

**D. Risk Factors.**

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

**Risks Related to the Development and Commercialization of Lumoxiti and Our Product Candidates**

***Biopharmaceutical development involves a high degree of uncertainty and most of our product candidates are in early stages of development, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.***

We are a biopharmaceutical company with one commercial product, Lumoxiti, which we acquired in October 2018 from AstraZeneca and which we have not yet begun to commercialize on our own. The rest of our portfolio consists of product candidates, some of which we are co-developing, in the early stages of clinical development and preclinical programs. Although we have generated limited revenue from product sales from our only product approved by regulatory authorities, Lumoxiti, we do not expect to have any other significant product sales or related revenue unless our additional product candidates or any future product candidates are approved for sale and successfully commercialized. Accordingly, our ability to predict our future operating results or business prospects is more limited than if we had a longer history of approved products on the market or later-stage clinical product candidates. Although Lumoxiti has been approved by the U.S. Food and Drug Administration, or the FDA, it has only been marketed for a short period of time and, to date, AstraZeneca has been responsible for its commercialization.

A key element of our strategy is to mature and expand our portfolio of proprietary and partnered product candidates to address unmet medical needs in immuno-oncology. Although our research and development efforts to date have resulted in a pipeline of product candidates, all of our product candidates require additional development, regulatory review and approvals, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be commercialized and before we can generate any revenue from product sales or royalties. If we or our collaboration partners are unable to successfully develop and market these product candidates, our business, prospects, financial condition and results of operations may be adversely affected.

Aside from our acquisition of Lumoxiti, our operations to date have been limited to developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates, including monalizumab, through our partnership with AstraZeneca, lacutamab and avdoralimab, our most advanced product candidates. The success in development of our current and future product candidates by us or our collaborators will depend on many factors, including:

- obtaining positive results in clinical trials including by demonstrating efficacy, safety and durability of effect of such product candidates;
- completing preclinical studies and receiving regulatory approvals or clearance for conducting clinical trials for our preclinical programs;
- receiving and maintaining approvals for commercialization of such product candidates from regulatory authorities;
- manufacturing or overseeing the manufacturing of our product candidates in acceptable quantities and at an acceptable cost;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter, and performing our obligations pursuant to such arrangements;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- avoiding and defending against third-party interference, infringement or other intellectual property claims; and
- maintaining and growing an organization of scientists, medical professionals, marketing, distribution and sales personnel and executives who can develop our product candidates and commercialize any approved products.

In addition, if we are unable to reduce our dependence on Lumoxiti and our current clinical and preclinical product candidates, either by licensing or acquiring new product candidates, developing our other product candidates or discovering new product candidates, we may be similarly adversely affected.

***We will become fully responsible for the commercialization of Lumoxiti by end of 2020 but we are in the process of building our sales, marketing or commercial product distribution organization and have no experience in marketing or managing the manufacturing of products.***

We are a biopharmaceutical company with one commercial product, Lumoxiti, which we recently acquired and have not yet begun to commercialize on our own. Even though we began to transition certain activities relating to the commercialization and manufacturing of Lumoxiti in the United States in the second half of 2019, AstraZeneca is still responsible for most of those aspects. We plan on being fully responsible for its commercialization by end of 2020 and for its manufacturing at a later date. We are in the process of building our sales, marketing or commercial product distribution capabilities and have no experience in managing the manufacturing of or marketing products. Developing our in-house marketing and sales capabilities and infrastructure requires significant expenses, management resources and time. If we are able to achieve this goal, we will compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing, sales and distribution personnel.

If we are unable or decide not to establish or expand internal sales, marketing and commercial distribution capabilities for Lumoxiti or any of the products we may develop, we will likely pursue contractual arrangements for the sale, marketing and distribution of such products. However, there can be no assurance that we will be able to establish or maintain such arrangements, and if we do, we may have little or no control over the sales, marketing and commercial distribution efforts of such third parties. Any revenue we receive will depend upon the efforts of these third parties, and their efforts may not be successful. Our revenue from product sales may be lower than if we had commercialized Lumoxiti or any future product candidates we may develop, if approved, ourselves. We will also face competition in our search for third parties to assist us with the sales, marketing and distribution efforts of Lumoxiti or any of our product candidates that receive regulatory approval.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party partners to successfully commercialize any product in the United States, Europe or elsewhere and, as a result, we may not be able to generate product revenue.

If we are unable to establish sales, marketing and distribution capabilities for Lumoxiti on a timely basis, we may not be successful in commercializing Lumoxiti.

We have a limited sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, including our approved product, Lumoxiti, we must either develop a sales and marketing organization or outsource these functions to third parties. Lumoxiti has only been commercially available for a short period of time and, to date, the responsibilities of commercialization have been handled by AstraZeneca. We plan to use a combination of focused in-house sales and marketing capabilities and third-party collaboration, licensing and distribution arrangements to sell any of our products that receive marketing approval.

The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming, could delay the continued commercialization of Lumoxiti and could delay any other potential product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our product candidates, we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

***The scientific evidence to support the feasibility of developing product candidates is both preliminary and limited.***

Our innovative approach to immuno-oncology aims to activate both the innate and adaptive immune systems against abnormal or cancerous cells and restore the body's ability to disrupt their proliferation, potentially leading to durable responses in patients. This approach is focused on developing checkpoint inhibitors, tumor-targeting antibodies and antibodies that affect the tumor microenvironment, and several of our product candidates rely on novel mechanisms of action for which we have limited scientific evidence and preclinical and clinical data.

We may not ultimately be able to provide the FDA, European Medicines Agency, or EMA, or other regulatory authorities with substantial clinical evidence to support a claim of efficacy and durability of response to enable the applicable regulators to approve our product candidates for any indication. This may occur because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the applicable regulator disagrees with how we interpret the data from these clinical trials or because the applicable regulator does not accept these therapeutic effects as valid endpoints in pivotal clinical trials that are sufficient to grant marketing approval. Additionally, because product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials our collaborators in earlier stages of clinical trials may eventually choose to discontinue later stage trials. For example, following initial promising results assessing the safety and efficacy of our product candidate lirilumab for the treatment of various cancer indications, our collaborator decided not to continue development after receiving Phase II clinical trial data.

In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and it is possible that we will as well. Based upon negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

We will also need to demonstrate that our product candidates are safe and well tolerated. We do not have significant data on possible harmful long-term effects of our product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and efficacy data sufficient to support submission of a marketing application or commercialization of our product candidates is uncertain and is subject to significant risk.

***We intend to develop monalizumab, avdoralimab (IPH5401) and other product candidates in combination with other therapies, which exposes us to additional risks.***

We are currently developing monalizumab and avdoralimab, and may develop other product candidates, in combination with one or more currently approved cancer therapies. Specifically, with AstraZeneca, we are currently evaluating monalizumab in an ongoing open-label Phase Ib/II trial in combination with cetuximab, an epidermal growth factor receptor, or EGFR, inhibitor, and also in a triplet setting with cetuximab and durvalumab, an anti-PD-L1 immune checkpoint inhibitor. AstraZeneca is also currently evaluating monalizumab in ongoing Phase I and II trials in combination with durvalumab. Additionally, we are currently conducting a Phase I/II clinical trial of avdoralimab in combination with durvalumab, initially in patients with select advanced solid tumors. Patients may not be able to tolerate our product candidates in combination with other therapies, and preliminary clinical results indicate that monalizumab, for example, has no meaningful clinical activity as a monotherapy. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other therapies or for indications other than cancer. This could result in our own products, if approved, being removed from the market or being less successful commercially.

We may also evaluate monalizumab, avdoralimab or any other future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell monalizumab, avdoralimab or any other product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve, revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the products or product candidates we choose to evaluate in combination with monalizumab, avdoralimab or any other product candidate we develop, we may be unable to obtain approval of or market monalizumab, avdoralimab or any other such product candidate we develop.

***We and our collaborators rely on third parties to conduct some of our preclinical studies and clinical trials and perform other clinical development tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, it may not be possible to obtain regulatory approval for, or commercialize, our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third parties to conduct clinical trials of our product candidates or product candidates that we have licensed to them. For example, under our license and collaboration agreements with AstraZeneca, AstraZeneca is responsible for a number of clinical trials relating to monalizumab and IPH5201, which are subject to such agreements. In addition, we and our collaborators are responsible for and are supporting several clinical trials that are sponsored by academic or research institutions, known as investigator-sponsored trials. By definition, the financing, design and conduct of an investigator-sponsored trial are the sole responsibility of the sponsor, and we or our collaborators, as applicable, have limited control over these aspects of these clinical trials, or the timing and reporting of the data from these trials. We and our collaborators also depend on independent clinical investigators and Contract Research Organizations, or CROs, to conduct clinical trials. CROs may also assist in the collection and analysis of data. There are a limited number of CROs that have the expertise to run clinical trials of our product candidates. Identifying, qualifying and managing performance of third-party service providers can be difficult and time consuming and can cause delays in our development programs. These investigators and CROs are not our employees and we are not able to control, other than by contract, the amount of resources, including the amount of time, that they devote to our product candidates and clinical trials. If the investigators sponsoring trials of our product candidates, independent investigators participating in clinical trials that we or our collaborators are sponsoring or CROs fail to devote sufficient resources to our clinical trials and development of our product candidates or product candidates we have licensed to others, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we or our collaborators develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated, and we may not be able to obtain adequate remedies for such disclosure or misappropriation. Further, the FDA, EMA and other regulatory authorities require that we comply with standards, commonly referred to as Good Clinical Practice, or GCP, and other local legal requirements, including data privacy regulations, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial subjects are protected. If clinical investigators or CROs fail to meet their obligations to us or comply with GCP procedures or other applicable legal requirements, the data generated in these trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with GCP regulations.

In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. If clinical investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocol or regulatory requirements, or for other reasons, our clinical trials or those of our collaborators may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***We are heavily dependent on the success of our current clinical-stage product candidates and we cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, these product candidates.***

Our business and future success depend on receiving regulatory approval for, and the commercial success of, our proprietary and partnered product candidates. We have agreements with AstraZeneca with respect to the advanced development, clinical trial collaboration and potential future registration and marketing of several of our product candidates, including monalizumab and IPH5201, and with Sanofi for the research and development of IPH61. Our near-term prospects depend heavily on AstraZeneca's successful clinical development and commercialization of monalizumab as well as the successful clinical development of our other product candidates. The clinical success of these product candidates will depend on a number of factors, including the ability and willingness of AstraZeneca and our other collaborators to complete ongoing clinical trials for monalizumab, our ability to complete the clinical trials for which we are responsible, and the safety, tolerability and efficacy of our product candidates.

***We may not be successful in our efforts to develop additional products that receive regulatory approval and are successfully commercialized.***

Other than our commercial product, Lumoxiti, our pipeline consists of various product candidates at different phases of preclinical and clinical development. The development of a product candidate is a long, costly and uncertain process, aimed at demonstrating the therapeutic benefit of a product candidate that competes with existing products or those being developed. There is no guarantee that we or our collaborators will be able to demonstrate a sufficient degree of clinical efficacy or safety of one or more of our proprietary or licensed product candidates in order to gain regulatory approval or to become commercially viable. The degree of uncertainty associated with clinical development and the risks associated with developing new product candidates may make it difficult to evaluate our current business and our future prospects.

We intend to continue to develop our product candidates that are currently in clinical trials, including monalizumab, lacutamab, avdoralimab and IPH5201. Monalizumab is currently being investigated in multiple Phase I and Phase II clinical trials under a co-development agreement with AstraZeneca. Lacutamab is currently being investigated in an open-label, multi-cohort Phase II clinical trial. Avdoralimab is currently being evaluated in Phase I and Phase II clinical trials. IPH5201 is currently being investigated in an open-label Phase I clinical trial sponsored by AstraZeneca. While we believe that we will eventually have the in-house capabilities to complete the development of monalizumab, lacutamab, avdoralimab and IPH5201, we have not yet completed the clinical trials for these or other product candidates, and there can be no assurance that these or other product candidates will gain regulatory approval or become commercially viable.

Delays in the preclinical development of a product candidate could lead to delays in initiating its clinical development. A failure in the preclinical development of a product candidate could lead to abandoning its development. Further delays or failures at the various clinical stages for a given indication could result in delay or halt the development of the product candidate in such indication or in other indications. Moreover, disappointing results during the initial phases of development are often not a sufficient basis for deciding whether or not to continue a project. At these early stages, sample sizes, the duration of studies and the parameters examined may not be sufficient to enable a definitive conclusion to be drawn, in which case further investigations are required. Conversely, promising results during the initial phases, and even after advanced clinical trials have been conducted, do not guarantee that a product candidate or an approved drug, such as Lumoxiti, will be successfully commercialized and marketed.

The risks related to the failure of a product candidate's development are highly related to the stage of maturity of the product candidate. Given the relatively early stage of the product candidates in our pipeline, there is a substantial risk that some or all of our product candidates will not obtain regulatory approval or be commercialized, which would have an adverse impact on our business, prospects, financial condition and results of operations.

***We may not be successful in our efforts to identify, discover or develop additional product candidates.***

We are seeking to develop a broad and innovative pipeline of product candidates in addition to monalizumab, lacutamab, avdoralimab and IPH5201. We may not be successful in identifying additional product candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential product candidates or the potential product candidates we identify may have harmful side effects, lack of efficacy or other characteristics that make them unmarketable or unlikely to receive regulatory approval.

Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional indications for our product candidates or to identify and develop new product candidates through internal research programs. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

***We may encounter substantial delays in our clinical trials, or may be unable to conduct our clinical trials on the timelines we expect.***

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays or failure in reaching a consensus with regulatory agencies on clinical trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and investigational sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and investigational sites;
- imposition of a temporary or permanent clinical hold by regulatory agencies, including as a result of a new safety finding that presents unreasonable risk to clinical trial participants, a negative finding from an inspection of our clinical trial operations or investigational sites, developments in trials conducted by competitors for related technology that raise regulators' concerns about risk to patients of the technology broadly or if a regulatory body finds that the investigational protocol or plan is clearly deficient to meet its stated objectives. For example, in November 2019, our TELLOMAK trial was put on full or partial holds in a number of countries. See "Item 4.B-Business Overview-Lacutamab, A Tumor Targeting Anti-KIR3DL2 Antibody-Clinical Development of Lacutamab-Phase II Clinical Trial (TELLOMAK);"



- delays in recruiting suitable patients to participate in our clinical trials;
- difficulty collaborating with patient groups and investigators;
- failure by us, our CROs or other third parties, including our collaborators, to adhere to clinical trial requirements;
- delays in having patients complete participation in a clinical trial or return for post-treatment follow-up;
- patients withdrawing from a clinical trial;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical trial protocols;
- regulatory feedback requiring us to amend the protocols of ongoing clinical trials in response to safety considerations, as we have previously been required to;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- transfer of manufacturing processes to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- batch recalls, recalls of manufactured product candidates or delays in manufacturing, testing, releasing, validating, or importing or exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***Lumoxiti or our product candidates in development may cause undesirable side effects or have other properties that could halt or delay their clinical development, prevent their regulatory approval, limit their commercialization or result in other negative consequences.***

Use of our approved product, Lumoxiti, or our product candidates in development could be associated with side effects or adverse events which can vary in severity and in frequency. Undesirable side effects or unacceptable toxicities caused by our products or product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials. The FDA or European regulatory authorities could delay or deny approval of our product candidates for any or all targeted indications and negative side effects could result in a more restrictive label for any drug that is approved. Side effects such as toxicity or other safety issues associated with the use of our product candidates could also require us or our collaborators to perform additional studies or halt development of product candidates or sale of approved products.

Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, as toxicities resulting from immunotherapy are not normally encountered in the general patient population and by medical personnel. Inadequate training in recognizing or managing the potential side effects of our product candidates or our approved product, Lumoxiti, could result in adverse effects to patients, including death. Any of these occurrences may have an adverse impact on our business, prospects, financial condition and results of operations.

***We face substantial competition from companies with significantly greater resources and experience.***

The biotechnology and pharmaceutical market, and notably the immuno-oncology field, is characterized by rapidly advancing technologies, products protected by intellectual property rights and intense competition and is subject to significant and rapid change as researchers learn more about diseases and develop new technologies and treatments. We face potential competition from many different sources, including major pharmaceutical companies, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we or our collaborators successfully develop will compete with existing therapies and new therapies that may become available in the future. If competing products are marketed before ours, or at lower prices, or cover a wider therapeutic spectrum, or if they prove to be more effective or better tolerated, our business, prospects, financial condition and results of operations could be affected.

Many of our competitors who are developing immuno-oncology and anti-cancer therapies have considerably greater resources and experience in research, access to patients for clinical trials, drug development, finance, manufacturing, marketing, technology and personnel than we do. In particular, large pharmaceutical companies have substantially more experience than we do in conducting clinical trials and obtaining regulatory authorizations. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors are also likely to compete with us to recruit and retain scientific and management personnel, acquire rights for promising product candidates and other complementary technologies, establish clinical trial sites and patient registration for clinical trials and acquire technologies complementary to, or necessary for, our programs, as well as to enter into collaborations with partners who have access to innovative technologies. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may never be profitable. Should any of these risks materialize, our business, prospects, financial condition and results of operations may be adversely affected.

We cannot guarantee that our product candidates or our approved product, Lumoxiti, will:

- obtain regulatory authorizations or become commercially available before those of our competitors;
- remain competitive in the face of other products developed by our competitors, which may prove to be safer, are more effective, have fewer or less severe side effects, are more convenient, have a broader label, have more robust intellectual property protection or are less expensive;
- remain competitive in the face of products of competitors that are more efficient in their manufacturing or more effective in their marketing; and
- not become obsolete or unprofitable due to technological progress or other therapies developed by our competitors.

In addition, while our approved product and any future product candidates that are approved may compete with many existing drugs or other therapies, to the extent they are solely used in combination with these therapies, our product candidates will not be competitive with such therapies but any sales of such products could be limited to sales of the combination therapy. In this case, we would be exposed to the same competitive risks as the product used in combination with our product, such as a product that is marketed before the combination therapy, has lower prices, covers a wider therapeutic spectrum or proves to be more effective or better tolerated. For additional information regarding competition to our business see "Business—Competition."

***We depend on enrollment of patients in our clinical trials for our product candidates.***

Successful and timely completion of clinical trials will require that we or our subcontractors enroll a sufficient number of suitable patients. Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, which is typically limited for rare or orphan diseases making the enrollment more difficult, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. For example, we are developing lacutamab for the treatment of cutaneous T-cell lymphoma, or CTCL. CTCL is an orphan disease, which means that the potential patient population is limited. In addition, there are several other product candidates potentially in development for the indications for which we are developing product candidates, and we may compete for patients with the sponsors of trials for those drugs. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of any of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the inability to obtain regulatory approval of our product candidates.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our approved product, Lumoxiti, and product candidates, if approved, which could make it difficult for us to sell our product or product candidates profitably.***

Successful sales of Lumoxiti and our product candidates, if approved, will depend, in part, on the availability of adequate coverage and reimbursement from government authorities and third-party payors, such as private health insurers and health maintenance organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States or the Social Security in France, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a 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.

Policies for coverage and reimbursement for products vary among third-party payors. No uniform policy of coverage and reimbursement for products exists among third-party payors, and third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of approved drugs and medical services, in addition to questioning their safety and efficacy. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us or our partners to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our product candidates or approved products.

Because our product candidates and our approved product, Lumoxiti, represent new approaches to the treatment of cancer and accordingly, may have a higher cost than conventional therapies and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be elevated. There are currently a limited number of immunotherapy products that are designed to treat cancer on the market and, accordingly, there is less experience or precedent for the reimbursement of such treatments by governmental entities or third-party payors.

***Government restrictions on pricing and reimbursement and other healthcare cost-containment initiatives may negatively affect our ability to generate revenues for Lumoxiti and other product candidates for which we obtain regulatory approval.***

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, including by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that pharmaceutical and biotechnology companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products.

In the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our or our partners' ability to sell our products profitably. By way of example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we collectively refer to as the ACA, was enacted in March 2010 and is having a significant impact on the provision of, and payment for, healthcare in the United States. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two executive orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In July and December 2018, Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, published final rules with respect to permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under its risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by the U.S. Congress as part of the Tax Cuts and Jobs Act of 2017 Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the Texas U.S. District Court ruling and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Both the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, or ATRA, further reduced Medicare payments to several providers and the ATRA increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our product candidates, if approved. This could harm our or our partners' ability to market any drugs and generate revenues. Cost containment measures that healthcare payors and providers are instituting and the effect of further healthcare reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses.

In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the U.S. Bureau of Labor Statistics consumer price index, and these rebates or discounts, which can be substantial, may affect our ability to raise commercial prices.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal years 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation. The Trump administration also released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In some countries, the proposed pricing for a biopharmaceutical product must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of biopharmaceutical product is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU member state may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

We believe that pricing pressures will continue and may increase, which may make it difficult for us to sell Lumoxiti or any of our product candidates that may be approved in the future at a price acceptable to us or any of our existing or future collaborators.

***Lumoxiti and any of our other product candidates, if approved and commercialized, may fail to achieve market acceptance by physicians, patients, third-party payors or the medical community to a degree that is necessary for commercial success.***

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

- the demonstration of the clinical efficacy and safety of the drug;
- the approved labeling for the drug and any required warnings;
- prevalence and severity of adverse side effects;
- the advantages and disadvantages of the drug compared to alternative treatments;
- ease of the drug's use;
- our ability to educate the medical community about the safety and effectiveness of the drug;
- the scope of any approval provided by the FDA or foreign regulatory authorities;
- publicity about our product or about competitive products;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the drug;
- the market price of our drugs relative to competing treatments; and
- due to the rarity of orphan diseases, it could be difficult finding patients seeking treatment for Lumoxiti.



Poor market penetration could have an adverse effect on our business, prospects, financial condition and results of operations.

*Even if some of our other product candidates receive marketing authorization, the terms of such approval, ongoing regulation and potential post-marketing restrictions or withdrawal from the market may limit how the drug may be marketed and may subject us to penalties for failure to comply with regulatory requirements, which could impair our ability to generate revenues.*

Even if any of our other product candidates receives marketing authorization, such approval may carry conditions that limit the market for the drug or put the drug at a competitive disadvantage relative to alternative therapies. Regulators may limit the marketing of products to particular indications or patient populations. Regulators may require warning labels and drugs with warnings are subject to more restrictive marketing regulations than drugs without such warnings. These restrictions could make it more difficult to market any drug effectively. Marketing restrictions may reduce the revenue that we are able to obtain.

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

The FDA, EMA and other national authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long-term observational studies on natural exposure. The FDA and other agencies, including the U.S. Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our product candidates or with manufacturing processes, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks, or the imposition of distribution or other restrictions including suspension of production and/or distribution and withdrawal of regulatory approvals. Failure to comply with these requirements may lead to financial penalties, compliance expenditures, total or partial suspension of production and/or distribution, product seizure or detention, refusal to permit the import or export of products, suspension of the applicable regulator's review of a company's submissions, enforcement actions, product recalls, injunctions and even criminal prosecution, any of which could materially and adversely affect our business, financial condition and results of operations.

***The recent global COVID-19 pandemic could adversely affect our business, financial condition and results of operations.***

An outbreak of a novel strain of coronavirus (i.e. COVID-19), which first emerged in the PRC in late December 2019, has since spread to other parts of the world, including the United States and Europe. We may experience or continue to experience disruptions relating to this pandemic that could severely impact our business, financial condition and results of operations.

In France, on March 12, 2020, the French government announced the closure of all schools and the closure of all non-essential businesses until further notice. On March 16, 2020, President Macron announced the confinement of the French population for a minimum of 15 days. Such confinement has been subsequently extended and, on April 13, 2020, President Macron announced that such confinement will not be lifted until at least May 11, 2020. On March 13, 2020, President Trump declared a national emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, and subsequently, many U.S. states closed their schools and public gathering places.

Because of these containment measures, we have temporarily closed all of our corporate sites in France and the United States, and in particular our Luminy site, where we carry out our laboratory experiments. However, our Luminy site has been partially reopened for our exploratory study on COVID-19 therapies. We may take further actions required by authorities or that we determine are in the best interests of our employees, customers, partners, suppliers and counterparts. We cannot be certain that such measures will be sufficient to mitigate the risks posed by COVID-19, and the implementation of such measures (or their insufficiency) could harm our ability to perform critical functions. The unavailability of our staff could adversely impact the quality and continuity of our operations. Furthermore, we expect these containment measures to delay our planned recruitment of additional employees, which is necessary to support our growth.

The closure of our sites could also cause a delay in obtaining certain data from our research and development programs, and thereby delay our mid-term development timelines. Restarting the Luminy site and its activities could be a potentially long, costly and complex process.

Because of the spread of COVID-19, we may experience or continue to experience the following adverse impacts on our clinical trials:

- diversion of investigational sites and physicians adhering to government recommended protocols that interfere with our clinical trials, including the clinical trials carried out by our hospital or industrial partners, whose crisis management decisions are not under our control;
- delays or difficulties in enrolling new patients in our clinical trials;
- delays or difficulties in continuing treatment of patients already enrolled in our clinical trials, which delays obtaining results from such trials;
- delays or interruptions of key clinical trial activities due to shortages or interruptions in the supply chain of third-party marketed drugs used in connection with our products in our clinical trials as well as active pharmaceutical ingredients or components used to manufacture our marketed drugs;
- deterioration of the quality and completeness of data obtained during our clinical trials due to limitations in patient monitoring as a result of containment measures and the possibility of participating patients to be infected with COVID-19, which could result in refusals of local regulatory authorities to accept data from such clinical trials;

- changes in local regulations as part of a response to the COVID-19 pandemic, which could require us to change the ways in which our clinical trials are conducted, which could result in unexpected costs or decisions to discontinue such clinical trials altogether; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, or the need of these institutions to prioritize COVID-19 matters.

It is not only true for trials we sponsor but also for trials sponsored by academic or industrial partners, which might take decision in this context that we cannot control. We expect those factors to have a higher impact on our product candidates at early clinical trial stages. For example, AstraZeneca has made the decision to temporarily pause enrollment of the Phase I clinical trial evaluating IPH5201, an anti-CD39 blocking monoclonal antibody, in adult patients with advanced solid tumors, due to the COVID-19 pandemic.

The COVID-19 pandemic could also delay or impair our sales of Lumoxiti. Since the end of the fourth quarter of 2019, we have become the primary commercial entity promoting Lumoxiti, having transitioned all sales and medical affairs activities, including medical science liaisons and sales representatives, from AstraZeneca to us. The COVID-19 pandemic could impair our ability to achieve our product development or commercialization objectives in the timeframes we had expected due to the factors listed above and, also due to limited opportunities for in-person marketing of Lumoxiti to oncology healthcare professionals due to social distancing measures and interruptions of treatments for Lumoxiti patients as a result of limited access to physicians.

As a consequence, we may not receive milestone or royalty payments from our partners. See “–If we do not achieve our product development or commercialization objectives in the timeframes we expect, we may not receive product revenue or milestone or royalty payments and we may not be able to conduct our operations as planned.”

The global COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic may affect our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the European Union, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the European Union, the United States and other countries to contain and treat the disease. Further, the adverse effect on the financial markets, on the market price of our ADSs and/or ordinary shares in the long term, is unknown. To date, the global economy remains catastrophically affected by the outbreak of the COVID-19 pandemic.

***We are exposed to a number of regulatory and commercial risks relating to the United Kingdom's exit from the European Union.***

The United Kingdom formally withdrew from the EU ("Brexit") on January 31, 2020 on the basis of the Third Reading of the Withdrawal Agreement Bill. There will be a short transitional/implementation period which is currently due to end on December 31, 2020 during which the United Kingdom and the EU are negotiating transitional arrangements. The United Kingdom has stated that it wants the transition period to expire, and the transitional arrangements to be agreed, by December 31, 2020. During the transition period the existing rules on trade, travel, and business for the United Kingdom and the EU continue to apply. Any changes that may occur after the transitional period are currently uncertain. There is still concern that the United Kingdom does not find an agreement with the EU regarding such transitional arrangements and the U.K. Government has commenced preparations for a "hard" or "no-deal" Brexit to minimize the risks for firms and businesses associated with an exit with no transitional agreement.

Our clinical trials in the U.K. are subject to the UK Medicines and Healthcare Products Regulatory Agency, or MHRA and EMA regulations. If the U.K. proceeds to leave the EU without any formal withdrawal arrangements, there could be considerable uncertainty as to the continued applicability of such regulations in the U.K. We are currently conducting clinical trials of lacutamab in the U.K. and we cannot be certain such trials will not be affected if the U.K. leaves the EU without any formal withdrawal arrangements. Lacutamab received an orphan drug designation in the EU, which provides for an exclusive 10-year marketing period during which no similar product may apply for a marketing authorization in the EU for the same indication, as well as an exemption from regulatory fees and other advantages. We may lose this designation and benefits for lacutamab in the U.K. in the event that the U.K. exits the EU without any formal withdrawal arrangements. Furthermore, if we obtain an MA in the EU, such authorization may not permit us to engage in commercial sales of our product candidates in the U.K. and we may not be able to obtain the required authorization from the U.K. regulator. If we are required to obtain additional authorizations in the U.K., we will incur additional costs to obtain such authorizations, which may be significant.

**Risks Related to our Financial Position and Capital Needs**

***We have incurred and may in the future incur significant operational losses related to our research and development activities.***

We have incurred net losses in each year since our inception except for the years ended December 31, 2016 and 2018. Our net income (loss) was €(48.4) million, €3.0 million and €(20.8) million for the years ended December 31, 2017, 2018 and 2019, respectively. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from selling, general and administrative expenses associated with our ongoing operations. We expect to incur significant expenses and operating losses for the foreseeable future.

We currently only have one product, Lumoxiti, that has received regulatory approval for sale or has generated revenues from commercial sales, and none of our other product candidates have received regulatory approval. Unless this happens, the likelihood and amount of our future operational losses will depend on several factors, including the commercialization of our approved product, Lumoxiti, the pace and amount of our future expenditures in connection with our product candidates and development programs and our ability to obtain funding through milestone or royalty payments under our license and collaboration agreements, equity or debt financings, strategic collaborations and government grants and tax credits. We expect that our main source of income for the near- and medium-term will be:

- revenue from the commercialization of Lumoxiti;
- payments received under our license and collaboration agreements with third parties, including AstraZeneca and Sanofi; and
- government grants and research tax credits.

The interruption of one of those sources of income, including as a result of the COVID-19 pandemic, could have a material adverse effect on our business, prospects, financial condition and results of operations. See “–The recent global COVID-19 pandemic could adversely affect our business, financial condition and results of operations.”

Our ability to be profitable in the future will depend on our ability to generate revenue from sales relating to our sole commercial product, Lumoxiti, and other product candidates, if approved, and our ability to obtain regulatory approval for marketing our product candidates. If our product candidates receive regulatory approval, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and market acceptance, reimbursement from third-party payors and market share. Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We may need to raise additional funding to complete the development and any commercialization of our product candidates, which may not be available on acceptable terms, or at all, and failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.***

We are currently advancing our product candidates through preclinical and clinical development, and anticipate relying on partners less as we develop into a commercial stage biopharmaceutical company with research, development and commercial capabilities. We currently retain the full development and marketing rights to lacutamab and avdoralimab and may retain rights to additional proprietary product candidates in the future. The development of immunotherapy product candidates is expensive, and we expect our research and development expenses to increase as we advance our product candidates through clinical trials and regulatory approvals. If clinical trials are successful and if we obtain regulatory approval for product candidates that we develop, we expect to incur commercialization expenses before these product candidates are marketed and sold.

We anticipate that our expenses will increase substantially if and as we:

- continue our research, preclinical and clinical development of our product candidates if our current collaboration partners cease their collaborations with us;
- expand the scope of our current clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies for our product candidates;
- further develop manufacturing processes for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing authorizations for our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize Lumoxiti and any other products for which we may obtain marketing authorization;

- seek to identify and validate additional product candidates that may result in additional preclinical, clinical or other product studies;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend and expand our intellectual property portfolio;
- attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company in the United States following the completion of the October 2019 global offering; and
- experience any delays or encounter issues with any of the above.

As of December 31, 2019, we had cash, cash equivalents, short-term investments and non-current financial assets of €255.9 million. We believe our cash, cash equivalents, short-term investments and non-current financial assets together with our cash flow from operations, will be sufficient to fund our operations for the next twelve months. However, in order to complete the development process, obtain regulatory approval and, if approved, commercialize our product candidates that we are developing in-house, including lacutamab and avdoralimab, develop our proprietary technology and develop a pipeline of additional product candidates, we will require additional funding. Our existing resources may not be sufficient to cover any additional financing needs, in which case new funding would be required. See “We have incurred and may in the future incur significant operational losses related to our research and development activities.” The conditions and arrangements for such new financing would depend, among other factors, on economic and market conditions that are beyond our control, including the current volatility in the capital markets as a result of the COVID-19 pandemic. See “The recent global COVID-19 pandemic could adversely affect our business, financial condition and results of operations.”

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Under French law, our share capital may be increased only with shareholders’ approval at an extraordinary general shareholders’ meeting on the basis of a report from the Executive Board. In addition, the French Commercial Code imposes certain limitations on our ability to price certain offerings of our share capital without preferential subscription rights (droit préférentiel de souscription), which limitation may prevent us from successfully completing any such offering. See “Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares.”

Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares or the ADSs to decline. The sale of additional equity or convertible securities would dilute our shareholders. We may seek funds through arrangements with collaborative partners or otherwise at an earlier stage of product development than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, prospects, financial condition and results of operations.

If we need and are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product or product candidate or we may be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could impair our growth prospects. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***The terms of our loan agreement with Société Générale and certain other loan obligations place restrictions on our operating and financial flexibility.***

In July 2017, we entered into a loan and security agreement with Société Générale (the “Loan Agreement”) in order to finance the construction of our future headquarters. The Loan Agreement is secured by collateral in the form of financial instruments valued at €15.2 million held at Société Générale. As of December 31, 2019, we had drawn down €15.2 million under the Loan Agreement. The Loan Agreement subjects us to a covenant to maintain a minimum balance of our total cash, cash equivalents and current and non-current financial assets as of each fiscal year end at least equal to the amount of outstanding principal under the Loan Agreement. Compliance with this covenant may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders. For example, if we fail to meet our minimum cash covenant and we are unable to raise additional funds or obtain a waiver or other amendment to the Loan Agreement, we may be required to delay, limit, reduce or terminate certain of our clinical development efforts.

Additionally, we may be required to repay the entire amount of outstanding indebtedness under the Loan Agreement in cash if we fail to stay in compliance with our covenant or suffer some other event of default under the Loan Agreement. Under the Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the Loan Agreement or we breach our covenant under the Loan Agreement. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant rights to others to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Société Générale could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

We are also subject to a €1.5 million PTZI loan (Prêt à Taux Zéro Innovation—interest-free loan for innovation) from Banque Publique d’Investissement, or BPI France, entered into in 2013. In addition, in 2008 we entered into a finance lease agreement with Sogebail, a subsidiary of Société Générale. The present value of all minimum lease payments under this agreement is €0.3 million as of December 31, 2019. Our business, financial condition and results of operations could likewise be substantially harmed if, among other things, we fail to make payments under these agreements, or we breach any of our covenants under these agreements.

***If we do not achieve our product development or commercialization objectives in the timeframes we expect, we may not receive product revenue or milestone or royalty payments and we may not be able to conduct our operations as planned.***

We have received and expect to continue to receive payments from our collaborators when we satisfy certain pre-specified milestones in our licensing or collaboration agreements. We currently depend to a large degree on these milestone payments from our existing collaborators in order to fund our operations and we may enter into new collaboration agreements that also provide for milestone payments. For example, we have granted options to license or acquire intellectual property rights in certain of our programs to our collaborators which, if exercised, will result in up-front option exercise fees and, assuming we meet all specified development, clinical, regulatory and sales milestones, could result in substantial milestone payments. These milestone payments are generally dependent on the accomplishment of various scientific, clinical, regulatory, sales and other product development objectives, and the successful or timely achievement of many of these milestones is outside of our control, in part because some of these activities are being or will be conducted by our collaborators. If we or our collaborators fail to achieve the applicable milestones, we may not receive such milestone payments. A failure to receive any such milestone payment may cause us to:

- delay, reduce or terminate certain research and development programs;
- reduce headcount;
- raise funds through additional equity or convertible debt financings that could be dilutive to our shareholders and holders of our ADSs;
- obtain funds through collaboration agreements that may require us to assign rights to technologies or products that we would have otherwise retained;
- sign new collaboration or license agreements that may be less favorable than those we would have obtained under different circumstances; and
- consider strategic transactions or engaging in a joint venture with a third-party.

In addition, although we may be eligible to receive an aggregate of approximately \$5.5 billion in future contingent payments from existing collaboration agreements and any license agreements that become effective upon the exercise by our collaborators of options to license future product candidates, there is no guarantee that we will receive any contingent payments or that our collaborators will exercise any options to license or acquire additional intellectual property rights in any of our programs. If our collaborators decide not to exercise such options with respect to a program, we will not receive the up-front option exercise fee and will not be eligible to receive any of the related commercial, development, royalty or other milestone payments. Even if our collaborators exercise such options with respect to a particular program, we may never achieve the related milestones for any number of reasons. The failure to receive milestone or royalty payments and the occurrence of any of the events above may have a material adverse impact on our business, prospects, financial condition and results of operations.

***The revenues generated from our collaboration and license agreements have contributed and are expected to contribute a large portion of our revenue for the foreseeable future.***



We have entered into collaboration and license agreements with pharmaceutical companies, including AstraZeneca. The cash payments received from our partners were €14.0 million, €40.3 million and €108.6 million for the years ended December 31, 2017, 2018 and 2019, respectively.

We also enhance our research efforts by establishing collaborations with academic or non-profit research institutions and other biopharmaceutical companies. The participation in these collaborations may generate revenue and funding in the form of operating grants or the reimbursement of research and development expenses.

We may not be able to renew or maintain our license agreements or collaborative research contracts or may be unable to sign new agreements with new collaborators on reasonable terms or at all. The early termination of a contract, the non-renewal of a contract or our inability to find new collaborators would adversely affect our business. Should any of these risks materialize, this could have an adverse effect on our business, prospects, financial condition and results of operations.

***We benefit from tax credits in France that could be reduced or eliminated.***

As a French biopharmaceutical company, we benefit from certain tax advantages, including the Research Tax Credit (*Crédit Impôt Recherche*), which is a French tax credit aimed at stimulating research and development. The Research Tax Credit is calculated based on our claimed amount of eligible research and development expenditures in France and represented €11.0 million, €13.5 million and €16.7 million for the years ended December 31, 2017, 2018 and 2019, respectively. The Research Tax Credit is a source of financing to us that could be reduced or eliminated by the French tax authorities or by changes in French tax law or regulations.

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

Until the end of the year ended December 31, 2018, we qualified as a small- and medium-size business and the French Treasury refunded each of our 2016, 2017 and 2018 Research Tax Credit claims immediately (meaning that, in practice, we received the refund during the year following the year in which the eligible research and development expenditures are made). We no longer qualify as a small and medium-size business for the year ended December 31, 2019, and therefore, we will no longer be entitled to the immediate reimbursement of the Research Tax Credit but instead will be reimbursed within the expiry of the period of three years mentioned above.

The French tax authorities, with the assistance of the Higher Education and Research Ministry, may audit each research and development program in respect of which a Research Tax Credit benefit has been claimed and assess whether such program qualifies in their view for the Research Tax Credit benefit. The French tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities (and therefore the amount of Research Tax Credit claimed), or the accelerated reimbursement allowed for small- and medium-size businesses and our credits may be reduced, which would have a negative impact on our revenue and future cash flows. Furthermore, the French Parliament may decide to eliminate, or to reduce the scope or the rate of, the Research Tax Credit benefit, either of which it could decide to do at any time. If we fail to receive future Research Tax Credit amounts or if our calculations are challenged, even if we comply with the current requirements in terms of documentation and eligibility of its expenditure, our business, prospects, financial condition and results of operations could be adversely affected.

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

We have accumulated tax loss carry forwards of €230.6 million as of December 31, 2019. Applicable French law provides that, for fiscal years ending after December 31, 2012, the use of these tax losses is limited to €1.0 million, plus 50% of the portion of net earnings exceeding this amount. The unused balance of the tax losses in application of such rule can be carried forward to future fiscal years, under the same conditions and without time restriction. There can be no assurance that future changes to applicable tax law and regulation will not eliminate or alter these or other provisions in a manner unfavorable to us, which could have an adverse effect on our business, prospects, financial condition, cash flows or results of operations.

***Changes to U.S. and non-U.S. tax laws could materially adversely affect our company.***

On December 22, 2017, the Tax Cuts and Jobs Act was signed into law and significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), implementation of a “base erosion anti-abuse tax,” which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxation of certain non-U.S. corporations’ earnings considered to be “global intangible low taxed income,” which is also referred to as GILTI, repeal of the alternative minimum tax, or AMT, for corporations and changes to a taxpayer’s ability to either utilize or refund the AMT credits previously generated, changes to the limitation on deductions for certain executive compensation particularly with respect to the removal of the previously allowed performance based compensation exception, changes in the attribution rules relating to shareholders of certain “controlled foreign corporations,” limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the U.S. corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Cuts and Jobs Act on holders of our ordinary shares or ADSs is also uncertain and could be adverse. For example, recent changes in U.S. federal income tax law resulting in additional taxes owed by U.S. holders (as described under “Material United States Federal Income Tax and French Tax Considerations–Material U.S. Federal Income Tax Considerations”) under the new GILTI tax rules or related to “controlled foreign corporations” may discourage U.S. investors from owning or acquiring 10% or greater of our outstanding ordinary shares or ADSs, which other shareholders may have viewed as beneficial or may otherwise negatively impact the trading price of our ordinary shares or ADSs. We are unable to predict what federal tax law may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. In addition, several of the measures implemented by the Tax Cuts and Jobs Act, including several of those discussed above, have been temporarily modified pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), which was signed into law on March 27, 2020. We urge our shareholders and holders of our ADSs to consult with their legal and tax advisors with respect to the Tax Cuts and Jobs Act, including the modifications made pursuant to the CARES Act and the potential tax consequences of investing in or holding our ordinary shares or ADSs.

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

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the French tax authorities, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the result could increase our anticipated effective tax rate.

#### **Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Legal Compliance Matters**

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, in particular in the United States or the European Union, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

The research and development of pharmaceutical products is governed by complex regulatory requirements. The regulatory agencies that oversee these requirements have the authority to permit the commencement of clinical trials or to temporarily or permanently halt a study. They are entitled to request additional clinical data before authorizing the commencement or resumption of a study, which could result in delays or changes to our product development plan. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with all applicable guidelines, rules and regulations. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The clinical trials of our product candidates are, and the manufacturing and marketing of our one approved product, Lumoxiti, and our other product candidates will be, subject to regulation by numerous government authorities in the United States, in the European Union and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate, with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, with respect to approval in the European Union, to the satisfaction of the EMA or, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use in each target indication.

When we acquired Lumoxiti, AstraZeneca had already obtained marketing approval from the FDA. We have never submitted a product candidate for marketing approval in the United States or elsewhere.

In the United States, we expect that the requisite regulatory submission to seek marketing authorization for our product candidates will be a Biologic License Application, or BLA, and the competent regulatory authority is the FDA. In the European Union, the requisite approval is a Marketing Authorization, or MA, which for products developed by the means of antibody-based therapeutics, gene or cell therapy products as well as tissue engineered products, is issued through a centralized procedure involving the EMA (see “Business-Regulation”). We submitted an MA application for Lumoxiti to the EMA, but have not received the MA yet and may not receive it. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, for example, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

Data from preclinical and clinical studies are likely to give rise to different interpretations, which could delay regulatory authorization, restrict the scope of any such authorization or force us to repeat trials in order to meet the requirements of the various regulators. Regulatory requirements and processes vary widely among countries, and we may be unable to obtain authorization within each relevant country in a timely manner. Regulatory authorities may prevent us from starting clinical trials or continuing clinical development if the data were not produced according to applicable regulations or if they consider that the balance between the expected benefits of the product and its possible risks is not sufficient to justify the trial.

Despite our efforts, our product candidates may not:

- offer improvement over existing, comparable products;
- be proven safe and effective in clinical trials; or

- meet applicable regulatory standards.

This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond our existing cash on hand. Of the large number of drugs in development globally, only a small percentage successfully complete the regulatory approval process and not all approved drugs are successfully commercialized. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary for us or our partners to bring a potential product candidate to market could have a material adverse effect on our business, prospects, financial condition and results of operations.

***The regulatory processes that will govern the approval of our product candidates are complex and changes in regulatory requirements could result in delays or discontinuation of development or unexpected costs in obtaining regulatory approval.***

Our product candidates are based on new technologies that are constantly evolving and have not been extensively tested on humans. The applicable regulatory requirements vary between jurisdictions and are also complex, potentially difficult to apply and subject to significant modifications. Modifications to regulations during the course of clinical development and regulatory review may lead to delays or the refusal of authorization.

In Europe, the United States and other countries, regulations can potentially:

- significantly delay or increase the cost of development, testing, manufacturing and marketing of our products;
- limit the indications for which we will be authorized to market our products; and
- impose new, more stringent, requirements, suspend marketing authorizations, or request the suspension of clinical trials or the marketing of our products if unexpected results are obtained during trials performed by other researchers on products similar to our products.

Marketing authorization in one jurisdiction does not ensure marketing authorization in another, but a failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the regulatory process in others. Failure to obtain marketing authorization in other countries or any delay or setback in obtaining such approval would impair our ability to develop additional markets for our product, Lumoxiti, or any additional product candidates that are approved. This would reduce our target market and limit the full commercial potential of our product or product candidates. Should any of these risks materialize, this could harm our business.

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

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

***Side effects that appear following the launch of a drug on the market may result in the product being taken off the market or additional warnings being added to the label despite having obtained all regulatory approvals.***

A drug's launch in the market may expose a large number of patients to potential risks associated with the treatment with a new pharmaceutical product. Certain side effects, which may not have been identified during clinical trials, can subsequently appear. For these reasons, regulatory agencies require companies to implement post-approval monitoring. Depending on the occurrence of serious undesirable effects, the agencies may require that we or a collaboration partner of ours take a drug off the market temporarily or permanently, even if it is effective and has obtained all the necessary marketing authorizations. Such an action would negatively impair our ability to generate revenue from such product and could more generally negatively affect our ability to develop, obtain regulatory approval for, and commercialize our other product candidates and our reputation generally, each of which could have a material adverse effect on our business and results of operations. In addition, if the product candidates we develop receive marketing authorization and we or others identify undesirable side effects caused by Lumoxiti or any other products after the approval, a number of potentially significant negative consequences could result, including that regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication, we may be required to create a medication guide outlining the risks of such side effects for distribution to patients and our reputation may suffer.

***Lumoxiti and any other product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our product and product candidates, when and if any of them are approved.***

Lumoxiti and any product candidate for which we obtain marketing approval, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities, including requirements relating to manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, restrictions for specified age groups, warnings, precautions or contraindications or to the conditions of approval.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription products, including requirements pertaining to marketing and promotion of products in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Prescription products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may also share truthful and not misleading information that is otherwise consistent with the labeling. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;

- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with the FDA, EMA or other regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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

Our future profitability will depend, in part, on our ability to commercialize Lumoxiti and our product candidates, if approved, in markets in Europe, the United States and other countries where we maintain commercialization rights. If we commercialize Lumoxiti and any of our product candidates, if approved, in multiple markets, we would be subject to additional risks and uncertainties, including:

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



- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations.

These and other risks associated with international operations may adversely affect our ability to attain or maintain profitable operations. Future sales of Lumoxiti or our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may affect milestone payments or royalties for Lumoxiti, monalizumab or any of our product candidates that are approved for commercialization in the future. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***Even if our product candidates obtain regulatory approval, they will be subject to continuous regulatory review.***

If marketing authorization is obtained for any of our product candidates, the candidate will remain subject to continuous review and therefore authorization could be subsequently withdrawn or restricted. We will be subject to ongoing obligations and oversight by regulatory authorities, including adverse event reporting requirements, marketing restrictions and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. For example, we will be responsible for the completion of an FDA required post-marketing trial of Lumoxiti.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

***Even if one of our product candidates has orphan drug designation, we may not be able to obtain any benefit from such designation. Furthermore, if a product is granted orphan drug exclusivity in the same indication for which we are developing lacutamab or our other product candidates that is granted orphan drug designation, we may not be able to have our product candidate approved by the applicable regulatory authority for a significant period of time.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. In the European Union, the European Commission may designate a product candidate as an orphan medicinal product if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affects not more than five in 10,000 persons in the European Union, or it is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which, subject to certain exceptions, precludes the FDA from approving the marketing application of another drug for the same indication for that time period or precludes the EMA, and other national drug regulators in the European Union, from accepting the marketing application for another medicinal product for the same indication. The applicable period is seven years in the United States and ten years in the European Union. The European Union period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. The granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Lacutamab has been granted orphan drug designation for CTCL in Europe and in the United States and we may pursue orphan drug designation for another product candidate that we may develop in the future in the United States and/or Europe. However, there is no assurance we will be able to receive orphan drug designation for other product candidates that we may develop in the United States and/or Europe or for any other product candidate in any jurisdiction. Even if we are successful in obtaining orphan drug designation, orphan drug status may not ensure that we have market exclusivity in a particular market. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product from competition because exclusivity can be suspended under certain circumstances. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, orphan exclusivity will not prevent a marketing authorization being granted for a similar medicinal product in the same indication if the new product is safer, more effective or otherwise clinically superior to the first product or if the marketing authorization holder of the first product is unable to supply sufficient quantities of the product. In addition, if another product is granted marketing approval and orphan drug exclusivity in the same indication for which we are developing a product candidate with orphan drug designation, we may not be able to have our product candidate approved by the applicable regulatory authority for a significant period of time.

***A fast track, breakthrough therapy or other designation by the FDA may not actually lead to a faster development.***

We may seek fast track, breakthrough therapy or similar designation for our product candidates. If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. We have received fast track designation for lacutamab for the treatment of adult patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies.

Additionally, we may in the future seek a breakthrough therapy designation for some of our product candidates that reach the regulatory review process. A breakthrough therapy is a drug candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

However, these designations do not ensure that we will experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw a designation if it believes that the designation is no longer supported by data from our clinical development program. A designation alone does not guarantee qualification for the FDA's priority review procedures.

***Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidates.***

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

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

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

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

- Articles 433-1 1° and 432-11 1° of the French Criminal Code (bribery of domestic public officials);
- Articles 433-1 2° and 432-11 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 445-1 and 445-2 of the French Criminal Code (bribery of private individuals);
- Article 433-2 of the French Criminal Code (influence peddling involving private individuals);
- 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); and
- French Law of December 9, 2017 on Transparency, the Fight Against Corruption and the Modernization of the Economy (Sapin 2 Law).

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

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

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our products, if approved. Our arrangements with such persons and third-party payors and our 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 research, market, sell and distribute our products, if we obtain marketing authorization. Restrictions under applicable U.S. federal, state and foreign healthcare laws and regulations include, but are not limited to, the following:

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, including those from civil whistle-blower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that impose criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which impose certain requirements on covered entities and their business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- U.S. federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals, and certain ownership and investment interests held by physicians or their immediate family members; and

· analogous state or foreign laws and regulations, such as state anti-kickback and false claims laws, including the French “Bertrand Law”, French Ordinance n°2017-49 of January 19, 2017, and the UK’s Bribery Act 2010, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We may collect, process, use or transfer personal information from individuals located in the European Union in connection with our business, including in connection with conducting clinical trials in the European Union. Additionally, we intend to commercialize Lumoxiti, and any of our product candidates that receive marketing approval, in the European Union. The collection and use of personal health data in the European Union are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, or EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals’ requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

#### Risks Related to our Reliance on Third Parties

*We depend upon our existing collaboration partners, AstraZeneca, Sanofi and other third parties, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our drugs.*

We have significant collaborations with AstraZeneca for the commercialization of Lumoxiti and the development of monalizumab, IPH5201 and other product candidates. We also collaborate with Sanofi for the development of IPH61, and we may enter into additional collaborations for other of our product candidates or technologies in development. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development, manufacturing or marketing of our products. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, including that they may have other, higher priority products in development or because our partnered programs may no longer be a priority for them. If any of our collaboration agreements were to be terminated, we could encounter significant delays in developing our product candidates, lose the opportunity to earn any revenues we expected to generate under such agreements, incur unforeseen costs, and suffer damage to the reputation of our product, product candidates and as a company generally.

In order to optimize the launch and market penetration of certain of our future product candidates, we may enter into distribution and marketing agreements with pharmaceutical industry leaders. For these product candidates, we would not market our products alone once they have obtained marketing authorization. The risks inherent in entry into these contracts are as follows:

- the negotiation and execution of these agreements is a long process that may not result in an agreement being signed or that can delay the development or commercialization of the product candidate concerned;
- these agreements are subject to cancellation or non-renewal by our collaborators, or may not be fully complied with by our collaborators;

- in the case of a license granted by us, we lose control of the development of the product candidate licensed; in such cases we would have only limited control over the means and resources allocated by our partner for the commercialization of our product; and
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

Should any of these risks materialize, or should we fail to find suitable collaborators, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***The late-stage development and marketing of our product candidates may partially depend on our ability to establish collaborations with major biopharmaceutical companies.***

In order to develop and market some of our product candidates, we rely on collaboration, research and license agreements with pharmaceutical companies to assist us in the development of product candidates and the financing of their development. For our most advanced clinical product candidate, monalizumab, we entered into an agreement with AstraZeneca, in part because of their late-stage development and marketing capabilities. As we identify new product candidates, we will determine the appropriate strategy for development and marketing, which may result in the need to establish collaborations with major biopharmaceutical companies. We may also enter into agreements with institutions and universities to participate in our other research programs and to share intellectual property rights.

We may fail to find collaboration partners and to sign new agreements for our other product candidates and programs. The competition for partners is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.



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

We make considerable use of third-party suppliers for the key materials used in our business. The failure of third-party suppliers to comply with regulatory standards could result in the imposition of sanctions on us. These sanctions could include fines, injunctions, civil penalties, refusal by regulatory organizations to grant approval to conduct clinical trials or marketing authorization for our products, delays, suspension or withdrawal of approvals, license revocation, seizure or recalls of our products, operating restrictions and legal proceedings. Furthermore, the presence of non-conformities, as detected in regulatory toxicology studies, could result in delays in the development of one or more of our product candidates and would require further tests to be financed. Although we are involved in establishing the protocols for the production of these materials, we do not control all the stages of production and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations. In particular, a partner's failure to comply with protocols or regulatory constraints, or repeated delays by a partner, could compromise the development of our products or limit its liability. Such events could also inflate the product development costs incurred by us.

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

Finally, we use third-party investigators to assist with conducting clinical trials. All clinical trials are subject to strict regulations and quality standards. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We do not and will not have access to all information regarding our product candidates that are subject to collaboration and license agreements. Consequently, our ability to inform our shareholders about the status of product candidates that are subject to these agreements, and our ability to make business and operational decisions, may be limited.***

We do not and will not have access to all information regarding our product candidates that are subject to our license and collaboration agreements with AstraZeneca, Sanofi and other third parties, including potentially material information about clinical trial design, execution and timing, safety and efficacy, clinical trial results, regulatory affairs, manufacturing, marketing and other areas known by our collaborators. In addition, we have confidentiality obligations under our collaboration and license agreements. Therefore, our ability to keep our shareholders informed about the status of product candidates subject to such agreements will be limited by the degree to which our collaborators keep us informed and allow us to disclose information to the public or provide such information to the public themselves. If our collaborators do not inform us about our product candidates subject to agreements with them, we may make operational and investment decisions that we would not have made had we been fully informed, which may have an adverse impact on our business, prospects, financial condition and results of operations.

## **Risks Related to the Manufacture of Lumoxiti and Our Product Candidates**

*We have no manufacturing capabilities and rely on third-party manufacturers for Lumoxiti and our product candidates.*

Our product candidates that are tested during our preclinical and clinical trials are manufactured by third parties. We have no production capabilities and rely on third parties to manufacture our products.

This strategy means that we do not directly control certain key aspects of our product development, such as:

- the quality of the product manufactured;
- the delivery times for drugs for a given clinical trial;
- the clinical and commercial quantities that can be supplied; and
- compliance with applicable laws and regulations.

Our reliance on third-party manufacturers creates risks that may not exist if we had our own manufacturing capabilities. These risks include:

- failure of third-party manufacturers to comply with regulatory and quality-control standards;
- production of insufficient quantities;
- damage during transport and/or storage of our product candidates;
- breach of agreements by third-party manufacturers; and
- termination or non-renewal of the agreements for reasons beyond our control.

Should our third-party manufacturers breach their obligations or should we fail to renew our contracts with them, we cannot guarantee that we will be able to find new suppliers within a timeframe and under conditions that would not be detrimental. We could also be faced with delays or interruptions in our supplies, which could result in a delay in the clinical trials and, ultimately, a delay in the commercialization of the product candidates that we are developing or a loss of product sales. For example, manufacturing issues, leading to out-of-specification product, can occur during a manufacturing campaign at the CMO in charge of the production of our product candidates.

Reproducing a batch of product is a lengthy and costly process and sometimes can lead to drug shortage that can in turn lead to a delay in the development of the candidate, or even an early stop of a clinical trial. This happened in the early clinical development of lacutamab and led to the decision to limit the number of patients in order to ensure drug supply for treated patients in the Phase I clinical trial.

In November 2019, Impletio Wirkstoffabfüllung GmbH (formerly known as Rentschler Fill Solutions GmbH), the subcontractor in charge of the fill-and-finish manufacturing operations of lacutamab, unilaterally decided to withdraw the certificates of conformance of all clinical batches produced at their facilities, including the lacutamab batch used for the TELLOMAK Phase II clinical trial assessing lacutamab in multiple indications. Impletio Wirkstoffabfüllung GmbH decided to withdraw the certificates of conformance even though the compliance of its manufacturing site with Good Manufacturing Practices has been confirmed by two on-site inspections performed by the Austrian Health Agency before and after we began to work with them.

The transfer of the manufacturing process to another contract manufacturing organization will be lengthy and we will not be able to receive new clinical batches before the second half of 2020. As a consequence and after discussions with the regulatory agencies of the countries in which the TELLOMAK trial is being conducted in a number of countries, the TELLOMAK trial has been placed on partial or full hold in the U.S., Spain, Germany and Italy. See "Item 4.B-Business Overview-Lacutamab, A Tumor Targeting Anti-KIR3DL2 Antibody-Clinical Development of Lacutamab-Phase II Clinical Trial (TELLOMAK)."

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

***We are reliant upon third parties to manufacture and supply components of certain substances necessary to manufacture Lumoxiti and our product candidates.***

We do not currently independently conduct manufacturing activities for Lumoxiti or our product candidates in development, and we are reliant on several third-party CMOs for the manufacture and supply of components and substances for all of the product candidates we are developing. In addition, certain component materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to manufacture these materials for us. We cannot assure you that, if required, we will be able to identify alternate sources with the desired scale and capability and establish relationships with such sources. A loss of any CMO or component supplier and delay in establishing a replacement could delay our clinical development and regulatory approval process.

***Manufacturing facilities and clinical trial sites are subject to significant government regulations and approvals and if our or our partners' third-party manufacturers fail to comply with these regulations or maintain these approvals, our business could be materially harmed.***

Our third-party manufacturers are subject to ongoing regulation and periodic inspection by national authorities, including the EMA, FDA and other regulatory bodies to ensure compliance with cGMP, when producing batches of Lumoxiti and our product candidates for clinical trials. CROs and other third-party research organizations must also comply with Good Laboratory Practices (GLP) when carrying out regulatory toxicology studies. Any failure to follow and document our or their adherence to such GMP and GLP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our products.

Failure to comply with applicable regulations could also result in national authorities, the EMA, FDA or other applicable regulatory authorities taking various actions, including:

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

Any of the foregoing actions could be detrimental to our reputation, business, financial condition or operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing authorization in Europe, the United States or elsewhere, our suppliers will have to pass an inspection by the applicable regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such inspections, and the inspections and any necessary remediation may be costly. Failure to pass such inspections by us or any of our suppliers would affect our ability to commercialize Lumoxiti or our product candidates in Europe, the United States or elsewhere. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations. For example, in November 2019, Impletio Wirkstoffabfüllung GmbH (formerly known as Rentschler Fill Solutions GmbH), the subcontractor in charge of the fill-and-finish manufacturing operations of lacutamab unilaterally decided to withdraw the certificates of conformance of all clinical batches produced at their facilities, including the lacutamab batch used for the TELLOMAK Phase II clinical trial assessing lacutamab in multiple indications, which resulted in partial or full holds in a number of countries. See "Item 4.B-Business Overview-Lacutamab, A Tumor Targeting Anti-KIR3DL2 Antibody-Clinical Development of Lacutamab-Phase II Clinical Trial (TELLOMAK)."

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

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

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

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

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

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

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

In France, we are required to comply with a number of national, regional and local legislative or regulatory provisions regarding radiation and hazardous materials, including specific regulations regarding the use, handling and storage of radioactive materials and the potential exposure of employees to hazardous materials and radiation. We must also comply with French regulations concerning the use and handling of genetically modified organisms, or GMOs, in confined spaces.

If we fail to comply with applicable regulations, we could be subject to fines and may have to suspend all or part of our operations. Compliance with environmental, health and safety regulations involves additional costs, and we may have to incur significant costs to comply with future laws and regulations in relevant jurisdictions. Compliance with environmental laws and regulations could require us to purchase equipment, modify facilities and undertake considerable expenses. We could be liable for any inadvertent contamination, injury or damage, which could negatively affect its business, although we have subscribed to an insurance policy covering certain risks inherent to its business.

## Risks Related to Our Organization and Operations

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

Our strategy involves continuing to grow our business internally. However, we may also grow externally through selective acquisitions of complementary products and technologies, or of companies with such assets, although no such plan is currently contemplated. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and sales, marketing and distribution for our approved product, Lumoxiti. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This risk is compounded by the fact that we are located in Marseille, France and compete with other locations that potential recruits may find more attractive.

Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing internal or external growth. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy.

If we were to acquire assets or companies, the success of such an acquisition would depend on our capacity to carry out such acquisitions and to integrate such assets or companies into our existing operations. The implementation of such a strategy could impose significant constraints, including:

- human resources: recruiting, integrating, training, managing, motivating and retaining a growing number of employees;
- financial and management system resources: identification and management of appropriate financing and management of our financial reporting systems; and
- infrastructure: expansion or transfer of our laboratories or the development of our information technology system.

In 2019, we initiated a significant upgrade of our information system to support our development, starting with the implementation of an Enterprise Resource Planning system to equip our company with robust and standard tools and reinforce the reliability of our financial operations and information. Such a project is transformative and involves a significant amount of human resources and presents risks, such as (i) the risk of delays in the operations during the first months of implementation, (ii) the risk of loss of data and/or quality of data during the migration process and (iii) the risk that our employees do not fully adhere to such new organizations and information systems (the so-called "change management risk").

If we are unable to manage internal growth or have difficulty integrating any acquisitions, it could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We will need to hire new employees and expand our use of service providers.***

As of December 31, 2019, we had 235 employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial and other personnel.

We currently rely, and for the foreseeable future will continue to rely, in part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize Lumoxiti and our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our ability to retain key persons in our organization and to recruit qualified personnel is crucial for our success. In particular, our success depends heavily on its ability to retain key people in our organization, including key scientific and medical personnel.

Should we be unable to retain the individuals who form our team of key managers and key scientific advisors, it could have a material adverse effect on our business and development and could consequently affect our business, prospects, financial condition and results of operations.

We will need to recruit qualified scientific and medical personnel to carry out our clinical trials and expand into new areas that require specialized skills, such as regulatory matters, marketing and manufacturing. We compete with other companies, research organizations and academic institutions in recruiting and retaining highly qualified scientific, technical and management personnel. Competition for such personnel is very intense in the biopharmaceutical field and there can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could harm our operations and our growth prospects. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We incur some of our expenses, and derive certain of our revenues, in currencies other than the euro. In particular, as we expand our operations and conduct additional clinical trials in the United States, we will incur additional expenses in U.S. dollars. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates.

We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, an unfavorable change in the value of the euro against the U.S. dollar could have a negative impact on our revenue and earnings growth. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ADSs being offered in the U.S. offering are quoted in U.S. dollars on Nasdaq, while our ordinary shares trade in euro on Euronext Paris. Our financial statements are prepared in euro. Therefore, fluctuations in the exchange rate between the euro and the U.S. dollar will also affect, among other matters, the value of our ordinary shares and ADSs.

Under our license and collaboration agreements with AstraZeneca, the payments we receive are in U.S. dollars. In the future, we could generate part of our sales in the United States and part in Europe and could therefore be subject to an unfavorable euro/dollar exchange rate. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euro at a reduced value. We could also sign contracts denominated in other currencies, which would increase our exposure to currency risk. In accordance with our business decisions, our exposure to this type of risk could change depending on:

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

At present, we have not put any specific hedging arrangements in place to address these risks. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.



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

Given that we develop therapeutic products intended to be tested on humans and used to treat humans, the risk that we may be sued on product liability claims is inherent in our business. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient's condition, injury or even death. For example, our liability could be sought after by patients participating in the clinical trials in the context of the development of the therapeutic products tested and unexpected side effects resulting from the administration of these products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third-party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities, may be forced to limit or forgo further commercialization of the affected products and may suffer damage to our reputation.

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

We have obtained liability insurance coverage for each of our clinical trials in compliance with local legislation and rules. In the United States, our aggregate insurance coverage for our ongoing clinical trials is €10.0 million in the aggregate. Our insurance coverage may not be sufficient to cover any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

To date, we have obtained product liability insurance with a coverage amount of €10 million per year. Our product liability insurance will need to be adjusted in connection with the commercial sales of Lumoxiti and our product candidates, and may be unavailable in meaningful amounts or at a reasonable cost. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we would incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of our product programs. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act will require, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year starting year ended December 31, 2020. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting for so long as we are an "emerging growth company," which may be up to five fiscal years following the date of the October 2019 public global offering. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not.

During the audit of our consolidated financial statements as of and for the years ended December 31, 2019, we identified material weaknesses in our internal control over financial reporting. A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's executive board, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement in our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In the course of auditing the consolidated financial statements as of and for the year ended December 31, 2019, several material weaknesses in our internal control over financial reporting were identified. The material weaknesses related to (i) the accounting for subcontracting clinical costs for which there was insufficient control on the input data coming from clinical studies and used in assessing their advancement (input data mainly includes expected termination date of the study, overall budget and/or number of patient visits), and (ii) the recognition of the revenue from our collaboration and licensing agreement with AstraZeneca on monalizumab for which there was insufficient review of the calculation of the transaction price and percentage of completion of costs incurred. Errors not detected in relation to topic (i) have led to incorrect amounts of R&D expenses for the year ended December 31, 2019, which were subsequently corrected prior to the issuance of our audited financial statements. The material weakness in relation to topic (ii) has led to a material misstatement of revenue for the year ended December 31, 2019, which was subsequently corrected prior to the issuance of our audited financial statements. In addition our information system, supporting the production of our financial information, also showed material weaknesses in terms of "general IT controls" (GITC) related to the management of access rights, including segregation of duties and change management.

We are in the process of implementing measures aimed at remedying such weaknesses. In particular, in 2019, we initiated a significant upgrade of our information system to support our development, starting with the implementation of an Enterprise Resource Planning system to equip our company with robust and standard tools and reinforce the reliability of our financial operations and information. In addition, we intend to allocate further human resources to our information systems and internal control departments in 2020.

We have taken and are taking steps to remediate the foregoing weaknesses and deficiencies. However, if we do not successfully remediate these issues or if we fail to design and operate effective internal controls in the future, it could result in material misstatements in our financial statements, result in the loss of investor confidence in the reliability of our financial statements and subject us to regulatory scrutiny and sanctions, which in turn could harm the market value of our ordinary shares and ADSs.

The rules governing the standards must be met for our management to assess 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 audit committee be advised and regularly updated on management's review of internal control over financial reporting. We have begun the process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation. This process is time-consuming, costly, and complicated. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are or 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 control over financial reporting adequate to meet the demands that are or will be placed upon us as a public company listed in the United States, our business and reputation may be harmed and the price of our ordinary shares and ADSs may decline. In addition, undetected material weaknesses in our internal control over financial reporting could lead to restatements of financial statements and require us to incur the expense of remediation. Any of these developments could result in investor perceptions of us being adversely affected, which could cause a decline in the market price of our securities.

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

We have implemented a security policy that are both intended to secure our data against impermissible access and to preserve the integrity and confidentiality of the data. Despite the implementation of such security measures, including a cybersecurity program under development since 2019, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, and other sources. Moreover, part of our information system is "cloud"-based and thus is not fully under our control.

In addition, our research and development facility and headquarters in Luminy, France is located in an area that may be more susceptible to wildfires. If our facility or computer systems are damaged by fire despite the fire prevention and data archiving measures we have put in place, we could suffer financial losses and delays in our operations.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities, including penalties under data privacy laws such as the GDPR and other regulations, and the further development of our product candidates could be delayed. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with legal requirements or the requirements of national authorities, the EMA, FDA and other government regulators, provide accurate information to applicable government authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States, Europe and elsewhere, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have a Code of Ethics that applies to all employees and consultants, and other policies and charters, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our partners, employees, consultants, outside scientific collaborators and sponsored researchers, and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We may acquire businesses or products in the future and we may not realize the benefits of such acquisitions.***

Although our current strategy involves continuing to grow our business internally, we may grow externally through selective acquisitions of complementary products and technologies, or of companies with such assets. If such acquisitions were to become necessary or attractive in the future, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions under favorable conditions, and could be led to finance these acquisitions using cash that could be allocated to other purposes in the context of existing operations. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from an acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction, which could have a material adverse effect on our business, financial conditions, earnings and prospects.

#### **Risks Related to Intellectual Property Rights**

***Our ability to compete may be adversely affected if we do not adequately obtain, maintain, protect and enforce our intellectual property or proprietary rights, or if the scope of intellectual property protection we obtain is not sufficiently broad.***

Our success depends, in large part, on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to Lumoxiti and our product candidates. However, we may not be able to obtain, maintain or enforce our patents and other intellectual property rights which could affect our ability to compete effectively. For example, we cannot guarantee:

- that we will file all necessary or desirable patent applications or that we will obtain the patents that we have applied for and that are under review;
- that we will be able to develop new patentable product candidates or technologies or obtain patents to protect such new product candidates or technologies;

- that we or our licensing or collaboration partners were the first to make the product candidates or technologies covered by the issued patents or pending patent applications that we license or own;
- that we will be able to obtain sufficient rights to all necessary or desirable patents or other intellectual property rights, whether at all or on reasonable terms;
- that the scope of any issued patents that we own or license will be broad enough to protect Lumoxiti or our product candidates or effectively prevent others from commercializing competitive technologies and product candidates; and
- that there is no risk of our owned and licensed patents being challenged, invalidated or circumvented by a third-party.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. For example, we do not intend to systematically file, maintain, prosecute and defend patents on Lumoxiti and our product candidates in all countries. Consequently, we may not be able to prevent third parties from exploiting products that are the same as or similar to our products and product candidates in countries in which we do not obtain patent protection, or from selling or importing such products in and into the countries in which we do have patent protection. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, CROs, outside scientific collaborators, sponsored researchers, and other advisors, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. In addition, in some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering technology that we license to or from third parties. For example, pursuant to our license agreement with AstraZeneca for monalizumab, AstraZeneca retains control of such activities for certain patents that we license to it under the agreement and patents that arise under the collaboration. We cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interest of our business. If any third-party that controls our patents and patent applications fails to maintain our patents or such third-party loses rights to our patents or patent applications, our rights to those patents and underlying technology may be reduced or eliminated and our right to develop and commercialize our product candidates that are subject to such rights could be adversely affected.

Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may also need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from circumventing our patents by developing similar or alternative technologies or products in a non-infringing manner, or otherwise provide us with any competitive advantage. Challenges from competitors or other third parties could reduce the scope of our patents or render them invalid or unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection for Lumoxiti and our product candidates. The legal proceedings that we may then have to enter into in order to enforce and defend our intellectual property could be very costly and could distract our management and other personnel from their normal responsibilities, notably in the case of lawsuits in the United States. The probability of disputes arising over our intellectual property will increase progressively as patents are granted and as the value and appeal of the inventions protected by these patents are confirmed. The occurrence of any of these events concerning any of our patents or intellectual property rights could have a material adverse effect on our business, prospects, financial condition and results of operations. These risks are even higher for us, because of our limited financial and human resources.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations, and prospects.

***Third parties may allege that we or our partners infringe, misappropriate or otherwise violate such third parties' intellectual property rights, which could prevent or delay our development efforts, stop us from commercializing Lumoxiti or our product candidates, or increase the costs of commercializing Lumoxiti or our product candidates.***

Our commercial success depends on our ability and the ability of our partners to develop, manufacture, market and sell Lumoxiti and our product candidates, and use our proprietary technologies, without infringing, misappropriating or otherwise violating any intellectual property or proprietary rights of third parties. The field of biopharmaceuticals involves significant patent and other intellectual property litigation, which can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions also may be uncertain and difficult to determine.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In general, in the United States patent applications are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be sure that we were the first to make the inventions claimed in any owned or licensed patents or pending patent applications, or that we were the first to file for patent protection for such inventions. If we were not the first to invent such inventions or first to file any patent or patent application for such inventions, we may be unable to make use of such inventions in connection with our products. We may need to obtain licenses from third parties (which may not be available under commercially reasonable terms, or at all), delay the launch of product candidates, or cease the production and sale of certain product candidates or develop alternative technologies that are the subject of such patents or patent applications, any of which could have a material adverse effect on our business, prospects, financial condition and results of operations. For example, third parties may claim that lacutamab and other product candidates may use technology protected by their patents. Although we believe that our current activities and our planned development of lacutamab does not and will not infringe on such patents, which expire in the near term, third parties may disagree.

Third parties may allege that we or our partners infringe, misappropriate or otherwise violate any such third-party's patents or other intellectual property rights and assert infringement claims against us, regardless of their merit. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize Lumoxiti and any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third-party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to:

- bear the potentially significant costs of proceedings brought against us;



- pay damages, which may include treble damages and attorney's fees if we are found to have willfully infringed a third-party's patent rights;
- cease developing, manufacturing and commercializing the infringing technology or product candidates; and
- acquire a license to such third-party intellectual property rights, which may not be available on commercially reasonable terms, or at all, and may be non-exclusive thereby giving our competitors and other third parties access to the same technologies licensed to us.

Even if resolved in our favor, litigation or other intellectual property proceedings may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares or ADSs. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Should one or more of the foregoing risks materialize, this could have a material adverse effect on our reputation, business, prospects, financial condition and results of operations.

***Our patents could be found invalid or unenforceable if challenged and we may not be able to protect our intellectual property.***

Our and our licensors' patents and patent applications, if issued, may be challenged, invalidated or circumvented by third parties. U.S. patents and patent applications may also be subject to interference proceedings, re-examination proceedings, derivation proceedings, post-grant review or inter partes review in the United States Patent and Trademark Office, or USPTO, challenging our or our licensors' patent rights. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office. For example, two of our European patents with claims directed to a class of anti-NKG2A antibodies defined by characteristics shared with monalizumab have been challenged in oppositions at the European Patent Office, or the EPO. Although the Opposition Division of the EPO issued a decision that some claims directed to such class of anti-NKG2A antibodies are valid, the Opposition Division's decisions for both patents are currently under appeal. We have also received notices that third parties filed oppositions challenging our in-licensed European patents directed to certain of our CD39 technology, and these oppositions are currently pending.

In addition, we may allege that third parties infringe our or our licensors' patents and the defendant could counterclaim that such patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution.

Any such patent litigation or proceeding could result in the loss of our or our licensors' patents, denial of our or our licensors' patent applications or loss or reduction in the scope of one or more of the claims of such patents or patent applications. Accordingly, our or our licensors' rights under any issued patents may not provide us with sufficient protection against competitive product candidates or processes, we could become unable to manufacture or commercialize Lumoxiti or our product candidates without infringing third-party patent rights, and the duration of the patent protection of Lumoxiti or our product candidates could be limited. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if we are successful, such litigation or proceedings may be costly and may distract our management and other personnel from their normal responsibilities. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO, and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or patent applications and any patent rights we may own in the future. In certain circumstances, we may rely on our licensing partners to pay these fees. The USPTO and various foreign patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

Depending upon the timing, duration and conditions of FDA marketing authorization of Lumoxiti and our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, fail to exercise due diligence during the testing phase or regulatory review process or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from Lumoxiti or an applicable product could be reduced, possibly materially, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

***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 in all jurisdictions where we seek intellectual property protection.***

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

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and other countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***Third parties may assert ownership or commercial rights to products, product candidates or technologies that we develop.***

Third parties have made, and may in the future make, claims challenging the inventorship or ownership of our intellectual property, which may result in the imposition of additional obligations on us, such as development, royalty and milestone payments. We have written agreements with partners or other third parties that provide for the ownership of intellectual property arising from our collaborations and our other work with such third parties. These agreements provide that we must negotiate certain commercial rights with partners and other third parties with respect to joint inventions or inventions made by our partners or such third parties that arise from the results of the collaboration or other work with such third parties. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise under our agreements. For example, Orega Biotech SAS, or Orega Biotech, has made claims of joint ownership of certain patents relating to IPH5201, and we and Orega Biotech have agreed to resolve those claims in an arbitration proceeding. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a third-party's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. We also may be unsuccessful in executing assignment agreements with each party who, in fact, conceives or develops intellectual property that we regard as our own, or such agreements might not be self-executing or might be breached.

Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, may lose our exclusive rights in such intellectual property or may be required to acquire a license to such intellectual property, which may not be available on commercially reasonable terms or at all. Any of the foregoing could have a material adverse impact on our business.

***If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business, and we may not be successful in obtaining necessary intellectual property rights.***

We license intellectual property from third parties that is critical to our business through license agreements, including but not limited to licenses related to the manufacture, composition, use and sale of our product candidates, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. For example, we depend on our license agreement with AstraZeneca for the commercialization of Lumoxiti and our license agreement with Novo Nordisk A/S for the development and commercialization of monalizumab. Our license agreements impose various obligations on us, which may include development, royalty and milestone payments. If we fail to comply with any of these obligations, our licensors may have the right to terminate the agreements. If our license agreements with AstraZeneca or Novo Nordisk A/S or any other current or future licensors terminate, we would lose valuable rights and may be required to cease our development, manufacture or commercialization of Lumoxiti or our product candidates, including monalizumab. In addition, our business would suffer if our licensors fail to abide by the terms of the agreements, if our licensors fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the counterparty that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our counterparties and us; and
- the priority of invention of patented technology.

The agreements under which we currently license intellectual property from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract dispute that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or modify in a manner adverse to us what we believe to be our or our counterpart's financial or other obligations under the relevant agreement, any of which could have material adverse effect on our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current license agreement on acceptable terms, we may be unable to unsuccessfully develop and commercialize the affected product candidates.

Additionally, the growth of our business may depend, in part, on our ability to acquire, in-license or use proprietary rights held by third parties. We may be unable to acquire or in-license intellectual property rights from third parties that we identify as necessary for our product candidates on reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

As part of our business, we collaborate with non-profit and academic institutions to accelerate our preclinical research or development under agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's or its employees' rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable development or commercialization program. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon the development and commercialization of the relevant program and our business, financial conditions, results of operations and prospects could be adversely affected.

***Third parties may assert that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or misappropriated trade secrets of their current or former employers.***

We employ individuals who are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

In addition to patent protection, because we operate in the highly technical field of biopharmaceutical drug development, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We seek to protect our trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, CROs, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by such party or made known to such party by us during the course of such party's relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets and confidential information and these agreements may be breached, and we may not have adequate remedies for any breach.

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

Our trade and technical secrets include:

- certain unpatented technical expertise that we believe provides us with an advantage in conducting research and development work in our field;
- certain scientific knowledge generated by the work we carry out;
- certain information relating to the product candidates we are currently developing; and
- certain information relating to the agreements signed between us and third parties.

The unauthorized disclosure or misappropriation of certain of these secrets could allow third parties to offer products or services to compete with ours or generally have a material adverse effect on our business.

The structures put in place to protect our trade and technical secrets do not constitute a guarantee that one or more of our trade and technical secrets will not be disclosed or misappropriated. The agreements or other arrangements to protect our trade secrets may fail to provide the protection sought, or are breached, or that our trade secrets are disclosed to, or developed independently by, our competitors. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

***Unauthorized use of our trademarks may generate confusion and result in costs and delays to the detriment of our marketing efforts.***

Our trademarks are a key component of our identity and our products. Although the key components of our trademarks have been registered, notably in France and the United States, other companies in the pharmaceutical sector might use or attempt to use similar trademarks or components of our trademarks, and thereby create confusion in the minds of third parties. Our registered trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. In addition, there could be potential trademark infringement claims brought by owners of other trademarks that incorporate variations of our registered or unregistered trademarks.



In the event we develop trademarks for products that conflict with intellectual property rights of third parties, we would then have to redesign or rename our products in order to avoid encroaching on the intellectual property rights of third parties. This could prove to be impossible or costly in terms of time and financial resources and could be detrimental to our marketing efforts. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are the same as or similar to Lumoxiti and our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our owned or licensed pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- adverse results of delays in our or any of our competitors' preclinical studies or clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the termination of a strategic alliance or the inability to establish additional strategic alliances;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- ordinary share and ADS price and volume fluctuations attributable to inconsistent trading volume levels of our ordinary shares and ADSs;

- price and volume fluctuations in trading of our ordinary shares on Euronext Paris;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent and other intellectual property protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

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

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

The trading market for the ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. As a public company in France since 2006, our equity securities are currently subject to coverage by a number of analysts. If fewer securities or industry analysts cover our company, the trading price for the ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of the ordinary shares and ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for the ordinary shares and ADSs could decrease, which could cause the price of the ordinary shares and ADSs or their trading volume to decline.

***We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ordinary shares and ADSs. In addition, French law (including any temporary measures taken in response to COVID-19 pandemic) may limit the amount of dividends we are able to distribute.***

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

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with accounting standards applicable in France. Moreover, pursuant to French law, we must allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends, should we propose to declare any, may be paid for that year, until the amount in the legal reserve is equal to 10% of the aggregate nominal value of our issued and outstanding share capital. In addition, payment of dividends may subject us to additional taxes under French law. Therefore, we may be more restricted in our ability to declare dividends than companies that are not incorporated in France. See “Description of Share Capital–Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares” for further details on the limitations on our ability to declare and pay dividends and the taxes that may become payable by us if we elect to pay a dividend.

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

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

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

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

Our ADSs are listed on Nasdaq, and our ordinary shares are admitted to trading on Euronext Paris. Trading of the ADSs or ordinary shares in these markets take place in different currencies (U.S. dollars on Nasdaq and euro on Euronext Paris), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and France). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on Euronext Paris could cause a decrease in the trading price of the ADSs on Nasdaq. Investors could seek to sell or buy our ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange, and the ordinary shares available for trading on the other exchange. In addition, holders of ADSs are not immediately able to surrender their ADSs and withdraw 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.

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

We are a French company with limited liability. Our corporate affairs are governed by our bylaws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our Executive Board and of our Supervisory 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 Executive Board is required by French law to consider the interests of our company, its shareholders, its employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties have interests that are different from, or in addition to, your interests as a shareholder or holder of ADSs. See “Item 16G.—Corporate Governance.”

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

Most of the members of our Executive Board and Supervisory Board and the experts named therein are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation’s interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters.

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

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

- under French law, the owner of 90% of the share capital or voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the EEA Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, a non-resident of France, as well as any French entity controlled by non-residents of France, may have to file a declaration for statistical purposes with the Bank of France (Banque de France) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- under French law, certain investments in a French company relating to certain strategic industries by individuals or entities not residents in a Member State of the EU are subject to prior authorization of the Ministry of Economy;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our Executive 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 would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders may in the future grant our Executive Board broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our ordinary shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;

- our Supervisory Board appoints the members of the Executive Board and shall fill any vacancy within two months;
- our Supervisory Board has the right to appoint members of the Supervisory Board to fill a vacancy created by the resignation or death of a member of the Supervisory Board for the remaining duration of such member's term of office, and subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our Supervisory Board;
- our Executive Board can be convened by the chairman of the Executive Board or other members of the Executive Board delegated for this purpose;
- our Supervisory Board can be convened by the chairman or the vice-chairman of the Supervisory Board. A member of the Executive Board or one-third of the members of the Supervisory Board may send a written request to the chairman to convene the Supervisory Board. If the chairman does not convene the Supervisory Board 15 days following the receipt of such request, the authors of the request may themselves convene the Supervisory Board;
- our Supervisory Board meetings can only be regularly held if at least half of its members attend either physically or by way of videoconference or teleconference enabling the members' identification and ensuring their effective participation in the Supervisory Board's decisions;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove members of the Executive Board and/or members of the Supervisory Board with or without cause;
- the crossing of certain ownership thresholds has to be disclosed and can impose certain obligations;
- advance notice is required for nominations to the Supervisory Board or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a member of the Supervisory Board can be proposed at any shareholders' meeting without notice;
- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Regulation 596/2014 of April 16, 2014; and
- pursuant to French law, our bylaws, including the sections relating to the number of members of the Executive and Supervisory Boards, and election and removal of members of the Executive and Supervisory Boards from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

***Purchasers of ADSs in the U.S. offering are not directly holding our ordinary shares.***

A holder of ADSs is not treated as one of our shareholders and does not have direct shareholder rights. French law governs our shareholder rights. The depositary, through the custodian or the custodian's nominee, is the holder of the ordinary shares underlying ADSs held by purchasers of ADSs in the U.S. offering. Purchasers of ADSs in the U.S. offering have ADS holder rights. The deposit agreement among us, the depositary and purchasers of ADSs in the U.S. offering, as an ADS holder, and all other persons directly and indirectly holding ADSs, sets out ADS holder rights, as well as the rights and obligations of us and the depositary.

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

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

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

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



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

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

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

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

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our Executive Board and Supervisory Board members are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Paris and file financial reports on an annual and semi-annual basis, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year. Accordingly, there is and 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 to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.***

As a foreign private issuer listed on Nasdaq, we are subject to their corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of their home country. Some corporate governance practices in France may differ significantly from Nasdaq corporate governance listing standards. For example, neither the corporate laws of France nor our bylaws require a majority of our Supervisory Board members to be independent and although the corporate governance code to which we currently refer (the AFEP/MEDEF code) recommends that, in a widely-held company like ours, a majority of the Supervisory Board members be independent (as construed under such code), this code only applies on a “comply-or-explain” basis and we may in the future either decide not to apply this recommendation or change the corporate code to which we refer. Furthermore, we include non-independent members of the Supervisory Board as members of our compensation and nomination committee, and our independent Supervisory Board members do not necessarily hold regularly scheduled meetings at which only independent members of the Supervisory Board are present. Currently, we intend to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. For an overview of our corporate governance practices, see “Item 16G.—Corporate Governance.”

***We are an “emerging growth company” under the JOBS Act and are able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which can make our ordinary shares ADSs less attractive to investors.***

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 not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute 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.

We cannot predict if investors will find the ordinary shares or ADSs less attractive because we may rely on these exemptions. If some investors find the ordinary shares or ADSs less attractive as a result, there may be a less active trading market for the ordinary shares or ADSs and the price of the ordinary shares or ADSs may be more volatile. We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer" with at least \$700 million of equity securities held by non-affiliates; (3) the issuance, in any three year period, by our company of more than \$1.0 billion in non-convertible debt securities held by non-affiliates; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering of the ADSs.

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

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made on June 30, 2020. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our Executive Board or Supervisory Board are residents or citizens of the United States, we could lose our foreign private issuer status.

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

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

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ended December 31, 2018, we believe that we were not a passive foreign investment company, or PFIC, for the taxable year ended December 31, 2019. However, there can be no assurance that we will not be a PFIC in the current year or for any future taxable year. Under the Code, a non-U.S. company will be a PFIC for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. holder (as defined below under "Item 10E.—Taxation – Material U.S. Federal Income Tax") holds our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are a PFIC for any taxable year during which a U.S. holder holds our ordinary shares or ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. For further discussion of the PFIC rules and the adverse U.S. income tax consequences in the event we are classified as a PFIC, see the section of this Annual Report titled "Item 10E.—Taxation—Material U.S. Federal Income Tax Considerations."

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

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Our group currently includes one U.S. subsidiary and, therefore, under current law our current non-U.S. subsidiary and any future newly formed or acquired non-U.S. subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Code. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.