration. If we are unable to enter into such arrangements when needed, we may not be able to commercialize any of our drug candidates that receive marketing authorizations, and, at all, we may not be able to successfully commercialize any of our drug candidates that receive marketing authorizations or any such commercialization may experience delays or limitations. Factors that may inhibit our ability to establish sales, marketing and distribution organization:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians, educate physicians about our drug candidates whom our drug candidates may be appropriate treatment options and attain adequate numbers of prescriptions from physicians to prescribe any drugs;
- the inability of reimbursement professionals to negotiate arrangements for formulary inclusion, reimbursement and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our drug candidates to the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

There are numerous competitors in the market for therapeutic treatments of inflammatory diseases.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant technological change as researchers learn more about diseases and develop new technologies and products. Numerous pharmaceutical companies, biotech companies, institutions, universities and other research organizations are engaged in the research, discovery, development and commercialization of therapeutic response to the diseases targeted by us. Significant competitive factors in our industry include: (i) product quality and breadth of an organization's technology; (ii) skill of an organization's employees; (iii) ability to recruit and retain key employees; (iv) timing and scope of regulatory approvals; (v) government support; (vi) the average selling price of pharmaceutical products; (vii) the availability of raw materials; (viii) manufacturing capacity; (ix) manufacturing costs; (x) intellectual property and patent rights; and (xi) sales and marketing capabilities. Given the intense competition in our industry, we believe that any of the products that we successfully develop will be clinically superior or scientifically

developed or introduced by competitors. In addition, obtaining regulatory approvals for their drug candidates more rapidly than us, which could place us at disadvantage or deny us marketing exclusivity rights.

Our competitors in the chronic inflammatory disease field are primarily large pharmaceutical companies, including, but not limited to, Eli Lilly, Johnson & Johnson, Pfizer, and Takeda. Several of these companies are being developed to improve the treatment of IBD. Many companies are working to develop new, more effective and better tolerated treatments with more practical formulations, especially small molecules and biologics, as opposed to accepted monoclonal antibodies that require administration by injection. See "Item 4.B—

Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have significantly greater financial resources and infrastructure for research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals, and marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries may re-

resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through partnership arrangements with larger pharmaceutical companies. These companies also compete with us in recruiting and retaining qualified scientific and technical personnel and establishing clinical trial sites and patient registration for clinical trials, and in developing technologies complementary to, or necessary for, our programs.

The development potential in the markets in which we operate is such that the arrival of new market entrants is probable. New market entrants, increased competition in specific areas, or in general, would have a negative effect on our business, income, financial position and outlook for growth.

We depend on, and will continue to depend on, collaboration and strategic alliances with third parties. To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be able to commercialize our products more effectively than we otherwise could. Our success is related to those collaborations and alliances.

An important element of our strategy for developing, manufacturing and commercializing our products is entering into partnerships and strategic alliances with other pharmaceutical companies or academic institutions as participants. The collaboration agreements that we have established, and any collaboration agreements we may enter into in the future, may not be successful, which would have a negative impact on our business, operations, financial condition and growth prospects.

Any partnerships or alliance we have or may have in the future may be terminated for reasons beyond our control or we may not be able to negotiate future alliances on acceptable terms, if at all. Termination of such alliances may result in us receiving less revenue than if we sold our products directly, may place the development and marketing of our products outside of our control, may require us to relinquish important rights in our products on unfavorable terms. Collaborative arrangements or strategic alliances will also subject us to various risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic collaborators may devote to the drug candidates;
- strategic partner/collaborators may experience financial difficulties;
- the failure to successfully collaborate with third parties may delay, prevent or otherwise limit the development or commercialization of our drug candidates or revenue expectations;
- products being developed by partners/collaborators may never reach commercial stage or may result in reduced or even no milestone or royalty payments;
- business combinations or significant changes in a collaborator's business strategy may affect a collaborator's willingness or ability to complete their obligations under collaborative arrangements;
- a collaborator could independently move forward with a competing product developed independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay or prevent development and may increase the cost of developing drug candidates.

Our partnerships and licensing agreements relating to the technologies belonging to us may not be successful.

The various drug candidates developed by us arise from proprietary or licensed technologies from academic partners, including Scripps Research Institute, University of Chicago, Brigham Young University, and the Montpellier Institute of Molecular Medicine. ~~Centra National de la Recherche Scientifique~~ the Institut Curie. If the clinical trials conducted by us were to reveal safety and/or therapeutic concerns, the use of one of the platforms were to violate an intellectual property right held by a third party, or if the use and operation of some of our technology platforms and require additional research and development, and additional time and expense to address these difficulties, with success not being guaranteed, a portion of our product portfolio would be affected, which would have a material adverse effect on our business, outlook, growth, financial position and income.

The reimbursement of drugs and treatments is beyond our control.

After achieving regulatory authorization and once marketing authorization is granted, the sales price of drugs and their reimbursement rates begins. The conditions for setting the reimbursement rate for drugs are beyond the control of pharmaceutical companies. They are determined by public committees and bodies and by social security or private insurance companies. In this case,

partners could be asked to perform additional studies on our products. These studies could be for us or our partners and lead to delays in marketing the drug, which could have an impact on our business.

There is significant uncertainty related to the reimbursement of newly-approved drugs. The reimbursement will impact market acceptance and sale of our drug candidates. Reimbursement is dependent on a number of factors, including, without limitation, the third-party payor's determination of whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

The possibility that we could receive royalties from our industrial partner or partners on our products and our ability to make sufficient profits on the marketing of our treatments or entering into distribution contracts will depend on these reimbursement conditions. If delays in the reimbursement procedure result in a significant delay in marketing, if our product does not obtain an appropriate reimbursement, or if the accepted price level and reimbursement rate of the treatments we market, our profitability will be reduced.

We are also unable to guarantee that we will succeed in maintaining, over time, the prices of our products or those for which licenses have been granted, or the accepted reimbursement rate. Under these circumstances, there could be a material adverse effect on our business, financial position and results of operations.

The pricing, insurance coverage and reimbursement status of newly-approved products is uncertain. We may not obtain or maintain adequate coverage and reimbursement for our drug candidates, if approved, which could result in our inability to market those products and decrease our ability to generate product revenue.

Successful sales of our drug candidates, if approved, depend on the availability of coverage and reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid in the United States, managed care organizations and commercial payors, among others. There is significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we have not received regulatory approval.

In the United States, no uniform policy for coverage and reimbursement exists, and coverage and reimbursement for drug products can differ significantly from payor to payor. Therefore, one payor's decision to provide coverage for a drug product does not assure that other payors will also provide coverage for the same product. Third-party payors often follow Medicare coverage policy and payment limitations in determining reimbursement rates, but also have their own methods and approval process apart from Medicare. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately. Even if coverage and adequate reimbursement will be applied consistently or obtained in the first instance, coverage policies and third-party reimbursement rates may change at any time. Even if favorable reimbursement status is attained for one or more products for which we receive regulatory approval, coverage policies and reimbursement rates may be implemented in the future.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain regulatory approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement rates may not be adequate or may require co-payments that patients find unacceptably high. Patients are prescribed medications for the treatment of their conditions, and their prescribing physicians may be pressured by third-party payors to reimburse all or part of the costs associated with their prescription of our products unless coverage is provided, and reimbursement is adequate to cover all or part of the cost of our products. Therefore, coverage and adequate reimbursement is critical to our business.

Additionally, we or our collaborators may develop companion diagnostic tests for use with our drug candidates. We or our collaborators will be required to obtain coverage and reimbursement for these tests, which is separate and apart from the coverage and reimbursement we seek for our drug candidates, once approved. Our inability to obtain coverage and reimbursement, applicable to pharmaceutical or biological products, for our companion diagnostics. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors for the drug candidates and companion diagnostic tests that we or our collaborators develop could have a material adverse effect on our business, financial position and results of operations.

which we obtain regulatory approval could have a material and adverse effect on our business, financial position and results of operations and prospects.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries require that products may be marketed only after a reimbursement price has been agreed. Some countries require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to available therapies. EU member states may approve a specific price for a product or it may impose direct or indirect controls on the profitability of the company placing the product on the market. EU member states allow companies to fix their own prices for products, but monitor and control company prices to ensure that the pressure on health care costs has become intense. As a result, increasingly high barriers are being put in place to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets create competitive pressure that may reduce pricing within a country. Any country that has price control policies in place may not allow favorable reimbursement and pricing arrangements, and prices are subject to periodic review, such that any given price may decrease upon various occurrences.

Additionally, the containment of healthcare costs has become a priority of federal and state governments. In the U.S., the prices of drugs have been a focus of this effort. The U.S. government, state legislatures and Congress have shown significant interest in implementing cost-containment programs, including price controls, increased competition, reimbursement and requirements for substitution of generic products. Adoption of price controls, increased competition, and adoption of more restrictive policies in jurisdictions with existing price controls could further limit our net revenue and results.

Price controls may be imposed in markets in which we operate, which may negatively affect our profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of drugs is subject to governmental control. In these countries, pricing negotiations with governments take considerable time after receipt of marketing approval for a product. In addition, there is pressure by governments and other stakeholders on prices and reimbursement levels, including containment measures. Political, economic and regulatory developments may further complicate negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reimbursement by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced states, can further reduce prices. In some countries, we or our collaborators may be required to conduct clinical trial or other studies that compare the cost-effectiveness of our drug candidates to other available treatments to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the countries and other countries. If reimbursement of our drug candidates is unavailable or limited in scope or set at unsatisfactory levels, there could be a material adverse effect on our business, financial results and operations.

If our information technology systems or those of the third parties upon which we rely, or our data is compromised, we could experience adverse consequences resulting from such compromise, including but not limited to: regulatory investigations or actions; litigation; fines and penalties; disruption of operations; reputational harm; loss of revenue and profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely process and store large amounts of data (including data we collect about trial participants in connection with clinical trials) and confidential information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive business plans, transactions, and financial information (collectively, sensitive data). We are aware that the data and information which we rely face a variety of evolving threats to information technology systems and data.

Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar threats to the confidentiality, integrity and availability of our sensitive data and information technology systems are threats to the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasing in frequency and severity, and come from a variety of sources, including traditional computer "hackers," threat actors, organized criminal threat actors, personnel (such as through error, theft or misuse), sophisticated nation-state-supported actors. For geopolitical reasons and in conjunction with military conflict and other activities, some actors have in the past and are expected to in the future engage in nefarious activities, war and other major conflicts, we and the third parties upon which we rely may be vulnerable to these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, our chain and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to and have experienced a variety of threats to our information technology systems and data, including but not limited to social-engineering attacks (including through deep fakes, which are more difficult to identify as a fake, and phishing attacks), malicious code (such as viruses and malware), denial-of-service attacks (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, server malfunctions, software or hardware failures, loss of data or other information technology systems, telecommunications failures, earthquakes, fires, floods, other natural disasters, attacks on our facilities and other similar threats. In particular, severe ransomware attacks are becoming increasingly frequent and severe, leading to significant interruptions in our operations, ability to provide our services, loss of sensitive data, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws and regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers, and devices outside of our facilities, including working at home, while in transit and in public locations. Additionally, future acquisitions or integrations could expose us to additional cybersecurity risks and vulnerabilities that could be negatively affected by vulnerabilities present in acquired or integrated entities' information technology systems. Furthermore, we may discover security issues that were not found during due diligence of acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data, including, without limitation, cloud-based infrastructure, cybersecurity monitoring, email, and other functions. We may also rely on third-party service providers to provide other services, or otherwise to operate our business. Our ability to monitor these third parties' information technology systems is limited, and these third parties may not have adequate information security measures in place. If a third-party service provider experiences a security incident or other interruption, we could experience a disruption of our services. While we may be entitled to damages if our third-party service providers fail to satisfy their contractual obligations to us, any award may be insufficient to cover our damages, or we may be unable to collect any award. In addition, supply-chain attacks have increased in frequency and severity, and we can be exposed to third parties' infrastructure in our supply chain or our third-party partners' supply chains if they are compromised.

While we have implemented security measures designed to protect against security incidents, we cannot guarantee that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including those of our third parties upon whom we rely). We may not, however, detect and remediate all such vulnerabilities including those that are not on an effective basis. Further, we may experience delays in developing and deploying remedial measures to address identified vulnerabilities. These vulnerabilities could be exploited and lead to a security incident.

Any of the previously identified or similar threats have caused and could cause a security incident that could result in unauthorized, unlawful, or accidental acquisition, modification, alteration, encryption, disclosure of, or access to or other compromise of our sensitive data and information, our information technology systems, or those of the third parties upon whom we rely. A security incident or compromise of our information technology systems or those of the third parties upon whom we rely could

disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trials) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security practices to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of a security incident, affected individuals, regulators, investors and others, of security incidents. Such disclosure or non-disclosure or the failure to comply with such requirements could lead to adverse consequences for our business.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: enforcement actions (for example, investigations, fines, penalties, audits, and inspections); reputational harm; loss of business; requirements and/or oversight; restrictions on processing sensitive data (including personal information); and other adverse consequences.

(including class claims); indemnification obligations; negative publicity; reputational harm; loss of business; diversions; interruptions in our operations (including availability of data); financial loss; and other adverse consequences. Security incidents and attendant consequences may cause customers to stop using our services, which could result in lost revenue, from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or losses related to data privacy and security obligations. We cannot be sure that our insurance coverage will be sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will cover all such liabilities.

Additionally, sensitive information of the Company could be leaked, disclosed, or revealed to third parties, which could result in a connection with our personnel's or vendors' use of generative AI technologies.

As an example of our being subject to the variety of cybersecurity threats discussed above, in 2023, we learned that two sites at which we conduct clinical trials experienced cybersecurity incidents. In response to these incidents, we conducted an investigation that largely relied upon the sites' investigations. These incidents, however, exemplify the types of threats we face including our reliance on service providers.

An outbreak of communicable diseases around the world may cause disruption to our business.

Any public health crisis due to the outbreak of communicable diseases may cause any of the following:

- delays or difficulties in recruiting patients for our clinical trials;
- delays or difficulties in launching clinical trial sites, including difficulties in obtaining regulatory approvals and clinical site staff; and
- diversion of health care resources from the conduct of clinical trials, of hospital operations, or of other critical services.

In addition to the risks listed above, and as part of our clinical trials in countries in which we also experience the following adverse effects:

- potential delays in the conduct of our research and preclinical studies, preventing preclinical studies from being conducted as planned;
- delays in obtaining authorizations from the administrative and regulatory authorities to conduct the planned preclinical studies and clinical trials;
- delays in the receipt of supplies and equipment necessary for the completion of our preclinical studies and clinical trials;
- interruption or delays affecting the activity of contractors who provide research services;
- refusal of the competent regulatory authorities to accept data from clinical trials conducted in geographical areas affected by the pandemic;
- the interruption of global maritime trade could affect the transportation of research materials, preclinical studies and clinical trials, such as experimental drugs and comparator drugs;
- delays in the necessary interactions with local authorities, ethics committees or other third-party co-contracting bodies due to limitations in human resources or forced lockdowns of employees.

If one or more of the above risks were to materialize, the planned and ongoing clinical trials, the publication of the data and results of these studies and all subsequent steps leading to the approval of candidates being studied, could be significantly delayed. Such a situation could have a material adverse effect on our business, income, financial position and growth.

The extent to which the outbreak of communicable diseases around the world may impact our clinical trials will depend on future developments, which cannot be predicted with certainty, including the nature, timing, and severity of the outbreak, the availability of vaccines, treatments, and other measures, of diseases that may be resistant to the vaccines or treatments currently available, access to healthcare, for the various populations worldwide, the final geographical spread of the disease, its duration, and social distancing measures in the European Union, the United States and other countries,

disruptions, and the effectiveness of measures taken in those countries to contain and treat, no assurance that the outbreak of communicable diseases around the world will not result in a financial markets, our share price and our ability to obtain finance.

The war between Ukraine and Russia may affect our business, industry and the markets in which

In February 2022, Russia invaded Ukraine. The conflict has already had major implications on the economy and the rate of inflation, particularly in relation to the supply of energy, raw materials. It has also caused intense volatility on the financial markets, something that is still ongoing. This has pushed down stock market prices around the world.

Given these developments, we have decided not to include Russia and Belarus in our global strategy for obefazimod in UC. However, the global scale of this conflict cannot be predicted at this time. We cannot rule out an adverse impact of this conflict on our business, including in terms of access to logistics, the performance of clinical trials and in relation to any future financing we may obtain.

The Phase 2b maintenance trial of obefazimod in moderately to severely active UC is our only clinical trial currently in progress in Ukraine. We have, however, terminated a few trial sites since the Russian invasion. The 12-month assessment was carried out in all the Ukrainian patients before the war broke out. The patients are therefore included in the one-year maintenance results that were reported on April 6, 2022. Patients who completed the two-year Phase 2b maintenance trial have been transitioned to the long-term maintenance trial that is still on-going. None of these sites are located in the Crimea Region of Ukraine, the People's Republic, or the so-called Luhansk People's Republic. We are also evaluating the possibility of including a few Ukrainian sites in the western part of Ukraine in the ABTECT Phase 3 clinical trials.

Risks Related to Intellectual Property

Our ability to exclusively commercialize our drug candidates may decrease if we are unable to obtain or maintain intellectual property rights or if these rights are insufficient for our purposes.

Our commercial success depends in part on our ability and the ability of our partners to obtain, enforce, against third parties, the protection of our patents, trademarks and related intellectual property rights or similar rights (such as trade secrets, business secrets and know-how) or to use them in the course of our business in Europe, the United States, Asia and other key countries. We have invested financial and human resources to this and intend to continue our policy of protection through patent applications as soon as we deem it appropriate.

Our technology is currently protected by patents and patent applications that we have filed. We may not have an exclusive license. However, we or our partners might not be able to maintain the protection of our intellectual property rights and we could, thereby, lose our technological and competitive advantage in part.

Firstly, our intellectual property rights and those of our partners offer protection for a limited period of time from one territory to another. The term of individual patents depends upon the legal term of protection in the countries in which they are obtained. In most countries in which we have obtained or are seeking patents for our drug candidates, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, the term of a patent may be lengthened by a patent term adjustment under the America Invents Act. The USPTO provides for term extension in the case of administrative delays at the United States Patent and Trademark Office ("USPTO") in granting a patent, or may be shortened if a patent is terminally disclaimed over a prior art. Earlier expiration date. Furthermore, in the United States, the term of a patent covering a drug may be eligible for a patent term extension under the Hatch-Waxman Amendments as compensation for the delay in FDA approval. The period of extension may be up to five years from the date of expiration of the patent but cannot extend the term of a patent beyond a total of 14 years from the date of FDA approval. Only one patent covering a single FDA-approved product among those eligible for an extension may be extended. In the future, if any of our drug candidates receives FDA approval, we expect to apply for a patent term extension, if available, to extend the term of the patent covering such approved drug product. In Europe generally, the term of a patent is 20 years from the date the patent application is granted. We understand that this period may be extended up to another five years if a supplementary protection certificate is filed and an additional six months if a pediatric investigation plan is applied. We expect to apply for extensions in any jurisdictions where they are available, however, there is no guarantee that such extensions will be granted, including the FDA, will agree with our assessment of whether such an extension is warranted. Even if granted, the length of such an extension.

Secondly, we and our partners could encounter difficulties in the filing or examination of patent, trademark or other intellectual property rights applications currently being examined/registered. In the patent application process, we may receive Office Actions from the USPTO or from comparable agencies in other jurisdictions rejecting the claims of the patent application. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. At the time a patent application is filed, we cannot be certain that we are the first to conceive of an invention relating thereto; in particular, it should be noted that in most countries, the patent application process takes place 18 months after the earliest priority date of patent filing, or in some countries, discoveries are sometimes only the subject of publication or patent application months or even years before filing one of our trademarks in a country where it is not covered, we could find that the trademark is not available in that country. A new trademark would then need to be sought for the country where the trademark was not available. A new trademark would then need to be sought for the country where the trademark was not available. We may not be able to prevent a third party from obtaining information to third parties that could have an impact on our future intellectual property rights. We cannot be certain that our current and future applications for patents, trademarks and other intellectual property rights will result in registrations.

Thirdly, the simple granting or registration of a patent, trademark or other intellectual property right does not guarantee validity or enforceability. Our competitors may at any time contest the validity or enforceability of our patents, trademarks or applications relating thereto before a court or in the administrative proceedings which, depending on the outcome of such disputes, could reduce their scope, result in the invalidation or allow them to be circumvented by competitors. In addition, developments, changes or divergences in the law may affect the validity or enforceability of our intellectual property rights.

conducting research or technologies without financial compensation. Moreover, there are still certain countries that do not have a legal framework governing intellectual property rights. In addition, the legal framework governing intellectual property rights in the same way as in Europe and the United States, and the rules necessary to ensure the defense of our rights may not exist in these countries. The certainty that our existing and future patents, trademarks and other intellectual property rights will be invalidated or circumvented, or that they will provide effective protection against competition.

Consequently, our rights to our owned or licensed patents, trademarks and related applications for intellectual property rights may not confer the protection expected against competition. We do not guarantee with certainty that:

- we will be able to develop novel inventions for which a patent could be filed or is being filed;
- applications for patents and other property rights currently under review will actually result in the granting of patents, trademarks or other registered intellectual property rights;
- patents or other intellectual property rights granted to us or our partners will not be invalidated or circumvented; or
- the scope of protection conferred by our or our partners' patents, trademarks and other intellectual property rights is and will remain sufficient to protect us against competition.

Were these eventualities to occur, they could have a material adverse effect on our business.

In addition, third parties (or even our employees) could use or attempt to use elements of our technology protected by an intellectual property right, which would create a detrimental situation for us. We may be compelled to bring legal or administrative proceedings against these third parties in order to enforce our intellectual property rights (patents, trademarks, designs and models or domain names) in court.

Enforcing a claim that a party illegally infringed or misappropriated our intellectual property rights can be expensive and time-consuming, and the outcome is unpredictable. Any litigation or dispute, regardless of the outcome, could lead to substantial costs, affect our reputation, negatively influence our financial position and possibly not lead to the desired protection or sanction. Some competitors with more resources than us may be able to bear the costs of litigation more easily.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships, we could lose rights that are important to our business.

Our ability to pursue the development of some of our drug-based candidates depends on the force of the licensing agreements entered into with various institutes. We have licenses granted by the University of Montpellier Institut for certain patents or patent co-ownership rights resulting from the research conducted by the University of Montpellier.

cooperation with the CNRS, the University of Montpellier, and the allowed obefazimod to be developed and a chemical library of more than 2,200 small molecules to be generated.

These license contracts provide the possibility for the licensor to end an agreed exclusive license in certain events, including the event of non-payment of fees, a dispute over the validity of the license or a violation by us of our obligations.

We may from time to time be party to license or collaboration agreements with third parties for the research or allow commercialization of current or future drug candidates. Such agreements may include various obligations, such as development, diligence, payment, commercialization, funding, milestone, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet certain timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed candidates and maintain the licenses. In spite of our best efforts, our licensors might conclude that we have not met our obligations under the license agreements and might therefore terminate the license agreements, thereby removing or restricting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying licensed rights fail to provide the necessary protection, could result in the loss of significant rights and could harm our ability to commercialize our drug candidates, and competitors or other third parties would have the freedom to seek regulatory approval for products identical to ours and we may be required to cease our development and commercialization of certain of our current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative arrangements;
- our diligence obligations with respect to the use of the licensed technology in research, development and commercialization of our current or future drug candidates, and whether we satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of technology by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technologies are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The adverse resolution of any contract interpretation disagreement that may arise could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes arise over the interpretation of the terms of the license agreements, we may be unable to successfully develop and commercialize the affected current or future drug candidates on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future drug candidates.

candidates, which could have a material adverse effect on our business, financial conditions, and prospects.

We may be sued for infringing or misappropriating the intellectual property rights of third parties, and such litigation could be costly and time consuming and could prevent or delay us from developing and commercializing our drug candidates.

Our commercial success will also depend on our ability to develop products and technologies without infringe the patents or other rights of third parties. It is important for the success of our business that we use our products and conduct research and development efforts leading to commercialization of our products without infringing patents or other third-party rights.

We continue to carry out, as we have done to date, the preliminary studies that we consider necessary in light of the above risks, before investing in the development of our various products and technologies.

intellectual property consulting and law firms, we monitor our competitors' activity (particularly patent filings).

We therefore cannot guarantee with certainty that:

- there are no prior patents or other intellectual property rights of third parties covering our products, methods, technologies, results or activities and that, consequently, third parties could bring an action for infringement or violation of their rights against us with a view to our cessation of interest and/or the cessation of our activities in the manufacture and/or commercialization of our products, methods and the like thus disputed;
- there are no trademark rights or other prior rights of third parties that could be the subject of an infringement or liability action against us; and
- our domain names are not subject, on the part of third parties who have prior rights in such domain names (trademark rights), to a Uniform Domain-Name Dispute-Resolution Policy ("UDRP") or to an infringement action.

In the event of intellectual property litigation, we may have to:

- stop developing, making, selling, offering for sale or using the product or product that is the subject of the disputed intellectual property;
- obtain a license from the holder of the intellectual property rights, however, such a license may be unobtainable or only be obtainable under unfavorable economic conditions for us; or
- revise the design of some of our products/technologies or, in the case of trademark rights, rename our products to avoid infringing the intellectual property rights of third parties, which may prove impossible or time-consuming and expensive, and could impact our marketing efforts.

Litigation can also result in an order to pay damages (including treble damages) and being enjoined from further activities.

Patent terms may be inadequate to protect our competitive position on our drugs for an adequate period of time, and we may seek to rely, but may not be able to rely, on other forms of protection, such as regulatory exclusivity.

Given the amount of time required for the development, testing and regulatory review of our drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, the certain patents protecting obehazimod's composition of matter expire in 2030 and the patents protecting obehazimod methods of use expire in 2035 which pose a risk to its successful commercialization. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent for a new active ingredient (or any additional indications approved during the period of extension) for a new indication, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may not grant extensions to our patents, or may grant more limited extensions than we request. We may also seek other forms of protection, such as regulatory exclusivity, but there can be no assurance that such extensions will be available or sufficient.

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 do seek protection.

Filing, prosecuting and defending patents on our drug candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries could be less extensive than those in the United States, assuming that rights are obtained. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection, 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 third parties from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent rights in those jurisdictions may not be effective or sufficient to prevent third parties from

In addition, the laws of some foreign countries do not protect intellectual property rights the federal and state laws in the United States. Many companies have encountered significant and defending intellectual property rights in certain foreign jurisdictions. The legal system, particularly in developing countries, do not favor the enforcement of patents and other intellectual property rights, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult to enforce 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 license a patent to third parties. In addition, many countries limit the enforceability of patents against third parties, government agencies or government contractors. In these countries, patents may provide limited protection. 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 some 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 diverting 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 being issued and could enable third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal environment in the United States and foreign countries may affect our ability to obtain adequate protection for our intellectual property. In addition, monitoring the unauthorized use of our technology and the infringement of our intellectual property rights is challenging. We cannot be certain that we will be able to prevent, take legal action against and obtain compensation for the misappropriation or unauthorized use of our products and technologies, particularly in foreign countries where rights are less well protected because of the territorial scope of intellectual property rights. To the extent we are unable to enforce our intellectual property rights around the world, we may be unable to obtain a sufficient competitive advantage from the intellectual property that we develop or license.

Further, in Europe, a new unitary patent system took effect June 1, 2023, which significantly changes the way European patents, including those granted before the introduction of such a system. Under the new system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be enforced by the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before June 1, 2023 will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the member states. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a revocation challenge that, if successful, could invalidate the patent in all countries where it is granted. We cannot predict with certainty the long-term effects of any potential changes.

In addition, geo-political actions in the United States and in foreign countries could increase the costs and time surrounding the prosecution or maintenance of our patent applications and the maintenance or defense of our issued patents. For example, the United States and foreign government actions, such as the invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of our intellectual property rights. If such an event were to occur, it could have a material adverse effect on our business. In March 2022, the Russian government adopted a law allowing Russian companies and individuals to use inventions owned by patentees from the United States without consent or compensation. Consequently, we may not be able to prevent third parties from practicing our inventions in Russia or from selling products made using our inventions in and into Russia. Accordingly, our competitive position may be impacted and our business, financial condition, results of operations and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected by us or our partners that develop our future products, then we may not be able to build name or brand recognition in our markets and our business may be adversely affected.

Our registered or unregistered trademarks and trade names and the registered or unregistered trade names that our partners will develop may be challenged, infringed, diluted, circumvented or determined to be infringing on other marks. We and our partners may not be able to protect our trademarks and trade names, which we need to build name and brand recognition among potential customers in our markets of interest. We expect to rely on our partners to protect the trademarks that they will develop, and they may not adequately protect such tradenames and trademarks, and we may have no recourse in respect thereof. At times, competitors may adopt trademarks and trade names that are similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in other jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to such objections, we may be unable to overcome such rejections.

to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings filed against our trademark applications or registrations, and our trademark applications or registrations surviving such proceedings. In addition, there could be potential trademark infringement claims against our other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name and brand recognition based on our trademarks, we may not be able to compete effectively and our business may be adversely affected.

Obtaining and maintaining patent protection depends on compliance with various procedural, disclosure, submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees for patent applications are required to be paid to the USPTO and various governmental patent agencies in the United States in several stages over the lifetime of the patents and applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee and other requirements during the patent application process and after a patent has issued. There may be consequences for non-compliance with these requirements. Non-compliance can result in abandonment or lapse of the patent or patent application, resulting in complete loss of patent rights in the relevant jurisdiction.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position may be adversely affected.

position could be harmed.

In addition to seeking patent protection for our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to establish and maintain our competitive position.

It is also important for us to protect against the unauthorized use and disclosure of our confidential information, know-how and trade secrets. Unpatented and/or unpatentable technologies, processes, know-how and data are considered trade secrets that we seek to protect, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors, university and/or institutional researchers and other third parties. We also have confidentiality and invention or patent assignment agreements with our employees, advisors and

In the context of collaboration, partnership or research contracts, or other types of contracts with researchers from academic institutions, and with other public or private entities, subcontractors or contracting third parties, various information and/or products may be entrusted to them in our tests and clinical trials. In such cases, we require that confidentiality agreements be signed. As a general rule, we take care that the collaboration or research contracts that we are party to give us sole ownership of results and/or inventions resulting from the collaboration, or to an exclusive ownership of results and/or inventions resulting from the collaboration.

Despite these efforts, counterparties may breach our agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Remedies may also be obtained by third parties by other means, such as breaches of our physical or computer security. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be independently developed by a competitor, we would have no right to prevent them, or those to whom we communicate it, from using that technology or information to compete with us. If any of our trade secrets are disclosed to, or independently developed by, a competitor, our competitive position would be harmed and our business may be adversely affected.

There can be no assurance that the agreements put in place to protect our technology and know-how being used will provide the protection sought or will not be violated, that we will obtain adequate remedies for such violations, or that our trade secrets will not be disclosed to or independently developed by competitors. In the context of contracts that we enter into with third parties, we sometimes require that they are not authorized to use third-party services or that they may only do so under certain conditions. However, it cannot be ruled out that some of these co-contractors may nevertheless use third-party services. We have no control over the conditions under which third parties with which we do not contract may use our confidential information, irrespective of whether we provide in our agreements with our co-contractors to undertake to pass on confidentiality obligations to their own co-contractors.

Such contracts therefore expose us to the risk of having the third parties concerned (i) infringe our intellectual property rights on our inventions or other intellectual property rights, (ii) fail to maintain the confidentiality of unpatented innovations or improvements of our confidential information and (iii) disclose our trade secrets to our competitors or independently develop these trade secrets. Such agreements, without our having an appropriate solution for such violations.

Consequently, our rights to our confidential information, trade secrets and know-how may not provide the expected protection against competition and we cannot guarantee with certainty that:

- our knowledge and trade secrets will not be obtained, stolen, circumvented, transmitted or disclosed without our authorization;
- our competitors have not already developed similar technologies or products, or one or more of them may have a purpose to ours;
- no co-contracting party will claim the benefit of all or part of the intellectual property rights in our inventions, knowledge or results that we hold in our own right or in co-ownership, or that we would be entitled to a license; or
- our employees will not claim rights or payment of additional compensation or fair payment for the creation of which they participated.

The occurrence of one or more of these risks could have a material adverse effect on our financial position, income and growth.

Intellectual property rights do not address all potential threats to our competitive advantage

The degree of future protection afforded by our intellectual property rights is uncertain. Intellectual property rights have limitations, and may not adequately protect our business, or permit us to fully realize our competitive advantage. The following examples are illustrative.

- Competitors may be able to formulate compositions that are similar to ours but that do not infringe our intellectual property rights.
- Competitors may independently develop similar or alternative compositions or otherwise use any of our applications or registrations without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive a particular invention, practice the inventions covered by the patents or patent applications that we own, or to obtain a patent or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have licensed.
- It is possible that any pending patent applications that we have filed, or will file, may not result in issued patents.
- Issued patents that we own may not provide us with any competitive advantage, or may be invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where patent rights are not available, or in countries where research and development safe harbor laws exist, which could enable them to use information learned from such activities to develop competitive products for sale in the United States.

commercial markets.

- Ownership of our patents or patent applications may be challenged by third parties.
- We may infringe on the patents of third parties or pending or future applications of third parties, and the patents of third parties or pending or future applications of third parties may have an adverse effect on our business.

Risks Related to Legal and Compliance

Our business is subject to a restrictive and changing regulatory framework.

One of the major issues for a growing company like ours is to successfully develop, along with our partners, products incorporating our technologies in an increasingly restrictive regulatory environment. The pharmaceutical industry faces constant changes in its legal and regulatory environment and in

the competent authorities, such as the National Agency for Medicines and Health Products Safety in France, the EMA in the European Union, the FDA in the United States or the PMDA in Japan, and other regulatory authorities in the rest of the world. At the same time, the public is demanding more guarantees regarding the safety and efficacy of products. This may at any time lead to a more restrictive regulatory environment for our products, which may have a material adverse effect on business, financial position, income, growth and outlook.

Health authorities oversee preclinical studies, clinical trials, the operations of pharmaceutical manufacturing and commercialization. This increasing stringency of the legislative and regulatory environment is common worldwide; however, requirements may vary from country to country. In particular, health authorities, especially the ANSM, EMA, FDA and PMDA, have imposed increasingly burdensome requirements in terms of the volume and quality of data required to demonstrate the efficacy and safety of a product. These requirements may have thus reduced the number of products authorized in comparison to the number of products filed. The risk/benefit ratio of products on the market is also subject to continuous monitoring by health authorities after their authorization. The delayed discovery of problems not identified at the research and development stage can lead at any time to marketing restrictions, suspension of the marketing or withdrawal of products from the market, and to an increased risk of litigation.

Therefore, the authorization process is long and expensive; it can take many years and is not always predictable and likely to continuously evolve. Insofar as new legal or regulatory provisions may be adopted, an increase in the requirements and associated costs for obtaining and maintaining product marketing authorization would limit the targeted indications for a product that a product targets or the economic value of the product. As an inventor, the growth prospects for the pharmaceutical industry, and us, could be reduced. If we do not complete, or if we terminate early, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate revenue will be delayed. The occurrence of one or more of these risks could have a material adverse effect on our business, financial position, income and growth.

We are subject to healthcare laws and regulations which may require substantial compliance efforts, which may expose us to criminal sanctions, civil and administrative penalties, contractual damages, reputational harm, diminished profits and future earnings, among other penalties.

Healthcare providers, including physicians, and others will play a primary role in the prescription of our products, if approved. Our arrangements with such persons and third-party payors for the sale of our products in general business operations will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we may market, sell and distribute our drugs, if we obtain marketing approval. Restrictions under applicable 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 from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or to reward either the referral of an individual for, or the purchase or lease, order or recommendation for, goods, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute in order to have committed a violation;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws such as the False Claims Act ("FCA"), which impose criminal and civil penalties, including those for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly or recklessly presenting, or causing to be presented, claims for payment that are false or fraudulent to the federal government, or causing a statement to avoid, decrease, or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with alleged off-label promotion of drugs, purportedly concealing price concessions in their contracts with the government, submitting false information to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill for the product. In addition, the government may assert that a claim for payment is false if it is for services resulting from a violation of the federal Anti-Kickback Statute constitute a claim for purposes of the FCA;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that impose criminal and civil liabilities for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit plan, or knowingly and willfully falsifying, concealing or covering up a material fact or making any false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute,

entity does not need to have actual knowledge of the healthcare fraud statute implementing HIPAA or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH") and its implementing regulations, which impose certain requirements on covered entities and their business associates, as well as their covered subcontractors, including minimum standards, with respect to safeguarding the privacy, security and transmission of individual health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate commercial activities and activities that potentially harm consumers;
- U.S. federal transparency requirements under the Physician Payments Sunshine Act, and the Affordable Care Act ("ACA"), that require applicable manufacturers of covered drugs, biologics and medical supplies for which payment is available under Medicare, Medicaid, and Children's Health Insurance Program, with specific exceptions, to track and annually report certain Medicare Part B ("CMS") payments and other transfers of value provided to certain other healthcare providers (such as physicians, assistants and nurse practitioners, hospitals, and require certain manufacturers and group purchasing organizations to disclose 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 Medicare, Medicaid, and state marketing and/or transparency laws applicable to manufacturers that have a scope of sales or distribution greater than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant guidance promulgated by the federal government and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in scope and may not have the same effect as HIPAA, thus complicating compliance efforts.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It cannot be excluded that governmental authorities will conduct investigations if our practices do not comply with current or future statutes, regulations or case law involving applicable federal or other healthcare laws and regulations. If our operations were found to be in violation of applicable federal or other governmental regulations that may apply to us, we may be subject to significant civil, criminal, administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from Medicare, Medicaid, and other healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, and future earnings and curtailment of our operations, any of which could substantially disrupt our business. 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 criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs. We may incur significant costs achieving and maintaining compliance with applicable federal and state privacy, security, and fraud laws. Any action against us for violation of applicable laws, if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business.

Current and future health reform measures could adversely affect our business operations.

In the United States and some foreign jurisdictions there have been, and we expect there will be, several legislative and regulatory changes and proposed reforms of the healthcare system to improve efficiency, quality, and expand access to care. For example, in March 2010, President Obama signed the ACA, which substantially changed the way healthcare is financed by both governmental and private insurers and is expected to significantly impact the United States pharmaceutical industry.

There have been judicial, congressional and executive branch challenges to certain aspects of the ACA. For example, on June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds. Moreover, there have been a number of health reform initiatives by the Biden administration to implement the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, a new law, which among other things, extends enhanced subsidies for individuals purchasing health insurance through 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 for covered drugs. It is unclear how other healthcare reform measures will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, led to aggregate reductions in Medicare payments to providers. These reductions went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect until 2032, unless Congressional action is taken.

Additionally, there have been several recent U.S. presidential executive orders, congressional proposed and enacted legislation at the federal and state levels designed to, among other things, increase transparency to drug pricing, review the relationship between pricing and manufacturer patient access, reduce the cost of drugs under Medicare, and reform government reimbursement methodologies for covered drugs. For example, on March 11, 2023, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price. On August 16, 2024, the IRA, among other things, (1) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain single-source drugs and biologics covered under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, (2) permits HHS to implement many of these provisions through guidance, as opposed to regulation, and (3) requires HHS to take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to litigation. It is currently unclear how the IRA will be implemented but it is expected to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's executive order, on February 14, 2023, HHS released a report outlining three new models for the Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to reduce costs, promote accessibility and improve quality of care. It is unclear whether the models will

healthcare reform measures that may be adopted in the future, may result in less rigorous coverage criteria and in additional downward pressure on the price that we receive for our product. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. The implementation of cost containment measures or other reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drug candidates or additional pricing pressures.

At the state level, legislatures have increasingly passed legislation and implemented regulations to control pharmaceutical and biological product pricing, including price or patient reimbursement discounts, restrictions on certain product access and marketing cost disclosure and transparency, some cases, designed to encourage importation from other countries and bulk purchasing. For example, on May 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, which drugs will be chosen, and whether it will be subject to legal challenges in the United States. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approvals, when implemented, may result in lower drug prices for products covered by those programs. If such reforms intended to curb healthcare costs are adopted, or if we experience negative publicity related to the pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we receive for our products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our drug candidates may be negatively impacted.

We expect that other healthcare reform measures that may be adopted in the future, may result in less rigorous coverage criteria and in additional downward pressure on the price that we receive for our product. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. The implementation of cost containment measures or other reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drug candidates.

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

We are subject to other laws and regulations governing our international operations, including those administered by the governments of the United States, and authorities in the European Union and other countries, including applicable export control regulations, economic sanctions on countries and persons, customs and trade regulations, currency exchange regulations, collectively referred to as the trade control laws.

We are also subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, as amended ("FCPA"), which prohibits any U.S. individual or business from paying, offering, or attempting to pay or offering of anything of value, directly or indirectly, to any foreign official, political party or official, or attempting to influence any act or decision of the foreign entity in order to assist the individual or entity in obtaining or retaining business, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, including the French anti-corruption laws:

- Article 433-1 of the French Criminal Code (bribery of domestic public officials);
- Article 433-2 of the French Criminal Code (influence peddling involving domestic public officials);
- Article 434-9 of the French Criminal Code (bribery of domestic judicial staff);
- Article 434-9-1 of the French Criminal Code (influence peddling involving domestic judicial staff);
- Articles 435-1 and 435-3 of the French Criminal Code (bribery of foreign or international public officials);
- Articles 435-7 and 435-9 of the French Criminal Code (bribery of foreign or international judicial staff);
- Articles 435-2, 435-4, 435-8 and 435-10 of the French Criminal Code (active and passive influence peddling involving foreign or international public officials and foreign or international judicial staff);
- Articles 445-1 and 445-2 of the French Criminal Code (bribery of private individuals);
- French Law No. 2016-1691 of December 9, 2016 on Transparency, the Fight Against Corruption and the Modernization of the Economy (Sapin 2 Law), which provides for numerous new obligations for large companies such as the obligation to draw up and adopt a code of conduct defining the different types of behavior to be proscribed as being likely to constitute corruption or influence peddling, to set up an internal warning system designed to detect and prevent corruption, to collect reports from employees relating to the existence of conduct or situations likely to constitute a breach of the company's code of conduct, to set up accounting control procedures, whether internal or external, designed to ensure that the books, registers and accounts are not used to conceal a breach of the company's code of conduct or a system for monitoring and evaluating compliance with the code of conduct.

The FCPA also obligates companies whose securities are listed in the United States to comply with provisions requiring the company to maintain books and records that accurately and fairly reflect the corporation's business, including international subsidiaries, and to devise and maintain an adequate system of accounting controls for international operations. Activities that violate the FCPA, even if they occur outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, or other penalties. The scope and enforcement of these laws is uncertain and subject to rapid change. Enforcement bodies have increased their scrutiny of interactions between healthcare companies and government providers. This has resulted in an increase in the number of investigations, prosecutions, and settlements in the healthcare industry. Responding to investigations can be both resource and time consuming and divert management's attention from the business. Any such investigation or settlement could increase our costs and otherwise have a material adverse effect on our business, outlook, financial position, income, and the price of our securities.

The FCPA and other anti-corruption laws are interpreted broadly and prohibit companies and their agents, contractors, and other collaborators from authorizing, promising, offering, or providing anything of value, directly or indirectly, to recipients in the public or private sector, or to third parties to sell our products outside the United States, to conduct clinical trials and

permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect relationships with government 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 and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities.

There is no complete assurance that we will be effective in ensuring our compliance with anti-corruption laws, including the FCPA, the French anti-corruption laws or other legal requirements and trade control laws. If we are not in compliance with the FCPA, the French anti-corruption laws and trade control laws, we may be subject to criminal and civil penalties, disgorgement and other remedial measures and legal expenses, which could have an adverse impact on our business, financial results of operations and liquidity. Likewise, any investigation of any potential violations of anti-corruption laws, other anti-corruption laws or trade control laws by U.S. or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition.

In addition, changes in our products and drug candidates or changes in applicable export regulations may create delays in the introduction or provision of our products and drug candidates in certain jurisdictions, prevent others from using our products and drug candidates or, in some cases, limit the import of our products and drug candidates to certain countries, governments or persons altogether. Such changes on our ability to export or provide our products and drug candidates could adversely affect our business, financial results of operations and liquidity.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of our drug candidates. Side effects of, or manufacturing defects in, drugs that we develop could result in the deterioration of a patient's condition, injury or even death. For example, our liability could increase if patients participating in the clinical trials in the context of the development of the therapeutic candidates experience unexpected side effects resulting from the administration of these drugs. In addition, we could be held liable for undetected side-effects caused by the interaction of our drugs with other drugs following the commercialization of a drug candidate to the market. Once a product is approved for sale and commercialized, the likelihood of lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory agencies, biopharmaceutical companies and any other third party using or marketing our drugs. These actions could result in claims resulting from actions by our partners, licensees and subcontractors, over which we have no control. These lawsuits may divert our management from pursuing our business strategy and may be costly. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities that could forgo further commercialization of the affected products and may suffer damage to our reputation.

We could be exposed to the risk of liability claims during the clinical development of our products. We could be held liable for particular product liability claims, related to the manufacture of therapeutic products and the use of these products in animals. We could be held liable by patients participating in clinical trials as part of the development of therapeutic products tested for unexpected side effects resulting from the administration of these products.

We could also be held liable during the commercialization phase of our products. Criminal or civil lawsuits could be filed or brought against us by patients, regulatory agencies, pharmaceutical companies and other third parties using or marketing our products. These actions may include claims arising from the use of our products, partners, licensees or subcontractors, over which we have little or no control. Physicians are required to comply with any warnings that identify known potential adverse effects and patients who should be monitored during the use of our drug candidates.

We maintain product liability insurance coverage for our clinical trials at levels which we believe are appropriate for our clinical trials. Nevertheless, we cannot guarantee that the insurance policy will provide contractually limited indemnification, if applicable, granted by our subcontractors will be sufficient to cover all claims that could be brought against us or losses we may suffer.

If our liability, or that of our partners, licensees and subcontractors, was thereby acted upon, and our partners, licensees and subcontractors were unable to obtain and maintain appropriate insurance coverage at an acceptable cost or protect ourselves in any way against liability claims, this would seriously impact our commercialization of our products and, more generally, have a material adverse effect on our business, financial position and outlook for growth.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived non-compliance with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we (and others on our behalf) collect, receive, store, use, transfer, archive, disclose, make accessible, protect, secure, dispose of, transmit, and share personal data and other sensitive information, including proprietary and confidential business information, intellectual property, sensitive third-party data, personal data/personal information, business information and financial information (collectively, sensitive data).

Our data processing activities subjects us to numerous data privacy and security obligations under applicable laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy laws, including data breach notification laws, personal data privacy laws, consumer protection of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the Consumer Privacy Act of 2018 (“CCPA”) requires businesses to provide specific disclosures in response to requests of California residents to exercise certain privacy rights. The CCPA provides for civil damages of up to \$7,500 per violation and allows private litigants affected by certain data breaches to seek damages. In addition, the California Privacy Rights Act of 2020 (“CPRA”), which becomes operative in January 2023, will expand the CCPA’s requirements, including applying to personal information of business partners and employees and establishing a new regulatory agency to implement and enforce the law.

Other states, such as Virginia, Colorado, Utah and Connecticut have also passed comprehensive data privacy and similar laws are being considered in several other states, as well as at the federal level. These developments may further complicate compliance efforts and may increase legal risk and compliance costs, and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, among other laws, the European Union’s Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as amended (“EU GDPR”), the United Kingdom’s GDPR (“UK GDPR”), Brazil’s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or “LGPD”) (Law No. 13,709/2018), Canada’s Personal Information Protection and Electronic Documents Act (“PIPEDA”), and China’s Personal Information Protection Law (“PIPL”) impose strict requirements for processing personal data.

The collection and use of personal health data in the European Union is governed by the EU GDPR. Under the EU GDPR, companies may face temporary or definitive bans on data processing and corrective actions; fines of up to €20 million or 4% of annual global revenue, whichever is greater; and litigation related to processing of personal data brought by classes of data subjects or consumer organizations authorized at law to represent their interests. We also engage in clinical trials in various jurisdictions.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other third party countries in which local data privacy laws are less stringent due to cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized and restricting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom (UK) have significantly restricted the transfer of personal data to countries whose privacy laws it believes are not adequate. These jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the UK to the United States in compliance with law, such as the Trans-Atlantic Data Privacy Framework, and UK’s standard contractual clauses, being specified that these mechanisms of standard contracts are subject to legal challenges, and there is no assurance that we can satisfy or rely on these mechanisms to transfer personal data to the United States or other third party countries. If there is no legal mechanism to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if a legally-compliant transfer are too onerous, we could face significant adverse consequences, including interruption or degradation of our operations, the need to relocate part of or all of our business activities to other jurisdictions at significant expense, increased exposure to regulatory action and penalties, the inability to transfer data and work with partners, vendors and other third parties, and the inability to transfer personal data necessary to operate our business. Such limitations have prevented companies from transferring personal data out of Europe for allegedly violating cross-border data transfer limitations.

In addition to data privacy and security laws, we may be contractually subject to industry standards and industry groups and may become subject to such obligations in the future. Depending upon the terms of our contracts, we may be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish and may publish by policy, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If our policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or otherwise inconsistent with our practices, we may be subject to investigation, enforcement actions by regulators, or other consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly complex, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with such obligations requires us to devote significant resources and may necessitate changes to our security technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

obligations requires us to devote significant resources and may necessitate changes to our security technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely to comply with such obligations, which could negatively impact our business operations. If we or the third parties which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government investigations (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class actions); additional reporting requirements and/or oversight; bans on processing personal data; and other restrictions on the use of personal data. Any of these events could have a material adverse effect on our reputation, our financial condition, including but not limited to: loss of customers; inability to process personal data in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to address any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to Ownership of Our ADSs and Our Status as a Non-U.S. Company with Foreign Private Issuer Status

There has been no market for our ADSs prior to our initial public offering of our ADSs in the United States, and an active and liquid market for our securities may fail to develop, which could harm the market for our ADSs.

Although our ordinary shares have been traded on Euronext Paris since mid-2015, prior to our initial public offering of our ADSs in the United States in October 2023 there was no public market on a U.S. exchange for our ADSs.

exchange for our ADSSs. An active trading market for our ADSSs may never develop or be sustained. If an active trading market for our ADSSs, investors may not be able to sell their ADSSs at a price at the time that they would like to sell.

If we do not achieve our projected development and commercialization goals in the timeframes we 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 regulatory and other product development objectives. These milestones may include our expected commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, the achievement of regulatory approvals, the initiation of commercialization objectives. From time to time, we may publicly announce the expected timing of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, the submission of regulatory filings, the achievement of regulatory approvals, or a commercial launch of a product. The achievement of many of these milestones is outside of our control. All of these milestones are based on a variety of assumptions which may cause the 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, including the extent of scheduling conflicts with participating clinicians 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 agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds and materials used in the manufacture of our drug candidates;
- the efforts of our collaborators with respect to the commercialization of our products;
- the securing of, costs related to, and timing issues associated with, product manufacturing, sales and marketing activities.

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

We may be a "passive foreign investment company" for U.S. federal income tax purposes, which could have adverse U.S. federal income tax consequences to U.S. investors.

Generally, if, for any taxable year, at least 75% of our gross income is passive income (as defined in U.S. federal income tax law) and at least 50% of the value of our assets (based on an average of the quarterly values of the assets) is attributable to assets that produce passive income or are held for the production of passive income, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes, among other things, dividends, interest, and capital gains from the sale or exchange of investment property and rents or royalties other than rents or royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Cash and cash equivalents are generally treated as passive assets. Goodwill is treated as an active asset to the extent associated with activities that produce active income. For purposes of the PFIC rules, a non-U.S. corporation is treated as a PFIC, indirectly, at least 25% by value of the equity interests of another corporation or partnership that is a PFIC, if the non-U.S. corporation or partnership owns, directly or indirectly, a proportionate share of the assets of the other corporation or partnership, and received directly or indirectly, more than 25% of the income of the other corporation or partnership. Equity interests of less than 25% by value of the non-U.S. corporation or partnership are treated as passive assets, regardless of the nature of the other corporation or partnership's business.

If we are a PFIC for any taxable year in which a U.S. Holder (as defined in "Material United States Federal Income and French Tax Considerations—Material U.S. Federal Income Tax Considerations for U.S. Holders") is a U.S. Holder, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder, including, but not limited to, the imposition of a 30% U.S. federal income tax on the U.S. Holder's tax liability on disposition gains and certain "excess distributions" and additional reporting requirements. For more information regarding the adverse U.S. federal income tax consequences that may apply to U.S. Holders, see "Material United States Federal Income and French Tax Considerations—Material U.S. Federal Income Tax Considerations for U.S. Holders—Passive Foreign Investment Company Rules."

Based on our analysis of our financial statements, activities and relevant market and share price, we do not believe that we were a PFIC for the taxable year ended December 31, 2023. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to interpretation. Whether we are a PFIC for any taxable year will depend on the composition of our assets, the composition, nature and value of our assets from time to time (including the value of our goodwill, which could fluctuate considerably). We cannot generate product revenues and therefore we may be a PFIC for any taxable year in which we do not generate sufficient amounts of non-passive income to offset our passive income. As a result, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year and our U.S. Holders should consult with respect to our PFIC status for any prior, current or future taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or the IRS, will not conclude that the IRS would not successfully challenge our position. Each U.S. holder should consult its tax advisor regarding these issues and any available elections to mitigate such tax consequences.

If a United States person is treated as owning at least 10% of the value or voting power of our ADSSs, such person may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly, or constructively) at least 10% of the aggregate value or voting power of our ADSSs, such person may be treated as a "United States person" for U.S. federal income tax purposes with respect to each "controlled foreign corporation" in our group (if any), which may subject such person to adverse U.S. federal income tax consequences. Our group currently includes one U.S. subsidiary corporation and one non-U.S. subsidiary corporation. Under current law our current non-U.S. subsidiary and any future newly formed or acquired non-U.S. subsidiary that are treated as corporations for U.S. federal income tax purposes will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States person who is a shareholder of a controlled foreign corporation generally is required to report annually and include in its U.S. federal income tax return its pro rata share of "Subpart F income," "global intangible low-taxed income," and investments in controlled foreign corporations, regardless of whether we make any distributions. An individual

States shareholder with respect to a controlled foreign corporation generally would not be allowed deductions or foreign tax credits that would be available to a United States shareholder that complies with these reporting obligations. Failure to comply with these reporting obligations may subject a United States shareholder to penalties and may prevent the statute of limitations with respect to such shareholder's U.S. income tax for the year for which reporting was due from starting. We cannot provide any assurances that investors in determining whether we are treated as a controlled foreign corporation or whether ADSs is treated as a United States shareholder with respect to any such controlled foreign corporation. Any United States shareholders information that may be necessary to comply with the aforementioned tax paying obligations. The United States Internal Revenue Service provided limited guidance to investors may rely on publicly available information to comply with their reporting and tax obligations with respect to foreign-controlled CFCs. Each U.S. holder of our ADSs should consult its advisors regarding the application of these rules to an investment in our 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.

We are a French company with limited liability. Our corporate affairs are governed by our laws governing companies incorporated in France. The rights of shareholders and the responsibilities of our Board 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 is required to consider the interests of our company, its shareholders, its employees and other stakeholders, as well as the interests of our shareholders and/or creditors. It is possible that some of these parties will have interests that conflict with the interests of our shareholders. In addition to, your interests as a shareholder or holder of ADSs.

You may face difficulties protecting your interests, and your ability to protect your rights in French courts may be limited because we are incorporated under the laws of France, all of our assets are located in the European Union and a majority of our directors and executive officers reside outside the United States.

We are constituted under the laws of France. A majority of our officers and directors reside in the United States. In addition, a substantial portion of their assets and our assets are located in the United States. As a result, you may have difficulty serving legal process within the United States upon us or our officers and directors. You may also have difficulty enforcing, both in and outside of the United States, judgments of U.S. courts against us or these persons in any action, including actions based upon the civil liability provisions of U.S. Federal or state securities laws. Furthermore, there is substantial doubt as to the enforceability of judgments of U.S. courts against us or against any of our directors and officers who are not residents of the United States, in actions for enforcement of judgments of U.S. courts, of liabilities based solely upon the civil liability provisions of the U.S. federal securities laws. In addition, shareholders in French corporations may not have the same right to bring a shareholder derivative action in U.S. federal courts.

As a result, our public shareholders may have more difficulty in protecting their interests against us, our management, our directors or our major shareholders than would shareholders of a company incorporated in a jurisdiction in the United States.

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and volatility of our securities.

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

Our by-laws and French corporate law contain provisions that may delay or discourage a takeover of our company.

Provisions contained in our by-laws and French corporate law could make it more difficult for an acquirer to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions in our by-laws and French corporate law, which could make it more difficult for shareholders to initiate or pursue corporate actions. These provisions include the following:

- under French law, the owner of 90% of the share capital or voting rights of a publicly traded company in a regulated market in a Member State of the European Union or in a state party to the Treaty of Rome, 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 a non-resident of France may have to file a declaration for statistical purposes with the Bank of France within 20 working days following the date of certain direct foreign investments including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15 million that lead to the acquisition of at least 10% of our

voting rights or cross such 10% threshold. See “Limitations Affecting Shareholders Company”;

- under French law, certain foreign investments in companies incorporated under French law subject to the prior authorization from the French Minister of the Economy, where a target’s business and activity relate to a strategic sector, such as energy, transport, telecommunications, research and development in biotechnologies, activities relating to etc.;
- a merger (i.e., in a French law context, a share for share exchange following which would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union requires the approval of our Board 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 requires the approval of 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the approval of the participating shareholder;
- our shareholders have granted and may grant in the future our Board broad authorization to issue our share capital or to issue additional ordinary shares or other securities, such as preferred shares, to the public or qualified investors, including as a possible defense for our company in connection with a tender offer for our shares;
- our shareholders have preferential subscription rights on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be exercised at an extraordinary general meeting by a two-thirds majority vote of our shareholders or by a two-thirds majority of the votes held by each shareholder;
- our Board has the right to appoint directors to fill a vacancy created by the resignation of a director, subject to the approval by the shareholders of such appointment at the next general meeting, which prevents shareholders from having the sole right to fill vacancies on the Board;
- our Board can be convened by our chairman, including upon request from our Chief Executive Officer or the positions of Chief Executive Officer and Chairman of the Board by the same person, 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 meetings can only be regularly held if at least half of the directors attend the meeting, which may be held by way of videoconference or teleconference enabling the directors’ identification and effective participation in the Board’s decisions;
- our shares are registered or bearer, if the legislation so permits, according to the applicable law;
- approval of at least a majority of the votes held by shareholders present, represented by proxy or voting by mail at the relevant ordinary shareholders’ general meeting is required to amend the by-laws with or without cause;
- advance notice is required for nominations to the Board or for proposing matters to be discussed at a shareholders’ meeting, except that a vote to remove and replace a director can be proposed at a shareholders’ meeting without notice;
- our by-laws can be changed in accordance with applicable French laws and regulations;
- the crossing of certain thresholds must be disclosed and can impose certain obligations on the company (including filing a mandatory public tender offer);
- transfers of shares shall comply with applicable insider trading rules and regulations, including those with the EU Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of our by-laws relating to the number of directors and the removal of a director from office, may only be modified by a resolution adopted by a two-thirds majority of the votes of our shareholders present, represented by a proxy or voting by mail at the relevant meeting.

Existing and potential investors in our ordinary shares or ADSs may have to request the prior authorization of the French Ministry of Economy prior to acquiring an interest in our ordinary shares or ADSs.

Under French law, direct and indirect acquisition of control of all or part of a branch of activity or investments of more than 10% in companies like ours whose shares are admitted to trading on a regulated market, by foreign individuals or entities (except, in the last case, EU/EEA investors), is deemed to be a strategic investment and is subject to prior authorization of the French Ministry of Economy. Articles L. 151-1 et seq. and R. 151-1 et seq. of the French Monetary and Financial Code. Investments in research and development essential to the protection of public health fall within the scope of this requirement. To protect strategic assets, the ministry may condition its authorization upon the commitment of the investor to structural and behavioral remedies that are necessary for the maintenance of strategic activities and intellectual property in France.

If an investment requiring the prior authorization of the French Minister of Economy is required, such authorization having been granted, the French Minister of Economy might order the relevant investor to (i) submit a request for authorization, (ii) have the situation prior to the completion of the investment under its own expense or (iii) amend the investment. Non-compliance with the authorization requirements may expose the relevant investor to a criminal fine which cannot exceed the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company, or €5 million (for an entity) or €1 million (for an individual). The French Minister of Economy may also take precautionary measures it deems necessary to protect strategic sovereign assets, including the prohibition or limitation of the distribution of dividends and remuneration attributable to the ownership by the investor should have been subject to prior authorization.

regulated in France. The French companies whose shares are admitted to trading on a regulated market in France are exempt from the authorization request provided for in Article R. 151-5 of the Monetary and Financial Code, provided that the investment project has been the subject of a prior simplified notification to the French Economy, and the French Minister of Economy did not request to follow the standard notification procedure. The transaction can proceed within ten working days following notification.

Failure to comply with such measures could result in significant consequences in the context of a takeover. Such measures could also delay or discourage a takeover or more broadly a foreign investment. We cannot predict whether these measures will result in a lower or more volatile market price of our ADSs.

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

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

Purchasers of ADSs may instruct the depositary of their ADSs to vote the ordinary shares underlying the ADSs. Otherwise, purchasers of ADSs will not be able to exercise voting rights unless they withdraw the ordinary shares underlying the ADSs they hold. However, a holder of ADSs may not know about the meeting or solicitation of consent or proxy until we ask for a holder of ADSs' instructions, the depositary 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 instruct the depositary to vote his or her ordinary shares or to withdraw his or her ADSs or that he or she can vote them. If the depositary does not receive timely voting instructions from a holder of ADSs, we will give a proxy to a person designated by us to vote the ordinary shares underlying his or her ADSs. The depositary and its agents are not responsible for failing to carry out voting instructions or for not distributing voting instructions. This means that a holder of ADSs may not be able to exercise his or her voting rights if there may be nothing he or she can do if the ordinary shares underlying his or her ADSs are not distributed or if the rights to lapse, in which case you will receive no value for these rights.

Purchasers of ADSs are not holders of our ordinary shares.

A holder of ADSs will not be treated as one of our shareholders and will not have direct ownership of the ordinary shares. French law governs our shareholder rights. The depositary will be the holder of the ordinary shares underlying the ADSs. Purchasers of ADSs will have ADS holder rights. The deposit agreement governs the rights and obligations of the depositary.

depositary and purchasers of ADSs, as ADS holders, and all other persons directly and indirectly holding ADSs, out ADS holder rights, as well as the rights and obligations of the depositary.

A double voting right is attached to each registered ordinary share (except treasury shares) and is exercisable by the holder of the same share for at least two years. However, the ordinary shares underlying the ADSs will not be entitled to double voting rights as the depositary will hold the ordinary shares underlying the ADSs.

The right as a holder of ADSs to participate in any future preferential subscription rights or dividends in shares may be limited, which may cause dilution to the holdings of purchasers of ADSs.

According to French law, if we issue additional securities for cash, current shareholders of our company will be entitled to subscription rights for these securities unless they waive those rights at an extraordinary general meeting of our shareholders by a two-thirds majority vote or individually by each shareholder. However, ADS holders will not be entitled to exercise or sell such rights unless we register the rights and the securities under the Securities Act or an exemption from the registration requirements is available. The deposit agreement provides that the depositary will not make rights available to purchasers of ADSs unless the rights are registered under the Securities Act. 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 right to receive dividends in either cash or shares, under the deposit agreement the depositary may receive dividends from us that extending the offer to holders of ADSs does not require registration under the Securities Act before making the option available to holders of ADSs. We are under no obligation to register the rights with the SEC or to file a registration statement with respect to any such rights or securities or to endeavor to cause the rights to be declared effective. Moreover, we may not be able to establish an exemption from the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offering or to receive dividends in shares and may experience dilution in their holdings. In addition, if the rights are not exercised or not distributed or if the sale is not lawful or reasonable, the rights to lapse, in which case you will receive no value for these rights.

Purchasers of ADSs may be subject to limitations on the withdrawal of the underlying ordinary shares.

Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may occur because the depositary has closed its transfer books or we have closed our transfer books, the withdrawal of the ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on the 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 provide for the withdrawal of the ordinary shares in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of the ordinary shares or other deposited securities.

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

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

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the courts.

Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. We cannot guarantee that a court in the City of New York will enforce a contractual pre-dispute jury trial waiver provision, and we cannot guarantee that a party knowingly, intelligently and voluntarily waived the right to a jury trial. We cannot guarantee that you will be able to bring a claim against us or the depository with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depository with respect to the deposit agreement or the ADSs, including claims under the laws of the State of New York, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claim, which may have the effect of limiting and discouraging lawsuits against us and the depository. If you bring a claim against either or both of us and the depository under the deposit agreement, it may be heard

justice of the applicable trial court, which would be conducted according to different civil procedure rules than a trial by jury would have, including results that could be less favorable to you than a trial by jury. In any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, and you are not able to bring a claim against us or the depository with a jury trial. No condition, stipulation or provision in the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depository of the right to a jury trial in compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws that would be applicable to a U.S. public company. This may limit the information available to holders of ADSs.

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, including the solicitation of proxies, consents or authorizations of action by shareholders of companies 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 rules under 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 obligations, we are not required to file financial reports on an annual and semi-annual basis, we will not be required to file financial statements with the SEC as frequently or as promptly as U.S. public companies are required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there will be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

As a foreign private issuer, we are permitted, and we expect, to follow certain home country corporate governance practices 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 Market.

As a foreign private issuer listed on the Nasdaq Global Market, we are subject to Nasdaq's corporate governance standards. However, Nasdaq rules provide that foreign private issuers are permitted to follow their home country corporate governance practices in lieu of Nasdaq's corporate governance standards, with the exception that as long as notification is provided to Nasdaq of the intention to take advantage of such exemptions, we must rely on exemptions for foreign private issuers and follow French corporate governance practices. Certain corporate governance standards, to the extent possible. Certain corporate governance practices of our home country, may differ significantly from Nasdaq corporate governance standards. For example, under French law, neither the corporate laws of France nor our by-laws require a majority of our directors to be independent, and we can include non-independent directors as members of our remuneration committee, and our 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 hold a general meeting for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding shares of the stock. Consistent with French law, our by-laws provide that a quorum requires the presence of at least (i) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting, or (ii) 25% of the shares entitled to vote in the case of an extraordinary shareholders' general meeting where shareholders are voting on a capital increase, reserves, profits or share premium. If a quorum is not present, the meeting is adjourned. There is no limit on the number of times a meeting may be reconvened, but the reconvened meeting may consider only those matters that were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, a quorum is required is 20% of the shares entitled to vote, except where the reconvened meeting is considered to be an ordinary general meeting. For these matters, no quorum is required for the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, the meeting may be adjourned for a maximum of two months.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act regarding audit committee composition and responsibilities. Under French law, the audit committee may only recommend the appointment and appointment of our statutory auditors, in particular, must be decided by the shareholders. Therefore, our shareholders may be afforded less protection than they otherwise would have under U.S. corporate governance standards applicable to U.S. domestic issuers. For an overview of our corporate governance practices, see "Part II—Item 16G—Corporate Governance."

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are “emerging growth companies”, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”), and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and shareholder approval of certain corporate payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of complying with new or revised accounting standards, the requirements for our compliance as a private company will be the same as those that will apply to public companies that are emerging growth companies.

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

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer are significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we are required to file periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We are required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, 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 cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described in the exemptions from procedural requirements related to the solicitation of proxies.

We may not be successful in obtaining or maintaining necessary rights to product components and our development pipeline through acquisitions and in-licenses.

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Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical development under written agreements with these institutions. In certain cases, these institutions have the option to negotiate a license to any of the institution's rights in technology resulting from our research. If we hold such an option, we may be unable to negotiate a license from the institution within the time period or under terms that are acceptable to us. If we are unable to do so, the institution may offer the rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive market that may be more established or have greater resources than we do and may also be pursuing strategies to acquire third-party intellectual property rights that we may consider necessary or attractive for our drug candidates. More established companies may have a competitive advantage over us due to their greater resources and greater clinical development and commercialization capabilities. In addition, due to our limited resources, we may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the additional drug candidates that we may seek to develop or market. If we are unable to obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights to our current drug candidates, our ability to develop and commercialize our drug candidates may be materially and adversely affected.

The market price of our equity securities may be volatile, and purchasers of our ADSs could incur losses.

The market price for our ADSs may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often resulted in significant fluctuations in the market price of our ADSs. As a result of this volatility, investors may purchase ADSs at or above the price originally paid for the security. The market price for our ADSs may be influenced by many factors, 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, ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community 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 ours;
- share price and volume fluctuations attributable to inconsistent trading volume levels;
- additions or departures of key management or scientific personnel;
- lawsuits threatened or filed against us, disputes or other developments related to our intellectual property, including patents, litigation matters, and our ability to obtain patent protection;
- changes to coverage policies or reimbursement levels by commercial third-party payors, government payors and any announcements relating to coverage policies or reimbursement rates;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders;
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs and may otherwise negatively affect the liquidity of the trading market for our ADSs.

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

The trading market for our ADSs depends in part on the research and reports that securities analysts publish about us or our business. If no or few securities or industry analysts cover us, the price for our ADSs would be negatively impacted. If one or more of the analysts who covers us publishes incorrect or unfavorable research about our business, the price of our ADSs could decline. If one or more of these analysts ceases coverage of our company or fails to publish research regularly, or downgrades our securities, demand for our ADSs could decrease, which could cause the price of our ADSs or their trading volume to decline.

The requirements of being a U.S. public company may strain our resources and divert management's attention from our business.

We are required to comply with various corporate governance and financial reporting requirements under the Sarbanes-Oxley Act, the Exchange Act, and the rules and regulations adopted by the SEC and the SEC's Accounting Oversight Board. Further, compliance with various regulatory reporting requirements requires significant commitments of time from our management and our directors, which reduces the time available for their other responsibilities. Our failure to track and comply with the various rules may harm our reputation, ability to obtain the necessary certifications to financial statements, lead to enforcement actions, and could adversely affect the value of our ordinary shares or ADSs.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company if the market price of its securities declines. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. If we were to experience a significant decline in our share price, which could be insufficiently covered by insurance, and a diversion of management's resources, which could harm our business.

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

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our operations and growth. You are not likely to receive any dividends on your ADSs for the foreseeable future and the value of your ADSs will depend upon any future appreciation in its value. Consequently, investors may not realize a return on their holdings of ADSs after price appreciation, which may never occur, as the only way to realize a return on their investment. There is no guarantee that the ADSs will appreciate in value or even that the ADSs will be sold. Investors seeking cash dividends should not purchase ADSs. Furthermore, certain of our debt instruments restrict the payment of dividends or require certain financial covenants. See "Part I—Item 8.A—Dividend Policy."

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 the accounting standards applicable in France. In addition, payment of dividends may subject us to additional