PART I

Item 1.Identity of Director, Senior Management and Advisers.

Not applicable.

Item 2.Offer Statistics and Expected Timetable.

Not applicable.

Item 3.Key Information.

A. Selected Financial Data

We have elected to comply with Item 3.A. of Form 20-F (Selected Financial Data); as amended February 10, 2021 and are omitting this disclosure in reliance thereon.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to the Discovery and Development of and Obtaining Regulatory Approval for Our Product Candidates

Our drug candidate development activities are focused primarily on the development of our drug candidate elafibranor in PBC as well as on other drug candidates for which development is less advanced. Drug development is subject to a number of risks.

Elafibranor, our most advanced drug candidate, is currently being evaluated in a Phase 3 ELATIVE clinical trial in PBC. Only two treatments are currently approved and marketed in this indication and do not meet the medical needs of all patients. A limited number of treatments are therefore approved for the management of this disease and we have little experience with drug development in this disease area. The development and approval of drug candidates to treat PBC may therefore present an even higher level of risk than in other indications.

As a result, it is possible that our ELATIVE clinical trial or other additional clinical trials in PBC in particular, and our other ongoing or future clinical trials in general, fail to meet their primary endpoints, as was the case with our Phase 3 RESOLVE-IT trial evaluating elafibranor in NASH in 2020, or are delayed, additional development is necessary or, despite a favorable outcome in clinical trials, the regulatory authorities consider that the clinical results of these trials are insufficient to grant or maintain a marketing authorization. These different risks are developed below.

Our other program, NTZ in fibrosis, is at an earlier stage of development. NTZ it is currently being evaluated in an independent investigator-led Phase 2 trial for the treatment of patients with NASH with severe fibrosis.

A clinical failure of elafibranor in PBC, a delay or an increase in the cost of its clinical development or the failure to receive marketing authorization would therefore have a negative impact, even more so since it would impact our primary program and the most advanced in our portfolio of drug candidates. As a result, we could be forced to discontinue our development in PBC, one of our main programs, which could significantly affect the future of our Group.

Clinical failure can occur at any stage of clinical development, as was the case with our Phase 3 RESOLVE-IT trial of elafibranor in NASH. The results of earlier clinical trials are not necessarily predictive of future results and elafibranor in PBC or any other product candidate that we or our collaborators advance through clinical trials may not have favorable results in later clinical trials, which may delay, limit or prevent our ability to receive regulatory approval or marketing authorization.

Clinical failure can occur at any stage of our clinical development or those of our current partner or a future partner. Clinical trials may produce negative or inconclusive results, and 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 or our collaborators do, which may delay, limit or prevent regulatory approval or marketing authorization.

Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us or our current and potential future collaborators, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development in particular in PBC even after seeing promising results in earlier clinical trials.

For example, in May 2020, we published the top line results of the interim analysis of our Phase 3 RESOLVE-IT trial of elafibranor in NASH. Elafibranor did not demonstrate a statistically significant effect on the primary surrogate efficacy endpoint of NASH resolution without worsening of fibrosis nor on the key secondary endpoints. These results led us to stop development of elafibranor in NASH in 2020 due to lack of efficacy but not due to safety reasons.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We or our collaborators may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If elafibranor or our other drug candidates are found to be unsafe or lack efficacy for any indication, we or our collaborators will not be able to obtain regulatory approval for them, and our prospects and business may be materially and adversely affected. For example, if the results of our Phase 3 ELATIVE trial of elafibranor in PBC does not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of elafibranor in PBC would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes or differences in trial protocols, patient distribution by clinical investigator site, standards of care across sites, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we or our collaborators are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term shareholder value will be limited.

Delays in the commencement, enrollment and completion of clinical trials, including our Phase 3 ELATIVE trial of elafibranor in PBC, could result in increased costs to us and delay or limit our ability and that of Terns Pharmaceuticals, our partner in some territories and for some indications and that of any future collaborators, to obtain regulatory approval for elafibranor and our other drug candidates.

We currently have underway two advanced phase clinical trials, in particular our Phase 3 ELATIVE trial of elafibranor in PBC for which the first patient was enrolled in September 2020. Delays in the commencement, enrollment and completion of our clinical trials or those of our partner Terns Pharmaceuticals or any future collaborator could increase our product development costs or limit our ability to obtain regulatory approval of our drug candidates. In the past, we have experienced some delays in enrollment in our clinical trials, including in our RESOLVE-IT clinical trial.

The results from these trials may not be available when we expect or we or our collaborators may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for our product candidates, including elafibranor. In addition, our clinical programs and those of our partner are subject to a number of variables and contingencies, such as the results of other trials, patient enrollments or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies in elafibranor or our other product candidates will begin on time or will be completed on schedule, if at all.

The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to demonstrate sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- inability to validate test methods to support quality testing of the drug substance and drug product;
- inability to determine dosing and clinical trial design;
- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- inability to reach agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA, EMA or other non-U.S. regulators regarding the scope or design of our clinical trials, which may occur at various times, including subsequent to the initiation of the clinical trial;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- varying interpretations of our data, and regulatory commitments and requirements by the FDA, EMA and similar regulatory agencies;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- lack of effectiveness of product candidates during clinical trials;
- suspension or termination by a data and safety monitoring board, or DSMB, that is overseeing the clinical trial;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;
- a breach of the terms of any agreement with, or termination for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, or investigators leading clinical trials on our product candidates;
- inability to timely manufacture or deliver sufficient quantities of the product candidate required for preclinical studies or clinical trials;

- difficulty identifying, recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the rarity of the disease or condition, the rarity of the characteristics of the population being studied, the nature of the protocol, the risks of procedures that may be required as part of the trial, such as a liver biopsy, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial, and competition from other clinical trial programs for the same indications as our product candidates;
- global health pandemics such as COVID-19 or natural disasters; and
- inability to retain enrolled patients after a clinical trial is underway.

For example, our RESOLVE-IT trial was a large and complex Phase 3 clinical trial in a disease without any approved therapies and the diagnosis of which generally involves invasive procedures such as liver biopsies. These specificities led us to face significant competition for patient enrollment, and to delay the publication date of our top line interim analysis.

As we engage in other large and complicated trials and trials in advanced disease populations, including our ongoing Phase 3 ELATIVE trial evaluating elafibranor in PBC, we may experience a number of complications that may negatively affect our plans or our development programs. The ELATIVE trial evaluating elafibranor in PBC in particular is made complex by the fact that it is an orphan disease with a small number of patients and the fact that one of our competitor’s product is the only one to have recently received market approval in this indication, and another phase 3 trial is enrolling patients at the same time as ours which may compromise our ability to retain or recruit patients or complete the trial on time . Potential discussions with the FDA, the EMA or other regulatory authorities outside the United States or Europe regarding the scope or design of our clinical trials may also happen at any time.

More broadly, changes in the treatment of PBC, such as the approval of a drug therapy for the treatment of PBC by one of our competitors, could result in difficulties retaining or enrolling patients in our clinical trials and those of our current or collaborators. Any difficulty retaining patients may in the future delay or produce negative or inconclusive results from our clinical trials, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. Any delay or compromises with respect to our clinical trials may have a material adverse effect on our business or decrease our competitive position relative to other biotechnology or pharmaceutical companies.

We cannot be certain that elafibranor or any of our other product candidates, even if they meet clinical and regulatory requirements, will receive regulatory approval, and without regulatory approval, we will not be able to market our product candidates.

We currently have no products approved for sale and we cannot guarantee that we or any of our current or future collaborators will ever have marketable products. Our business currently depends substantially on the successful development and commercialization of elafibranor in PBC. Our ability to generate revenue related to product sales will depend on the successful development and regulatory approval of elafibranor in the indications we are developing in the United States, the European Union and other countries. Our ability to generate substantial revenue is also dependent on the future of the development and marketing of an IVD test using our NIS4 technology.

The development of drug candidates and NIS4 and issues relating to their approval and marketing are subject to extensive regulation by the FDA in the United States, the European Union and EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country.

We (or a future partner of ours) will not be permitted to market our drug candidates in the United States or Europe until we receive approval of a New Drug Application, or NDA, from the FDA or a marketing authorization application, or MAA, from the European Commission (based on the positive opinion of the EMA), as applicable. The same is true for other countries, including the United Kingdom since Brexit. We have not submitted at this time any marketing applications for any of our product candidates and neither has Terns Pharmaceuticals, our development partner for elafibranor in some territories and for some therapeutic indications, for its products. NDAs, MAAs and marketing applications in other countries must include extensive preclinical and clinical data and supporting information to establish the drug candidate’s safety and effectiveness for each desired indication. These marketing applications must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a NDA, MAA or other marketing authorization is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval.

We cannot predict whether our ongoing or planned future trials and studies will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date, or for ongoing trials, with our interim results.

Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates and diagnostics with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate or diagnostic in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

If we, our partner Terns Pharmaceuticals or a future partner are unable to obtain approval from the FDA, the EMA or other regulatory agencies for elafibranor, NIS4 and our other product candidates, or if, subsequent to approval, we, our partner Terns Pharmaceuticals or a future partner are unable to successfully commercialize elafibranor, NIS4 or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

We have obtained breakthrough therapy designation from the FDA for elafibranor in the treatment of PBC and we may seek to avail ourselves of such mechanisms to expedite the development or approval of elafibranor for another indication or in combination in the future or in order to accelerate the development or approval of our other drug candidates, but such mechanisms may not actually lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that elafibranor will receive marketing approval for this indication.

In 2019, the FDA granted breakthrough therapy designation for elafibranor for the treatment of PBC. We may also seek breakthrough therapy designation for elafibranor in a different indication or in combination or for any other drug candidate that we may develop in the future. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that are designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a drug candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA.

In addition, even if one or more drug candidate qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Even though we have obtained orphan drug designation for elafibranor for the treatment of PBC in both the US and EU, we may not be able to obtain or maintain the benefits associated with orphan drug status, including market exclusivity. We may also seek the same designation for elafibranor in a different indication or for any of our other drug candidates, but we may not be able to obtain it or maintain the benefits associated.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for that time period.

We received orphan drug designation in both the US and the EU for elafibranor for the treatment of PBC in 2019, and we or a future partner may request the orphan drug designation for elafibranor in another indication or for other drug candidates that we may develop in Europe and/or the United States.

However, we or our partner may not receive such designation for other drug candidates that we or our partner may develop in Europe and/or the United States or for any other drug candidate in any other jurisdiction, or for elafibranor in any other indication. Even if we or our partner successfully receive the orphan drug designation, the orphan drug designation does not necessarily guarantee market exclusivity on a given market. Even if we or our partner successfully obtain the exclusivity pertaining to the orphan drug designation for any of our drug candidates, this exclusivity may not protect the product efficiently as exclusivity may be suspended under certain circumstances. In the United States, even after a drug is granted orphan exclusivity and 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, the exclusivity pertaining to the orphan drug designation will not prevent the marketing approval of a similar drug for the same condition if the later drug is shown to be safer, more effective or otherwise clinically superior to the first drug, or if the owner of the market approval of the first product does not have the capacity to deliver sufficient quantities of the product. In addition, if another orphan designated product receives marketing approval and exclusivity for the same condition as the one for which we or a future partner seek to develop a drug candidate, we or our partner may not be able to receive approval of our drug candidate by the relevant regulatory authorities for a significant period of time.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are currently conducting a clinical-stage program based on drug repositioning to develop an anti-fibrotic drug candidate, nitazoxanide, or NTZ, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. The Phase 2 investigator-initiated clinical trial of NTZ in NASH-induced fibrosis was allowed based on the existing FDA evaluations of safety in the currently-approved indication, which is a hallmark of the Section 505(b)(2) regulatory pathway. As we progress the clinical program, we plan to initiate such discussions with the FDA. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as we anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we or a future partner are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Due to our limited resources and access to capital, our strategic decisions with respect to the development of certain product candidates may affect the development or timing of our business prospects.

Because we have limited resources and access to capital to fund our operations, we have chosen to concentrate a significant amount of our resources on the development of elafibranor as a potential treatment for PBC, as well as, to a lesser extent, on the development of our NIS4 technology and other product candidates in our pipeline. In 2020, we announced a cost reduction plan,

to reduce operational expenses and eliminate non-essential expenses. Our goal is to reduce our cash burn rate from €110 million annually before we announced our Phase 3 RESOLVE-IT data, to approximately €45 million annually, beginning in 2022. 2021 will be a transition year with a targeted cash burn of approximately €75 million (excluding the partial OCEANEs buyback transaction for €47.5 million in cash) mainly due to the residual expenses related to the termination of the RESOLVE-IT clinical trial, and to costs associated with the workforce reduction plan. As a result, our resources available to allocate to research, collaboration, management and financial resources toward particular compounds, programs, product candidates or therapeutic areas are limited. We may be restricted in the opportunities we can pursue, and we may be required to collaborate with third parties to advance a particular product candidate at terms that are less than optimal to us. Because of our limited resources, we may also have to decline to pursue opportunities that may otherwise prove to be profitable.

Our product candidates may have undesirable side effects which may require us to stop a clinical trial or which may delay or prevent marketing approval, or, if approval is received, require our product candidates to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our product candidates could arise either during clinical development, forcing us to potentially stop or terminate a trial, or, if approved, after the approved product has been marketed. If severe side effects were to occur, or if elafibranor or one of our other product candidates is shown to have other unexpected characteristics, we or our current or future collaborators may need to either restrict our use of such product to a smaller population or abandon our or their development.

In addition, our product candidates are being developed as potential treatments for severe, life-threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. For example, PBC patients may suffer from other co-morbidities such as osteoporosis that may increase the likelihood of certain adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our product candidates or some other factor, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drugs and drug candidates. We further cannot assure you that additional or more severe adverse side effects with respect to elafibranor, NTZ or any other drug candidate will not develop in current or future clinical trials or commercial use, which could delay or preclude their regulatory approval, limit their commercial use or require them to be taken off the market.

If we or others later identify undesirable or unacceptable side effects caused by our products or product candidates:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we or current or future collaborators may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us or current or future collaborator(s) to take our approved product off the market;
- we or current or future collaborator(s) may be subject to litigation or product liability claims; and
- our reputation or that of our current or future collaborator(s) may suffer.

Risks Related to the Discovery and Development of, and Obtaining Regulatory Approval for, our Diagnostic Test

The development of our NIS4 technology and tests powered by this technology requires access to clinical trials, data and clinical samples in NASH patients and therefore our development is subject to the risks related to these trials.

In January 2019, we entered into a license agreement with Labcorp to allow them to develop and deploy a test powered by NIS4 technology in the clinical research space. We believe that leveraging the capabilities of a large diagnostic company such as Labcorp, through its Covance laboratory network, will allow for early adoption of NIS4 technology and result in third party publications. In September 2020, we entered into a five-year exclusive licensing agreement for NIS4 technology with Labcorp. As part of the agreement, Labcorp will develop and commercialize a blood-based molecular diagnostic test powered by NIS4 technology throughout the U.S. and Canada enabling widespread access to healthcare providers. We expect this agreement with

Labcorp to provide broad clinical availability of a LDT powered by NIS4 technology to specialty and primary care physicians across the U.S. and Canada. Labcorp will leverage its deep experience in commercializing innovative diagnostics to educate providers on NASH and the importance of non-invasive testing. We believe this recent agreement will enable broader test availability to support evidence generation, demonstration of clinical utility, and favorable market access of the test powered by NIS4. We intend to benefit from these advantages to support the next step of the development, clearance, and commercialization of an IVD powered by NIS4 to enable even broader availability of the clinical diagnostic outside of the central lab setting.

Development of an IVD will nevertheless require us to keep gathering clinical data within the framework of trials or observational studies in which NIS4 is currently being evaluated or within the framework of potential additional clinical trials or observational studies to come.

In these trials or observational studies, we will continue to use human samples. Even if we have preferred access to the samples collected during the clinical development of elafibranor in NASH, we may be unable to access a sufficient quantity of samples or samples of a sufficient quality or usability, in which case the continuation of the development of NIS4 could be slowed down or even interrupted. In order to have access to samples, we may be required to enter into partnership agreement with hospitals or key opinion leaders, and we may not be able to enter into these agreements under satisfactory conditions or within the desired timeframes, if at all.

The strength of NIS4 technology initially identified on a relatively limited number of samples could turn out to not be sufficient during potential future validation studies on larger target populations, and notably not display sufficient levels of accuracy, sensitivity or specificity in order to allow for the development of a competitive test for clinical care that would be adopted by the medical community.

Despite the care applied to the development of NIS4 technology, we may not exclude the appearance after the development phase of inherent defects to the product or technology that were undetectable or inconspicuous defects based on the existing technical and scientific knowledge during the development. A failure may occur at any time during one of these clinical developments. The results of earlier clinical trials or studies does not allow predicting future results and NIS4 technology may not obtain favorable results in the clinical studies that we will keep conducting. In particular, these may not allow to reinforce the state of knowledge pertaining to it and to demonstrate its clinical utility nor the medico-economic benefit. It is possible, in particular, that an LDT or IVD powered by NIS4, at the time of its launch on the market for clinical care, will not replace the current tests and medical examinations. In that case, the place of a test powered by NIS4, initially or as a complement or substitute of certain examinations would have to be assessed through additional clinical studies that would allow evaluating its medico-economic benefit often required to obtain reimbursement. The results of these studies may not allow to define for NIS4 a place that answers the needs of clinical practitioners or to demonstrate its favorable economic outcome. With such results, a test powered by NIS4 may not obtain reimbursement, especially in European countries, and see its sales stagnate at a low level, or even not be able to be sold.

Moreover, the data gathered during these trials and studies are subject to different interpretations, and regulatory authorities may not interpret our data as favorably as us or our collaborators, which may delay, limit or prevent the regulatory authorization for the use of an IVD powered by NIS4 as a diagnostic tool for clinical care. Besides, the design of these trials may determine if their results can support the application for market approval and procedural defects of a trial may not be visible before the trial reaches an advanced stage. We or our collaborators may not be able to design and conduct a clinical trial sufficient to support a regulatory market approval of an IVD powered by NIS4 for clinical care, which may have a significant unfavorable impact on our perspectives and activities.

Changes in regulatory requirements or guidelines issued by the regulatory authorities, or unforeseen events occurring during these trials may force us or our collaborators to alter the protocol or impose new requirements within the framework of these trials or studies, which may result in higher costs and delays in the development schedule of NIS4 technology. If delays occurred in the completion of these clinical trials, or if they were terminated, or if additional clinical trials or studies were required besides the planned ones, this would impact the commercial perspectives of an IVD powered by NIS4 and our ability to generate direct or indirect industrial revenue from this product would be delayed.

We intend to develop and market an in-vitro diagnostic or IVD powered by NIS4 as a clinical diagnostic and as such, NIS4 remains a product in development subject to the hazards of diagnostic product development. In addition, there is no assurance that we will be able to receive the necessary regulatory approvals to market an IVD, powered by NIS4 technology or achieve commercialization of this product candidate for our intended market.

We intend to develop an IVD powered by NIS4 to identify patients with NASH and fibrosis who may be eligible for therapeutic interventions in a field where no NASH-specific non-invasive test has been approved nor commercialized for clinical care to date and for which clinical experience is currently limited. Our development approach relies therefore on new methodologies. It is thus possible that, in this context, our clinical trials do not meet a favorable outcome or that, despite a favorable outcome, regulatory authorities evaluate that the results of our clinical trials or those of our collaborators are insufficient to grant market approval for an IVD test using the NIS4 technology for clinical care. Despite the care applied to the development of NIS4, we may not exclude the appearance after the development phase of inherent defects to the product that were undetectable or inconspicuous defects based on the existing technical and scientific knowledge during the development.

In order to be allowed to directly market and sell an IVD powered by NIS4 in the European Union and the United States, the product must achieve CE marking from a qualified Notified Body in Europe and FDA approval/clearance in the United States. Other relevant regulatory requirements must be met to market in other countries.

In the United States, IVD tests are regulated as medical devices. Therefore, to be commercially distributed for clinical care, an IVD diagnostic product must demonstrate, depending on its regulatory classification, either its safety and efficiency through a pre-market approval, or its substantial equivalence to a previously FDA-approved medical device through clearance of a 501(k) premarket notification. This regulatory classification may not be obtained. A clinical trial is almost always required to support a pre-market approval or PMA application and is sometimes required for 510(k) clearance. All clinical studies of medical devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements.

Alternatively, the product may be marketed as a Laboratory Developed Test or LDT, which does not require FDA approval, but requires the laboratory conducting the test to have been certified under the Clinical Laboratory Improvement Amendments of 1988 Act or CLIA and certain state laboratory licenses. Both testing services by Labcorp and Covance are currently conducted within the framework of CLIA, which establishes quality standards that must be followed in laboratory testing in order to ensure accuracy, reliability and speed of patient test results wherever the test is conducted. This law has instated an accreditation program for clinical laboratories, which Labcorp and Covance have received.

We currently do not have any IVD approved or cleared test that has been approved for marketing through such a regulatory process and we cannot guarantee that we or potential or future collaborators will ever own marketable IVD tests. We have not submitted any marketing applications for any IVD test, and, in particular, we have not submitted any marketing application for NIS4.

As with approval of our drug candidates, the process for obtaining marketing authorization of diagnostic candidates for clinical care is lengthy, uncertain and expensive. In the United States, IVD tests are regulated as medical devices. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labelling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance.

Concurrently with evaluating the FDA approval process for our IVD test, we are collecting data to obtain CE Mark and the subsequent market authorization in the key European markets. Like the U.S. approval process, the CE marking process in Europe may be lengthy and expensive, and the exact date of market approval issuance, if received at all, remains hard to predict.

Each regulatory authority may indeed refuse to issue approval, impose its own conditions to such issuance, or require additional data prior to issuance, even when such approval would have been already granted by regulatory authorities in other jurisdictions. Regulatory authorities may also modify their approval policies, particularly by adding new or additional conditions to grant approval. The European Commission, for example, published in 2012 two European regulation proposals in order to replace the currently applicable directives on medical devices. The European Commission indicated at the time that the European regulations may be adopted in 2014 and come into force between 2017 and 2019. Since then, the European Parliament has adopted legislative resolutions on the proposed regulations at first reading on April 2, 2014. The new regulation was unanimously approved by the European Council during its June 2015 session. These modifications mostly require the implementation of a new classification of in-vitro diagnostic medical devices (IVDMD) and the strengthening of requirements regarding the level of detail to be presented about relevance and clinical validation. After its adoption by the European Council on March 7, 2017 and the

European Parliament on April 5, 2017, the new (EU) 2017/746 regulation on in-vitro diagnostic medical devices (IVDMD) came into force on May 25, 2017. The transition period will last 5 years, until 2022, during which medical devices manufacturers will be required to update their technical documentation process.

We or our potential collaborators may therefore be subject to delays in obtaining the approval required to market NIS4 for clinical care, or even not be successful in receiving approval. Such delay or failure may have an unfavorable impact on our ability to market NIS4 and our ability to generate direct or indirect revenue from this activity.

Even after regulatory approval has been granted or declarations of commercialization have been filed with regulatory authorities, IVD tests remains subject to pharmacovigilance monitoring of incidents and risks of incidents related to their use. Even though these are relatively rare with non-invasive products like IVD tests, such incidents may occur and lead regulatory authorities to suspend or even revoke the market authorization of such products. Regulatory authorities may also conclude that procedures put it place by us or our collaborators are insufficient in order to identify and handle incidents, and could suspend commercialization of the products until these procedures are considered sufficient.

Risks Related to the Commercialization of Our Drug Candidates and Diagnostic Test

Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.

The commercial success of elafibranor as a potential treatment for PBC, an LDT or IVD powered by NIS4 or our other drug candidates, if approved or cleared, will depend upon their acceptance among the medical community, including physicians, healthcare payors and patients. Given that there are a limited number of products approved for the treatment of PBC, we do not know the degree to which elafibranor would be accepted as a therapy, if approved. Additionally, we cannot be assured that an LDT or IVD powered by NIS4 will be accepted by the medical community as a means of identifying patients with NASH or fibrosis who may be appropriate candidates for therapeutic intervention, and even if an LDT or IVD powered by NIS4 is used, a physician may still require additional testing (e.g. liver biopsy) to confirm diagnosis. The degree of market acceptance of elafibranor, an LDT or IVD powered by NIS4 and any of our other drug candidates that may be approved will depend on a number of factors, including:

- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our product candidates, such as competitors' product candidates for the treatment of PBC or an alternative to liver biopsy for the diagnosis of NASH and fibrosis;
- limitations in the approved clinical indications or patient populations for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- limitations or warnings, including boxed warnings, contained in our drug candidates' FDA- or EMA-approved labeling;
- in the case of elafibranor, our ability and that of our partner, Terns Pharmaceuticals or of a potential future collaborator to access the PBC market;
- for an LDT powered by NIS4, the ability of our partner, Labcorp or of a potential future collaborator to access the clinical research or clinical diagnostic market,
- for an IVD powered by NIS4, our ability to develop, obtain regulatory approval and commercialize an IVD test for clinical care;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of coverage and adequate reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies or diagnostic solutions at similar or lower cost, including generics and over-the-counter products;

- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug or diagnostic candidates are designated under physician diagnostic and treatment guidelines for the treatment of the indications for which we, our partner, Terns Pharmaceuticals or a potential future partner have received regulatory approval;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If we, or our current or future collaborators are unable to establish sales, marketing and distribution capabilities for elafibranor or our other product candidates, we may not be successful in commercializing those product candidates if and when they are approved.

We have no sales, marketing or distribution experience and if we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved. To develop internal sales, distribution and marketing capabilities, we have already begun to invest significant amounts of financial and management resources, and we may continue to do so, even prior to any confirmation that our product candidates will be approved. In particular, if elafibranor obtains marketing authorization in an indication, we may decide to market elafibranor in certain territories by ourselves, and/or market it in other territories in collaboration with one or more pharmaceutical partners and/or specialized local distributors. For example, in June 2019, we entered into a licensing and collaboration agreement with Terns Pharmaceuticals to develop and commercialize elafibranor for the treatment of NASH and PBC in mainland China, Hong Kong, Macau and Taiwan (Greater China). Additionally, in connection with the development of NIS4 technology, we entered into a license agreement with Labcorp to allow them to develop and deploy a test powered by NIS4 in the clinical research space through their subsidiary Covance. In September 2020, we entered into a five-year exclusive licensing agreement for NIS4 technology with Labcorp. As part of the agreement, Labcorp will develop and commercialize a blood-based molecular diagnostic test powered by NIS4™ technology throughout the U.S. and Canada enabling widespread access to healthcare providers. We believe this agreement with Labcorp will provide broad clinical availability of a LDT powered by NIS4 technology to specialty and primary care physicians across the U.S. and Canada.

If we decide to market any of our products ourselves, we would need to develop our own sales and marketing capabilities. For elafibranor or any other product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force;
- our sales personnel may be unable to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

If we are unable to establish our own sales, marketing and distribution capabilities and decide to enter into arrangements with third parties to perform these services for the products on the markets or indications that are not already subject to licensing agreements, our revenue and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any products that we develop ourselves. Additionally, such collaboration agreements with current or potential collaborators may limit our control over the marketing of our products and expose us to a number of risks, including the risk that the partner will not prioritize the marketing of the product candidate or diagnostic test candidate or does not provide sufficient resources for its commercialization.

We have entered into, and may continue to seek and form, strategic alliances or enter into licensing or co-marketing arrangements to commercialize our approved drugs or diagnostic products, and we may not realize the benefits of such arrangements.

We may enter into licensing arrangements with third parties that we believe will complement or augment our commercialization efforts, particularly with respect to elafibranor and the diagnostic use of NIS4 for clinical care. For example, we have entered into a licensing and collaboration agreement with Terns Pharmaceuticals to develop and commercialize elafibranor for the treatment of NASH and PBC in Greater China and we have entered into a license agreement with Labcorp to allow them to deploy an LDT powered by NIS4 in the clinical research and clinical diagnostics spaces. Any of these relationships may require us to incur costs, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. Our likely collaborators include, in the case of elafibranor, large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies, or, in the case of NIS4, a major global diagnostic company. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of elafibranor or any other product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Collaborations involving elafibranor, an LDT or IVD powered by NIS4 or any of our other drug candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue commercialization or may elect not to continue or renew commercialization programs based on changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if the collaborators believe that competitive products are more likely to be successfully commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of any such product candidate;
- collaborators may not properly maintain or defend our intellectual property 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;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;

- collaboration agreements may not lead to commercialization of our product candidate in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaborators may be unable to obtain the necessary marketing approvals.

If future collaboration partners fail to develop or effectively commercialize elafibranor, an LDT or IVD powered by NIS4 or any other drug candidate for any of these reasons, such product candidate may not be cleared for sale and our sales of such product candidate, if approved, may be limited, which would have an adverse effect on our operating results and financial condition.

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

Even if we or our collaborators receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies or diagnostic solutions. For instance, a regulatory approval may limit the indicated uses for which we or our collaborators can market a product or the patient population that may utilize the product, or may be required to carry a warning, such as a boxed warning, in its labelling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively.

Additionally, any of our product candidates for which we or our collaborators obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labelling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the EMA, FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping.

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the EMA and the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug.

After approval, most changes to the approved drug, such as adding new indications or other labelling claims and some manufacturing and supplier changes are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for marketed drugs, as well as new application fees for certain supplemental applications. Once approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including adverse effects of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labelling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a risk evaluation and mitigation strategy, or REMS. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Elements to assure safe use can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can be costly to establish and can materially affect the potential market and profitability of the drug.

Depending on the outcome, the FDA or EMA could revoke the previously granted approval.

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labelling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil, criminal and administrative penalties. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Similarly, if an IVD powered by NIS4 is authorized for marketing for clinical care in the United States, the test will be subject to quality system regulation, or QSR, labelling regulations, registration and listing, the Medical Device Reporting regulation which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur and the Reports of Corrections and Removals regulation which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA. The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled or public warning letter to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMAs already granted; and criminal prosecution.

Accordingly, assuming we or our current or future collaborators receive marketing approval for one or more of our product candidates, we and our collaborators will continue to expend time, money and effort in all areas of regulatory compliance.

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

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

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. In addition, in the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our or our collaborators' ability to raise commercial prices. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore,

coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us or our collaborators to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The continuing efforts of third-party payors of healthcare costs to contain or reduce costs of healthcare may negatively affect our or our collaborators commercialization prospects, including:

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

Our or our collaborators' ability to obtain an acceptable reimbursement rate for our drugs from third-party payors will be determined in the coming years, in particular at the end of the development of elafibranor in PBC, which is our most advanced drug candidate. We cannot be sure that coverage and reimbursement will be available for any potential product candidate that we or our collaborators may commercialize and, if reimbursement is available, what the level of reimbursement will be. Since few drugs have been commercialized in PBC, we are currently working internally on market access and pricing, but cannot predict the conditions of elafibranor's future reimbursement. However, because negotiations with the payors are traditionally based on the results (intermediate, or otherwise) of Phase 3 clinical trials, we have only had preliminary discussions with the organizations concerned. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our collaborators obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, is significantly impacting the provision of, and payment for, healthcare. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Some of the provisions of the ACA have yet to be implemented, and there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In addition, the Centers for Medicare & Medicaid Services, or CMS, promulgated regulations to give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made or how the Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation and the health reform measures of the Biden administration will impact the ACA and our business.

In addition, both the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 have instituted, among other things, mandatory reductions in Medicare payments to certain providers. However, the Medicare sequester reductions under the Budget Control Act of 2011 will be suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Legislation is currently pending in Congress that would further extend the suspension through December 31, 2021. 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 coverage and/or reimbursement of our product candidates, if approved.

Moreover, recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. 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.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, at both the federal and state levels in the United States, as well as internationally, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product candidate. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new U.S. presidential administration. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

Failures to reimburse an LDT or IVD powered by NIS4, if commercialized for clinical care, or changes in reimbursement rates by third-party payors and variances in reimbursement rates could materially and adversely affect our revenues and could result in significant fluctuations in our revenues.

Our ability or that of a potential future collaborators to commercialize an LDT or IVD powered by NIS4 also will depend in part on the extent to which coverage and adequate reimbursement for this test will be available from third-party payors, such as government health administration authorities, private health insurers and other organizations. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of a newly commercialized diagnostic test. It is uncertain as to what extent third-party payors will provide coverage for an LDT or IVD powered by NIS4, if commercialized for clinical care. We will also likely experience volatility in the coverage and reimbursement of LDT or IVD test due to contract negotiation with third-party payors and implementation requirements.

The reimbursement amounts we receive from third-party payors will vary from payor to payor, and, in some cases, the variation is material. Third-party payors have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostic test industry. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in the reimbursement rate provided by third-party payors may occur in the future. Reductions in the price at which an LDT or IVD powered by NIS4 is reimbursed could have a material adverse effect on our revenues. If we and our potential future collaborators are unable to establish and maintain broad coverage and adequate reimbursement for an LDT or IVD powered by NIS4 or if third-party payors change their coverage or reimbursement policies with respect to the LDT or IVD test, our revenues could be materially and adversely affected.

Our future growth depends, in part, on our or our collaborators' ability to penetrate international markets, where we or they would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend on our or our collaborators' ability to commercialize our product candidates in the United States, Europe and other territories around the world. If we or our collaborators commercialize our product candidates in international markets, we would be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing non-U.S. regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in non-U.S. countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or other governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some countries outside the United States, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing reimbursement landscapes globally;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by laws outside the United States in the event of a contract dispute.

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

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

Future sales of our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, the COVID-19 pandemic or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for elafibranor, an LDT or IVD powered by NIS4 or any of our product candidates that are approved for commercialization in the future. In addition, there have been concerns for the overall stability and suitability of the euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the euro as a common European currency or an otherwise diminished value of the euro could materially and adversely affect our future product revenue from European sales of our products.

Risks Related to the Dependency on Third Parties

We depend on third-party contractors for a substantial portion of our operations, namely contract research organizations or CROs for our clinical trials and contract manufacturing organizations or CMOs for manufacturing of our active ingredients and therapeutic units and may not be able to control their work as effectively as if we performed these functions ourselves.

Under our supervision, we outsource substantial portions of our operations to third-party service providers, including preclinical studies and clinical trials, collection and analysis of data and manufacturing of our drug candidates and the realization of certain analyses pertaining to an LDT or IVD powered by NIS4 for use in the clinical research and clinical diagnostics markets. In particular, we subcontract the design and/or conduct of our clinical trials to CROs, as well as the manufacturing of our active ingredients and therapeutic units to CMOs, especially with regard to our Phase 3 ELATIVE trial evaluating elafibranor in PBC.

We also contract with external investigators and other specialized services providers, for example with respect to certain statistical analyses, to perform services such as carrying out and supervising, and collecting, analyzing and formatting of data for our trials. Although we are involved in the design of the protocols for these trials and in monitoring them, we do not control all the stages of test performance and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations. In particular, a contractor’s failure to comply with protocols or regulatory constraints, or repeated delays by a contractor, could compromise the development of our products or result in liability for us. Such events could also inflate the product development costs borne by us.

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 therapeutic units (pre-packaged lots specifically labeled for a given clinical trial);
- the clinical and commercial quantities that can be supplied; and
- compliance with applicable laws and regulations.

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

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

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

We rely entirely on third parties for the manufacturing of our drug candidates and the future manufacturing of an IVD powered by NIS4 for use as a clinical diagnostic including one manufacturer for the active ingredient in elafibranor and another manufacturer for the therapeutic units of elafibranor used in our clinical trials. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product or tests, or fail to do so at acceptable quality levels or prices.

We do not intend to manufacture the drug products nor future test kits related to an IVD powered by NIS4 that we plan to sell if the latter is approved for use as a clinical diagnostic. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for our preclinical studies and clinical trials that we plan to conduct prior to and after seeking regulatory approval and, if applicable, for the manufacturing of the first commercial lots of the product. We rely on one supplier for the active ingredient in elafibranor and another manufacturer for the therapeutic units of elafibranor used in our clinical trials and, if applicable, for the provision of the first commercial lots. If either of those contract manufacturers should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials and, if applicable, for the commercial launch while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

While we believe that our current inventory and drugs in production at various levels of the production chain are sufficient for our needs on a short-term basis, a failure at both of the storage sites of the therapeutic units used for ongoing ELATIVE Phase 3 study evaluating elafibranor in PBC would be critical.

We are also in the process of qualifying duplicate manufacturing units for our active ingredient and therapeutic units; however, the process has not been completed. For example, we have had to face the temporary closing of one of these units for a duration of 15 days due to a suspected case of COVID-19, even though this unit has indicated to us that this would not affect the provision of future clinical lots. However, in case of failure of these units, we may not be able to enter into additional long-term commercial supply agreements for elafibranor with other third-party manufacturers on terms sufficiently advantageous to us. We do not have agreements for long-term supplies of any of our other product candidates. We currently obtain these supplies and services from our third-party contract manufacturers on a purchase order basis.

Additionally, the facilities used by any contract manufacturer to manufacture elafibranor or any of our other product candidates must be the subject of a satisfactory inspection before the FDA, the EMA or the regulators in other jurisdictions that approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our products or product candidates will not be approved or, if already approved, may be subject to recalls or other enforcement action.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the products or product candidates, including:

- the possibility that we are unable to enter into or renew a manufacturing agreement with a third party to manufacture elafibranor or our product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or disruption of commercialization of our products or product candidates, cause us to incur higher costs, prevent us or our potential future collaborators from commercializing our products and product candidates successfully or disrupt the supply of our products after commercial launch. Furthermore, if any of our contract manufacturers fail to deliver the required commercial quantities of finished product on acceptable commercial terms and we or our current or future collaborators are unable to find one or more replacement manufacturers capable of production at substantially equivalent cost, volume and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply and to have any such new source approved by the government agencies that regulate our products.

We have entered, and may in the future enter into, collaboration, licensing or co-marketing agreements with third parties for the development and eventual commercialization of our product candidates and NIS4 diagnostic technology, and may not generate revenues from these agreements.

We have limited experience in product development and marketing and may seek to enter into collaborations with third parties for the development and potential commercialization of our product candidates including those at an early and preclinical stage, particularly those candidates outside of our main therapeutic areas of interest. In January 2019, we entered into a license agreement with Labcorp to allow them to deploy NIS4 in the clinical research space and in September 2020, we entered into a five-year exclusive licensing agreement for NIS4 technology with Labcorp to develop and commercialize an LDT powered by NIS4 technology for clinical diagnostics. In June 2019, we entered into a collaboration and license agreement with Terns Pharmaceuticals, Inc., or Terns, pursuant to which we granted Terns rights to develop and commercialize elafibranor in Greater China for the treatment of NASH and PBC. Should we seek to collaborate with additional third parties with respect to our development programs, we may not be able to locate a suitable collaborator and may not be able to enter into an agreement on commercially reasonable terms or at all.

Any new collaboration may require additional expenditures, increase our short and long term investments, require us to issue new shares and dilute our existing shareholders or disrupt our management team or activities. With our current agreements, or even if we succeed in securing collaborators for the development and commercialization of our product candidates, we have limited control over the amount and timing that our collaborators may dedicate to the development or commercialization of our product candidates.

These collaborations and licensing agreements pose a number of risks, including:

- the means and resources used within the framework of these agreements remain, for the most part, at the discretion of the partner;
- the partner might not fulfill its contractual obligations;
- the partner might interrupt the development or commercialization or decide to interrupt or not renew the development or commercialization programs due to a change in strategic orientation, a lack of financing or external factors such as an acquisition that would reallocate resources or induce different priorities;
- the partner might develop, independently or with the assistance of third parties, products, in the case of pharmaceuticals or in-vitro tests, in the case of diagnostic technologies that are in direct or indirect competition with our product candidates or future IVD powered by NIS4 if it believes that it is easier to successfully commercialize competing products under more attractive economic conditions than ours;
- the partner, as holder of the commercialization and distribution rights on a product candidate or technology for a set time period or a specific territory or territories, might not allocate sufficient resources to these activities;
- the partner might not protect or defend our intellectual property rights in an appropriate manner or might use exclusive information that belongs to us in a manner resulting in disputes that may compromise or discredit our exclusive information or expose us to potential disputes;
- the partner might not respect the property rights of third parties, which might expose us to litigation and potentially involve our liability;

- disputes might arise between us and the partner, which could result in delays or suspension of the commercialization of the product candidate, or legal action or costly procedures that would monopolize resources as well as divert management's attention;
- we might lose certain important rights obtained through these partnerships, notably in the case of change of control of our company;
- the collaboration might be terminated and, in such case, require additional financing to further develop or market the product candidate licensed to it;
- the partner has access to our discoveries and might use this information to develop future competing products;
- the collaboration, due to its nature, might have a negative impact on our attractiveness for collaborators or potential acquirers;
- the collaboration might not result in the development and commercialization of the product candidate(s) in an optimal fashion or never fulfill its objectives; and
- if the partner were to take part in a merger, the continuity of advancement and the central nature of our commercialization program might be delayed, reduced or suspended by it.

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. For example, although we have entered into a license agreement with Labcorp to enable them to develop and commercialize an LDT powered by NIS4 for clinical research and clinical diagnostic purposes, Labcorp is under no obligation to do so and may choose not to further develop and deploy the test. There is no guarantee that our collaboration with Labcorp will result in widespread clinical or commercial use of an LDT powered by NIS4 for clinical care. Similarly, although we have entered into a collaboration and license agreement with Terns for the treatment of NASH and PBC with elafibranor in Greater China, Terns is under no obligation to do so and may choose not to further develop and market elafibranor in either indication or within all relevant territories. There is no guarantee that our partnership with Terns will successfully result in a generalized clinical or commercial use of elafibranor for these indications and in those jurisdictions.

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

If the manufacturing facilities of our third-party manufacturers of drug candidates as well as the central testing laboratories of Labcorp fail to comply with applicable regulations or maintain these approvals, our business will be materially harmed.

We do not currently and do not intend in the future to manufacture the drug candidates we or our collaborators intend to sell. We outsource the manufacturing of our products to third parties, who are, in turn, subject to ongoing regulation and periodic inspection by the EMA, FDA and other regulatory bodies to ensure compliance with current Good Manufacturing Practices, or cGMP. Any failure to follow and document their adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our products.

Failure to comply with applicable regulations could also result in 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 or our current or future collaborators to suspend or put on hold one or more of our clinical trials;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;

- requiring us or our current or future collaborators or our third-party manufacturers to suspend manufacturing activities or product sales, imports or exports;
- requiring us or our current or future collaborators 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 or that of our current or future collaborators to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the United States, Europe or elsewhere, our suppliers will have to pass an audit by the applicable regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits, and the audits and any audit remediation may be costly. Failure to pass such audits by us or any of our suppliers would affect our ability or that of our current or future collaborators to commercialize our product candidates in the United States, Europe or elsewhere.

The deployment of an LDT powered by NIS4 depends on the ability of the central laboratories of our partner Labcorp that conduct the diagnostic test to retain its CLIA certification, which certification sets quality standards that must be followed in laboratory testing in order to ensure accuracy, reliability and speed of test results for the patients wherever the testing is conducted. We do not plan on manufacturing the test kits that we plan on marketing and that will be associated with an IVD powered by NIS4 if it were to be approved on the market of routine care; and the manufacturing sites of the contractor that we or our potential collaborators may choose for their production would also be subject to significant authorizations and regulations.

Risks Related to Our Operations

As the result of our multi-year cost cutting program and workforce reduction plan, we may encounter difficulties in managing development of our product candidate pipeline, which could disrupt our operations.

Our multi-year cost reduction program and workforce reduction program could have a negative impact on the outcome of our research and development programs and our operations. Our limited resources may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. These changes in our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage these changes efficiently, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our operations.

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

Our success depends to a significant degree upon the technical and management skills of our co-founders, scientific advisers, senior management team, including, in particular, Pascal Prigent, our chief executive officer, Jean-François Mouney, our chairman, and Dean Hum, our chief operating officer. The loss of the services of Messrs. Prigent, Mouney or Hum would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified scientific, management, marketing, technical, and sales executives and personnel, despite our recent workforce reduction plan. We compete for key personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. In addition, there is risk of departures or difficulties in hiring qualified personnel following the announcement of disappointing clinical results, such as those we announced in May 2020 regarding our Phase 3 RESOLVE-IT trial and our recent workforce reduction plan. 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.

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

Our research and development processes for our product candidates involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. During their work, our researchers come into contact with a number of potentially dangerous substances, including in particular (1) genetically modified organisms, or GMO, the safety of which is overseen in France by the Ministry in charge of Research with the assistance of High Council for Biotechnologies (or the *Haut Conseil des Biotechnologies*), (2) animals used for experimentation, the authorization of which is overseen by the local préfet with the assistance of the local Department for the Protection of People, or DDPP (for *Direction départementale de la protection des populations*) and (3) human samples. This research is subject to application for authorization from the competent authorities, in particular the National Drug and Health Product Authority, or ANSM (for *Autorité Nationale de Sécurité du Médicament et des produits de santé*) to assess the usefulness of the research, ensure that patients have been properly informed, and assess the management of information obtained from the sampling.

We may be subject to fines or sued for any injury or contamination resulting from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets, and we may also suffer reputational harm. European, French and U.S. federal, state, local or foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with health, safety and/or environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. Furthermore, we could face the rejection, suspension or withdrawal of regulatory approval for our drugs candidates or an IVD powered by NIS4 if they had received market approval. In addition, we cannot predict the impact on our business of new or amended health, safety and/or environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

Our growth strategy could include potentially in-licensing rights to drug candidates in clinical development, and in the future, we may acquire companies or technologies facilitating or enabling us to access to new medicines, new research projects, or new geographical areas, or enabling us to express synergies with our existing operations. If such acquisitions occur 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 on favorable terms, which could require us to finance these acquisitions using our existing cash resources that could have been allocated to other purposes. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses or the expected synergies if we are unable to successfully integrate them with our existing operations and company culture.

Our internal information technology systems and those of our current or future collaborators or those of our third-party contractors or consultants, may fail or suffer security breaches, any of which could result in a material disruption of our product development and commercialization programs.

Despite the implementation of security measures, our internal information technology systems and those of our current or future collaborators, or third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive

software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Any of these developments could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts or those of our current or collaborators and significantly increase our costs to recover or reproduce the lost data.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data, as could information stored in the networks or systems of our current or future collaborators. In addition, outside parties may attempt to penetrate our systems, those of our current or future collaborators or those of our vendors or fraudulently induce our personnel or the personnel of our current or future collaborators or our vendors to disclose sensitive information in order to gain access to our data and/or systems.

We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems, those of our collaborators or our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Use of social media may materially and adversely impact our reputation.

Unauthorized communications, such as press releases or posts on social media, purported to be issued by us, may contain information that is false or otherwise damaging and could have an adverse impact on the price of our securities. Negative or inaccurate posts or comments about us, our research and development programs, and our directors or officers could seriously damage our reputation.

In addition, our employees and collaborators and other third parties with whom we have business relationships may use social media and mobile technologies inappropriately, for which we may be held liable, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information. Such uses of social media and mobile technologies could have a material adverse effect on our reputation, business, financial condition and results of operations.

We are exposed to a number of regulatory and commercial risks related to the United Kingdom leaving the European Union..

The United Kingdom left the European Union on January 31, 2020, a development commonly known as Brexit. Given the lack of precedent in the history of the European Union, the financial, commercial, regulatory and legal consequences of the withdrawal of the United Kingdom from the European Union are unclear. Brexit is the source of economic and financial uncertainty on a worldwide scale and might notably generate volatility in exchange rate and regulatory changes. Furthermore, following the Brexit vote in the United Kingdom, the European Union has decided to transfer the EMA headquarters from the

United Kingdom to the Netherlands, which has affected the work of the EMA and might delay the granting of market approval for requests submitted for new products to this European authority.

Our clinical trials in the United Kingdom are subject to the requirements of the Medicines and Healthcare products Regulatory Agency or MHRA and the regulations of the EMA. For example, we plan to open new investigation sites in the United Kingdom for our ELATIVE Phase 3 trial evaluating elafibranor in PBC and potentially other clinical trials. In that context, we may not be certain that these trials will not be affected if the UK and the EU are not able to come to an organized withdrawal agreement. Furthermore, if we or our potential future collaborators obtain market approval within the European Union, this market approval may not allow us to commercially market our product candidates in the United Kingdom and we or our potential future collaborators may not be in a position to obtain the required approval from the British regulatory authority. If we or our potential collaborators need to obtain additional approvals in the United Kingdom, we will have to bear additional costs which could be considerable.

The outbreak of the novel coronavirus disease, COVID-19, has adversely impacted and could continue to adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus disease, SARS-CoV-2, identified as COVID-19, was identified in Wuhan, China. This virus has since spread globally, including throughout the United States, across Europe and in France, where we are headquartered, and in countries where we have planned or ongoing clinical trials, or where our important subcontractors – for clinical research and manufacturing of our API and drug product for elafibranor are located. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities have been closed and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen.

Strict confinement measures have been taken by the governments in the majority of countries where there has been a COVID-19 outbreak. Although as of the date of this Annual Report, some confinement measures have been lifted in some countries, there is no guarantee that governments will not take additional measures in the event there is a new outbreak of the disease or variants thereof in certain regions.

In response to the spread of COVID-19, in 2020, we made several changes to our operations, including:

- putting all of our Phase 1 clinical trials on hold;
- suspending the initiation of combination studies;
- temporarily suspending our planned Phase 3 study of elafibranor in PBC;
- suspending enrollment of patients in our pharmacokinetic/pharmacodynamics trial of elafibranor in pediatric patients with NASH and in our Phase 2 clinical trial assessing liver fat;
- enacting remote working for certain of our employees, including most of our general administrative and finance personnel, and applying social distancing and other safety measures for employees who continue to work at our offices and in the laboratories; and
- strictly limiting business travel to that which is considered absolutely critical to our operations.

As of the date of this Annual Report, the COVID-19 pandemic continues to impact operations. Furthermore, several of the aforementioned trials were terminated due to our decision to terminate all development of elafibranor in NASH. However, as the result of measures implemented in consultation with our CRO, including virtual appointments, biological evaluations performed by local laboratories and delivery of the drug candidate to the patients' homes, to ensure the safety of participants in the ELATIVE study, the ELATIVE Phase 3 clinical trial of elafibranor in PBC was able to enroll its first patient in September 2020. Although we had initially estimated that enrollment in the ELATIVE study would take 12 months, we believe that, as a result of the current situation, enrollment will take approximately 18 months. With regards to use of NIS4 in the context of NASH clinical trials, testing of clinical samples by Covance, a subsidiary of Labcorp, has continued but at a slower pace than originally expected. The COVID-19 pandemic has also impacted the timing of Labcorp's commercial launch of an LDT powered by NIS4 in the clinical care space in the United States and may potentially impact net sales in 2021. More generally, we have observed that the COVID-19 pandemic has diverted our collaborators' resources towards the prevention, diagnosis and treatment of COVID-19 patients, to the detriment of other activities, including our programs.

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions, some of which could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in manufacturing active pharmaceutical ingredients or drug products used in our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including initiation of their activities, in particular for newly launched trials or trials in preparation, difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, in particular the FDA and EMA, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19; and
- refusal of the FDA or EMA to accept data from clinical trials in affected geographies.

In addition, the outbreak of COVID-19 could disrupt our operations for a significant period of time, due to absenteeism or inability to work from home by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to mandated quarantines. COVID-19 could also impact members of our board of directors, resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full board of directors or its committees needed to conduct meetings for the management of our affairs.

The global outbreak of COVID-19 continues to rapidly evolve. The extent to which COVID-19 may impact our business, clinical trials and financial situation will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, variations in the virus, the duration of the outbreak, travel restrictions and social distancing in France, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken around the world to contain and treat the disease, including the vaccination efforts currently underway in some countries. In addition, the world economy has been strongly impacted by the epidemic and many economists, governments and business leaders predict a severe impact on gross world product. We cannot predict the extent of the impact of this epidemic on the financial markets or on our stock price and as a result, on our ability to obtain additional funding if we should seek to raise additional funding.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability or that of a potential future partner to commercialize our product candidates successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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.

For example, on May 15, 2019, Nashpharm, a French company, brought before the Paris High Court (Tribunal de Grande Instance de Paris) an action for a declaration of invalidity against the French part of European patent EP 2 504 005 related to the use of the drug candidate elafibranor. This action is under review by the pre-trial judge. No court date has been set. A negative decision on this patent could have a significant negative impact on us.

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

complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position or that of our current of future collaborators could suffer.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications, or ANDAs, to the FDA, in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives or those of our current of future collaborators.

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

Even if we have or obtain patents covering our product candidates or compositions, we may still be prevented from making, using, selling, offering for sale, or importing our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. These filings could materially affect our ability or that of current or future collaborators to develop our product candidates or sell our products if they are approved. Because patent applications can take many years to issue and are not published for a period of time after filing, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technologies, the defendant could counterclaim that the patent covering one of our product candidates or technologies is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability of an asserted patent or patents are common. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review and/or inter partes review and equivalent proceedings in foreign jurisdictions, such as, opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. Similarly, we may initiate proceedings before the Patent Trial and Appeal Board, or PTAB, of the USPTO, such as post grant review, or PGR, derivation, or inter partes review, against patents granted to third parties. For example, NTZ, which is being evaluated as an anti-fibrotic in an investigator-initiated Phase 2 clinical trial, has been commercialized by Romark Laboratories (Romark) for use as an anti-parasitic drug. We have a number of granted U.S. patents covering the use of NTZ as an anti-fibrotic in certain organs, including in the liver for the treatment of liver fibrosis consecutive to NASH. Romark has obtained a reissued U.S. patent which claims the use of NTZ in liver fibrosis. This delays us from obtaining issued patents with similar claims in the U.S. and prompts additional proceedings in the USPTO against such patent or against other third party applications or patents or consider the need or benefit of entering into a license agreement with such third party or parties in order to exploit such patent alone or together with Romark or such other third party or parties. In the event that we do not prevail or the settlement terms with the adverse party are unfavorable, or we are unable to reach an agreement on terms sufficiently favorable to us, our ability to market our product candidates may be affected or delayed. The outcome following legal assertions of invalidity and unenforceability in the PTAB or the federal courts is unpredictable. With respect to validity, for

example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, in particular, in the United States, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs or ordinary shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims in the federal courts, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

In addition, if one of our patents is revoked or abandoned as a result of an adverse court decision or a settlement, we may face the risk that government, private third party payers or purchasers of pharmaceuticals products may claim damages alleging that they have over-reimbursed or overpaid for a drug. Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

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

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

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

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our technologies without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with

respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could, in certain circumstances, be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims may also be made that we have misappropriated the confidential information or trade secrets of third parties, which could have a similar negative impact on our business.

Developments in patent law in the United States and in other jurisdictions could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business. In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. In certain areas, these changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act, or any subsequent U.S. legislation regarding patents, may affect our ability to obtain patents, and if obtained, to enforce or defend them.

Furthermore, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances for diagnostic method claims and gene patents.

In view of these and other U.S. federal appellate cases, we cannot guarantee that our efforts to seek patent protection for our tools and biomarkers will be successful.

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

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. We expect to seek extensions of patent terms for certain patents in the United States and, if available, in other countries where we are prosecuting patents and seeking approval of various products. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments; similarly, selected patents outside the U.S., may be eligible for supplementary protection certificate, or SPC, under corresponding legislation in Europe and several other countries.

Depending upon the circumstances, the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information.

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

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

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe could be less extensive than those in the United States and Europe, assuming that patent rights are obtained in the United States. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. 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 in developing countries, do not favor the enforcement of patents and other intellectual property rights, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties for certain products. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

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

Third parties may assert ownership or commercial rights to inventions we develop.

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

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

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. For example, in 2020 we received an anonymous whistleblower allegation that CymaBay Therapeutics, Inc. ("CymaBay") had improperly acquired and disclosed the protocol synopsis ("Protocol") for our Phase 3 ELATIVE™ clinical trial of elafibranor in PBC. We subsequently filed a Complaint on January 15, 2021 against CymaBay in the U.S. District Court for the Northern District of California alleging that CymaBay, among other things, violated the U.S. federal Defend Trade Secrets Act and the California Uniform Trade Secrets Act when it misappropriated the Protocol. On the same day that we filed the Complaint, we sought a temporary restraining order ("TRO") against CymaBay, and on March 12, 2021 the Court granted the TRO (which has since been converted into a preliminary injunction). While the ultimate outcome of the litigation remains uncertain, the Court found, in relevant part, that we are likely to succeed on the merits of our trade secret claims. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations.

If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a negative impact on our cash position. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- us having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

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

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

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

Risks Related to Legal and Other Compliance Matters

We are subject to transparency, ethics and healthcare laws and regulations that 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 and others in the healthcare and pharmaceutical sector will play a primary role in the clinical development and potential regulatory approval of our product candidates and their recommendation and prescription, if approved. Our arrangements with them and third party payors as well as our activities expose us to broadly applicable federal and state fraud and abuse and other healthcare laws, which may restrict these arrangements and relations through which we research and develop our products, and if approved, we or our current or future collaborators will market and distribute them. These laws may thus impact, among other things, our research, development, proposed sales, marketing and education programs of our product candidates that obtain marketing approval. Restrictions under applicable U.S. federal, state and non-U.S. healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws impose penalties, 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. federal 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, or HITECH, and its implementing regulations, which impose certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform functions or activities that involve HIPAA Protected Health Information on their behalf, 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 the CMS payments and other transfers of value provided to physicians (defined to include doctors,

optometrists, podiatrists and chiropractors) and teaching hospitals, and certain ownership and investment interests held by physicians or their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioner, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives;

- analogous state or non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines, laws requiring manufacturers to declare information related to payment and other gratification to physicians and other healthcare providers or to publicly divulge the expenses related to marketing products and communicate information on their price, and laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts;
- the Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or 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 requires companies whose securities are listed in the United States to comply with 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. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts. The FCPA presents particular challenges for the pharmaceutical industry since, in many countries, hospitals are managed by the government, and their physicians and other employees are considered foreign public agents. As such, some payments to hospitals related to clinical trials and other work have been regarded as irregular payments to foreign agents and lead to enforcement action on the basis of the FCPA; and.
- the equivalent anticorruption laws in foreign countries, such as the French law of December 9 2016 or the UK Bribery Act of 2010 that may also be invoked under similar circumstances related to corrupt practices.

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. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

We are subject to laws and regulations related to data privacy, both in the United States and the European Union whose breach might have a significant negative impact on our activities.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information, known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to covered subcontractors and business associates, defined as a person or organization, other than a member of

a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

We may collect, process, use or transmit personal data of persons located within the European Union during the course of our activities, including clinical trials conducted within the European Union. Furthermore, we may market those of our drug candidates that receive market approval within the European Union.

In addition, third parties (principally CROs during clinical trials) manage a significant part of the personal data we may use.

The collection and use of personal data related to health within the European Union are subject to the General Data Protection Regulation (EU) 2016/679 or GDPR. This regulation lays out requirements to set a legal basis for personal data processing of identifiable persons and the transfer of such information outside the European Economic Area, including the United States, by providing such persons with information regarding the use of their personal data, securing personal data, entering in data processing agreements with third parties that process personal data, responding to requests from individuals to exert their rights regarding their personal data, reporting security violations involving personal date to the relevant national data protection authority and the affected individuals, nominating data protection officers, conducting an impact study on data protection and record keeping. The GDPR imposes new responsibilities regarding the personal data we handle and we may have to implement additional procedures to guarantee compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. In any case, the costs associated with ensuring GDPR compliance be onerous and non-compliance with GDPR requirements and the national laws of EU member states related to data protection, including data managed by third parties for which we are not able to verify their compliance with GDPR may trigger significant fines, other administrative sanctions and civil lawsuits against us, which could adversely affect our business, financial condition, results of operations and prospects.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with legal requirements or the requirements of FDA, EMA and other government regulators, provide accurate information to applicable government authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical and diagnostic products that are intended to be tested and evaluated on humans in an initial phase, then commercialized. 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 or that of our current or future collaborators could be sought after by patients participating in the clinical trials in the context of the development of the therapeutic or diagnostic 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 collaborators, licensees, service providers and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products, which may harm our reputation. Patients may not follow warnings identifying potential known side effects, including some patients who should not be using our drug candidates.

We maintain product liability insurance coverage for our clinical trials at levels which we believe are appropriate for our clinical trials and at levels granted by insurers to biopharmaceutical companies like us. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, insurance coverage has become more and more expensive, and in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or for sufficient amounts to otherwise protect against potential product or other legal or administrative liability claims by us or our current or potential collaborators. A successful liability claim against our products may lower the value of our stock, and if the decision awards damages that exceed our insurance coverage, might reduce our available funds and have an unfavorable effect on our activities. It could notably prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval. Product liability claims could also harm our reputation, which may adversely affect our ability to commercialize our products successfully.

Risks Related to our Financial Position and Capital Needs

Currently, we have no products approved for commercial sale, and to date we have not generated any significant recurring revenue from product sales. As a result, our ability to reduce our losses, reach profitability and rebuild our shareholders equity on our own is unproven, and we may never achieve or sustain profitability.

We have never generated profits from product sales and we do not expect to be profitable in the foreseeable future. The disappointing results of our RESOLVE-IT trial make profitability even less likely in the foreseeable future. We have incurred net losses over the last years, including a net loss of €101.2 million for the year ended December 31, 2020. Our revenue and other income in 2020 resulted principally from tax credits, including research tax credits, in France. Historically, we have also received funding from co-research alliances with other pharmaceutical companies, although we do not currently have any such alliances in place. The only material revenue that we have recorded in the recent past is the upfront payment in 2019 upon signature of our collaboration and license agreement with Terns Pharmaceuticals.

We are exposed to foreign exchange risk as a growing portion of our operations are denominated in US dollars, and as a result, following our March 2019 IPO on the Nasdaq Global Select Market, we chose not to convert the dollar-denominated gross proceeds into euros. We do not currently have significant recurring revenues in euros, dollars or other currencies, and as a result, we expect to face an increase in our exposure to exchange rate risk.

We have devoted substantially all of our resources to our research and development efforts relating to our drug candidates and NIS4 diagnostic program, providing general and administrative support for our operations, protecting our intellectual property and engaging in activities to prepare for the potential commercialization of our drug candidates and an LDT or IVD powered by NIS4. With the exception of the upfront payment under the collaboration and licensing agreement with Terns Pharmaceuticals and revenues from our agreement with Labcorp, we have not yet generated any direct or indirect profit from the sale of our products or technologies as we do not yet have any products approved for sale.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for elafibranor in PBC and an IVD powered by NIS4. We could also continue to have significant expenses related to the preparation for commercialization of our products, and additional infrastructure and personnel in the United States, Europe and other territories to support our product development and commercialization efforts and operations as a public company in both France and the United States. We anticipate that any such losses could be significant for the next several years as we continue the development of elafibranor and its potential commercialization, in certain indications.

In addition, despite our decision in July 2020 to discontinue our RESOLVE-IT trial in NASH, we continue to have expenses for the closing of this trial.

As of December 31, 2020, our losses recognized in our unconsolidated financial statements exceeded the amount of our equity, resulting in negative equity in the amount of €23.6 million. As a result, and in accordance with Article L.225-248 of the French Commercial Code, we must submit to the upcoming general meeting a resolution to decide to continue our activities. If this resolution is approved, we must nevertheless, by December 31, 2023, have reconstituted (in the unconsolidated financial statements) positive shareholders' equity at least equal to half of the share capital, otherwise any interested party could sue to dissolve the Company. As indicated above, we will likely continue to generate losses during this period and the reconstitution of shareholders' equity can therefore only take place through capital increases, strategic alliances or new licensing or co-marketing agreements generating significant income or any other transaction which allows for recapitalization.

Our ability to be profitable in the future will depend on our ability and that of our current or future collaborators to obtain marketing approval for and commercialize our product candidates, particularly our lead product candidate, elafibranor, and an LDT or IVD powered by NIS4 for clinical care.

Our ability to be profitable in the future will depend on our ability and that of our current or future collaborators to obtain marketing approval for and commercialize our product candidates, particularly our lead product candidate, elafibranor and an LDT or IVD powered by NIS4 for clinical care. We may not be successful in our efforts to obtain such approval and to commercialize our products.

Obtaining marketing approval will require us or our current or future collaborators to be successful in a range of challenging activities, including:

- obtaining positive results in our clinical trials;
- regulatory bodies determining that clinical data are sufficient, without further clinical data, to support an application for approval, whether or not conditional or accelerated;
- obtaining approval to market elafibranor;
- obtaining positive results in our formal validation studies required to commercialize a test powered by NIS4 for clinical care;
- expanding our manufacturing of commercial supply for elafibranor;
- establishing sales, marketing and distribution capabilities to effectively market and sell elafibranor and an LDT or IVD powered by NIS4 in the United States, Europe and in other territories;
- market acceptance by patients and the medical community of elafibranor;
- market acceptance by patients and the medical community of an LDT or IVD powered by NIS4 as a diagnostic complement to liver biopsy for clinical care;
- negotiating and securing coverage and adequate reimbursement from third-party payors for elafibranor and an LDT or IVD powered by NIS4; and
- expanding our contract manufacturing for the commercial supply of elafibranor and the manufacturing under license of the diagnostic kit accompanying the potential commercialization of an IVD powered by NIS4 for clinical care.

We are conducting pre-commercial activities, such as patient profiling, intended to better understand how physicians care for and diagnose NASH patients. NASH is a disease with no approved drug therapy. As such, there is significant uncertainty in the

degree of market acceptance that future treatments or diagnostic tools will have among NASH patients and their healthcare providers as well as third-party payors.

Even if we or our collaborators receive marketing approvals for our product candidates and commence our commercial launch, we may not be able to generate significant revenues in the near term. We cannot foresee if our product candidates will ever be accepted as a therapy in PBC eventually resulting in sustained revenues and it may take the passage of a significant amount of time to generate significant sustained revenues even if elafibranor becomes accepted as a therapy in PBC.

NASH is currently an under-diagnosed disease, and we believe that an LDT or IVD powered by NIS4 will facilitate the identification of patients with NASH and fibrosis who may be eligible for therapeutic intervention. If an LDT or IVD powered by NIS4 does not obtain marketing authorization or is able to be commercialized, we, or our collaborators, may not be able to generate sufficient test volume to generate significant revenues.

If elafibranor, an LDT or IVD powered by NIS4 or any of our other product candidates fails in clinical trials or do not gain regulatory approval, or do not achieve market acceptance, we may never become profitable. Our net losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with pharmaceutical and diagnostic product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding to develop and commercialize our products, if approved, which may not be available to us, in particular given our current financial situation, or to our current or future collaborators on acceptable terms, or at all, and, if not so available, may require us or them to delay, limit, reduce or cease our operations.

We are currently advancing elafibranor through clinical development in PBC and other drug candidates through clinical or preclinical development. Additionally, we are also planning formal validation studies of an IVD powered by NIS4 in preparation for submitting the test for marketing authorization for clinical care. Developing pharmaceutical and diagnostic products, including conducting preclinical studies and clinical trials, along with obtaining necessary validation, is expensive.

Subject to obtaining regulatory approval of any of our drug candidates or an IVD powered by NIS4, we or our current or future collaborators expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate incurring significant expenses in connection with our planned commercialization of an IVD powered by NIS4, along with an increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States, France and other countries. We also expect to incur additional costs associated with operating as a public company in the United States and further plan on expanding our operations in the United States, Europe and in other territories. This risk is particularly heightened due to our current financial situation. We will continue to require substantial additional capital in connection with our continuing operations, including continuing our clinical development and pre-commercialization activities. Because successful development of our drug candidates and diagnostic program is uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products under development.

Our stock price may never reach a price at which certain bondholders will deem conversion economically viable, in which case we would need to repay the nominal amount at maturity in October 2025. The terms of our convertible bonds require us to meet certain operating covenants, and if we fail to comply with those covenants the bondholders would be able to accelerate our repayment obligations. Additionally, the conversion of some or all of our bonds into ordinary shares would dilute the ownership interests of existing shareholders.

In October 2017, we issued bonds convertible and/or exchangeable into new and/or existing ordinary shares due October 16, 2022, for a nominal amount of €180.0 million, or 6,081,081 bonds that would convert into 6,081,081 new ordinary shares if such bonds were settled into new ordinary shares in the event of conversion. The bonds bear interest at a nominal rate of 3.5% payable semi-annually in arrears on April 16 and October 16 of each year with a first interest payment date having occurred of April 16, 2018.

On January 29, 2021, we amended the terms and conditions of these bonds - mainly we extended the maturity by an additional three years, from October 16, 2022 to October 16, 2025, and increased the conversion ratio from one (1) share per bond to 5.5 shares for one bond, i.e., an implicit conversion price of €5.38 per share instead of €29.60. In addition, we carried out a

partial repurchase resulting in €94.3 million nominal amount of bonds remaining outstanding on January 29, 2021 (compared to €180 million nominal amount initially). Between this date and the date of this Annual Report, 1,252,159 additional bonds have been converted and the outstanding nominal amount is therefore €57.2 million.

As of the date of this Annual Report, our stock price remains below €5.38. Even if many bonds have already been converted, it is possible that if our stock price does not reach a price at which the bondholders will deem conversion economically viable, we will be required to repay the nominal amount at maturity in October 2025.

Our ability to repay the bonds at maturity depends in part on our future performance, which is subject to the success of our research and development programs and future operations, as well as on economic, financial and competitive factors that are beyond our control. In addition, we may incur additional debt in the future, some of which may be secured debt. Even if we are permitted by the terms and conditions of the convertible bonds to incur additional debt or to take other measures with regard to the incurrence of new debt, the terms of the bonds could reduce our ability to repay new debts at maturity.

The agreement governing the bonds contains customary negative covenants and events of default. The negative covenants include restrictions on creating other liens on our assets, incurring certain additional indebtedness and engaging in certain mergers or acquisitions. If we default under the agreement governing the bonds, the bondholders may accelerate all of our repayment obligations, which would significantly harm our business and prospects and could cause the price of our ordinary shares to decline.

Finally, the conversion of some or all of our currently outstanding convertible bonds into ordinary shares would dilute the ownership interests of existing shareholders, including holders of our ADSs. Any sales in the public market of the ordinary shares issuable upon such conversion or any anticipated conversion of our convertible bonds into ordinary shares could adversely affect prevailing market prices of our ordinary shares.

We have carried out a specific review of our liquidity risk and consider that we will be able to meet our maturities for the next 12 months. As of December 31, 2020, the Group has €172.49 million in cash, cash equivalents and other financial assets (as of December 31, 2019: €278.47 million). In view of these amounts as of December 31, 2020, and in light of the renegotiation of the convertible bonds in January 2021, including the extension of their maturity, we do not consider that we are exposed to a short-term liquidity risk. In particular, we believe that the amount of cash, cash equivalents and current financial instruments is sufficient to ensure our financing, in view of its projects and current obligations, over the next twelve months.

Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may adversely affect our results of operations.

As a French biopharmaceutical company, we have benefited from certain tax advantages, including, for example, the French Research Tax Credit, or CIR *(Crédit d'Impôt Recherche*), which is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess, if any, may be refunded. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and was €7.9 million for the year ended December 31, 2020. We believe, due to the nature of our business operations, that we will continue to be eligible to receive the CIR tax credit. However, if the French Parliament decides to eliminate, or to reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

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

The market price of our equity securities is particularly volatile and may decline regardless of our operating performance.

The trading price for our ADSs and ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance ofc particular companies. As a result of this volatility, investors may not be able

to sell their ADSs or ordinary shares at or above the price originally paid for the security. The market price for our ADSs and ordinary shares may be influenced by many factors, including:

- announcements of clinical trial results;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- lawsuits threatened or filed against us, including securities litigation, disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- 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 our ordinary shares and ADSs.

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

Our ADSs are listed on the Nasdaq Global Select Market, and our ordinary shares trade on Euronext Paris. We cannot predict the effect of this dual listing on the value of our ADSs and ordinary shares. However, the dual listing of our ADSs and ordinary shares may dilute the liquidity of these securities in one or both markets and may adversely affect the trading market or price for our ADSs and ordinary shares.

We are currently the subject of a securities class action litigation and may become subject to additional litigation, which could harm our business and financial condition.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. We may have actions brought against us by shareholders relating to past transactions, changes in our stock price or other matters. For example, in May 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint was filed in state court in the Commonwealth of Massachusetts, naming us, our board of directors and certain members of our senior management as defendants, alleging that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. In October 2020, the plaintiff voluntarily dismissed the Commonwealth of Massachusetts action, but in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those

in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering. In March 2021, we and the other defendants filed a motion to dismiss before the state court of New York and intend to vigorously defend this action. However, this and future actions could give rise to substantial damages, and thereby have a material adverse effect on our financial position, liquidity, or results of operations. Even if this action is not resolved against us, the uncertainty and expense associated with shareholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

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

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of our 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 our ordinary shares and ADSs could decrease, which could cause the price of our 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 our ordinary shares and ADSs. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ordinary shares or ADSs for the foreseeable future and the success of an investment in ordinary shares or ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ordinary shares or ADSs after price appreciation, which may never occur, as the only way to realize any future gains 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. Investors seeking cash dividends should not purchase our ADSs or ordinary shares.

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. 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 not based in France.

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

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

As of April13, 2021, we had 45,775,250 ordinary shares issued and outstanding. 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 securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our ordinary shares and ADSs are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly.

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

We are a French company with limited liability. Our corporate affairs are governed by our bylaws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our board of directors are in

many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our board of directors is required by French law to consider the interests of our company, its shareholders, its employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder or holder of ADSs. See the sections of this annual report titled "Item 6. Directors, Senior Management and Employees—Board Practices" and the documents referenced in "Item 10. Additional Information—Memorandum and Articles of Association."

U.S. investors may have difficulty enforcing civil liabilities against our company and directors and senior management and the experts named in this annual report.

Certain members of our board of directors and senior management and certain experts named in this annual report are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Courts outside the United States may refuse to hear a U.S. securities law claim because non-U.S. courts may not be the most appropriate forums in which to bring such a claim. Even if a court outside the United States agrees to hear a claim, it may determine that the law of the jurisdiction in which the non-U.S. 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 non-U.S. 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 95% of voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the European Economic Area, or EEA, Agreement, including 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, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;

- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting by a two-thirds majority vote of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can be convened by our chairman, including upon request from our managing director, if any, or, when no board meeting has been held for more than two consecutive months, from directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;
- our shares are registered or bearer, if the legislation so permits, according to the shareholder's choice;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our bylaws can be changed in accordance with applicable French laws and regulations;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the documents referenced in the section of this annual report titled "Item 10. Additional Information—Memorandum and Articles of Association;"
- transfers of shares shall comply with applicable insider trading rules and regulations and, in particular, with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of our Bylaws relating to the number of directors and election and removal of a director from office, may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

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 (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

A holder of ADSs may instruct the depositary of the ADSs to vote the ordinary shares underlying his or her ADSs. Otherwise, such holder will not be able to exercise voting rights unless he or she withdraws the ordinary shares underlying the ADSs that he or she holds. However, a holder of ADSs may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for a holder of ADSs' instructions, the depositary, upon timely notice from us, will notify him or her of the upcoming vote and arrange to deliver our voting materials to him or her. We cannot guarantee to any holder of ADSs that he or she will receive the voting materials in time to ensure that he or she can instruct the depositary to vote his or her ordinary shares or to withdraw his or her ordinary shares so that he or she can vote them. If the depositary does not receive timely voting instructions from a holder of ADSs, it may give a proxy to a person designated by us to vote the ordinary shares underlying his or

her 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 a holder of ADSs may not be able to exercise his or her right to vote, and there may be nothing he or she can do if the ordinary shares underlying his or her ADSs are not voted as he or she requested.

Holders of ADSs are not holders of 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 is the holder of the ordinary shares underlying ADSs. The deposit agreement among us, the depositary and all persons directly and indirectly holding ADSs sets out ADS holder rights, as well as the rights and obligations of the depositary.

A double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years. However, the ordinary shares underlying our ADSs will not be entitled to double voting rights as the depositary will hold the shares underlying our ADSs in bearer form.

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

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, ADS holders 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 purchasers of ADSs unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the 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.

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

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

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

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

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising

under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company. This may limit the information available to holders of ADSs and our ordinary shares.

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Paris and have filed, and expect to continue to file, financial reports on an annual and semi-annual basis, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there is, and will continue to be, less publicly available information concerning our company than there would be if we were not a foreign private issuer.

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

As a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq's corporate governance standards. However, Nasdaq rules provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq's corporate governance standards as long as notification is provided to Nasdaq of the intention to take advantage of such exemptions. We have relied, and expect to continue to rely, on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq's corporate governance standards, to the extent possible. Certain corporate governance practices in France, which is our home country, may differ significantly from Nasdaq corporate governance standards. For example, as a French company, neither the corporate laws of France nor our bylaws require a majority of our directors to be independent and we can include non-independent directors as members of our remuneration committee, and our independent directors are not required to hold regularly scheduled meetings at which only independent directors are present.

We are also exempt from provisions set forth in Nasdaq rules which require an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is

no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting. Therefore, our shareholders may be afforded less protection than they otherwise would have under Nasdaq's corporate governance standards applicable to U.S. domestic issuers. For an overview of our corporate governance practices, see "Item 6. Directors, Senior Management and Employees—Board Practices."

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 could make our ADSs less attractive to investors.

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to continue 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 of 2002, or 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 of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. We have not taken advantage of, and do not intend to take advantage of, the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (2) December 31, 2024; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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, the next determination will be made with respect to us on June 30, 2021. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (1) the majority of our executive officers or directors are U.S. citizens or residents; (2) more than 50% of our assets are located in the United States; or (3) our business is administered principally in the United States.

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

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

Our tax treatment is subject to the enactment of, or changes in, tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, U.S. federal tax legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act or the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the U.S. Internal Revenue Service, or IRS, and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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, 2020, we believe that we were classified as a passive foreign investment company, or PFIC, for the taxable year ended December 31, 2020. Whether we are a PFIC for any taxable year will depend on our assets and income (including whether we receive certain non-refundable grants or subsidies, and whether such amounts along with reimbursements of certain refundable research tax credits and certain intercompany service payments will constitute gross income for purposes of the PFIC income test) in each year, and because this is a factual determination made annually after the end of each taxable year there can be no assurance that we will not be considered a PFIC in any taxable year. In addition, we hold a substantial amount of cash and cash equivalents. Because the calculation of the value of our assets may be based in part on the value of our ordinary shares or ADSs, the value of which may fluctuate considerably, our PFIC status may change from year to year and it is difficult to predict whether we will be a PFIC for the current year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current taxable year. However, we could continue to be considered a PFIC for the current taxable year or a future taxable year if the current percentage of our passive assets compared to our total assets remains the same or increases. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

Under the Internal Revenue Code of 1986, as amended, or the Code, a non-U.S. company will be considered 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 10. Additional Information—Taxation") holds our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds our ordinary shares or ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC,

including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section of this annual report titled "Item 10. Additional Information—Taxation."

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. Because our group currently includes one U.S. subsidiary, our non-U.S. subsidiary (and any other non-U.S. subsidiaries we form or acquire in the future) could 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.

We must maintain effective internal control over financial reporting, and if we are unable to do so, 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.

As a public company, we must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act requires, among other things, that our management assesses the effectiveness of our internal control over financial reporting beginning with this Annual Report.

The rules governing the standards that 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. To comply with this obligation, we must maintain an extensive framework of internal control over financial reporting, that we need to regularly update and test. This process is time-consuming, costly, and complicated. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company," which may be through December 31, 2024. 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 now applicable to us as a public company listed in the United States.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2018, our independent registered public accounting firm identified a control deficiency in our internal control over financial reporting. The material weakness was remediated and in the audit of our financial statements for the years ended December 31, 2019 and 2020, no material weakness were identified.

If we fail to maintain the remediation efforts or to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to maintain the remediation efforts, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in our failure to meet our reporting obligations in a timely manner under the Exchange Act, additional restatements of our consolidated financial statements, a decline in the price of our

ADSs, suspension or delisting of our ADSs from the Nasdaq Global Select Market, and could adversely affect our reputation, results of operations and financial condition.

Item 4.Information on the Company.

A. History and Development of the Company

We were incorporated as a French société anonyme, or S.A., on September 21, 1999. Our principal executive offices are located at Parc Eurasanté, 885 avenue Eugène Avinée, 59120 Loos, France. We are registered at the Register of Commerce and Companies of Lille Métropole (*Registre du commerce et des sociétés*) under the number 424 341 907. In July 2003, we incorporated our wholly owned U.S. subsidiary, Genfit Corp. Our other wholly owned subsidiary, Genfit Pharmaceuticals SAS, was incorporated in France in December 2011. Our telephone number at our principal executive offices is +33 3 20 16 40 00. Our agent for service of process in the United States is Corporation Service Company, located at 1180 Avenue of the Americas, Suite 210, New York, NY 10036.

Our actual capital expenditures for the years ended December 31, 2018, 2019 and 2020 amounted to €3.0 million, €2.1 million and €0.9 million, respectively. These capital expenditures primarily consisted of IT and scientific equipment, and office fixtures. We expect our capital expenditures to remain significant as we continue our research and development efforts and advance the clinical development of elafibranor, as well as our NIS4 technology and our other drug candidates, in the United States, Europe and elsewhere. We anticipate our capital expenditures in 2021 to be financed from our existing cash and cash equivalents and/or new bank loans as well as the financing opportunities offered by the French government in the context of the COVID-19 pandemic. For the near future, our investments will mainly remain in France where our research and development facilities are currently located.

The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. Our website address is www.genfit.com. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this annual report is not part of this annual report.

B. Business Overview

Overview

We are a late-stage clinical biopharmaceutical company dedicated to the discovery and development of innovative drug candidates and diagnostic solutions targeting metabolic and liver-related diseases where there is considerable unmet medical need. We are a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning two decades. Since 2016, we have been evaluating our most advanced drug candidate, elafibranor, in a pivotal Phase 3 clinical trial as a potential treatment for nonalcoholic steatohepatitis, or NASH (the RESOLVE-IT trial). On May 11, 2020, we published the topline data from the interim analysis. Elafibranor did not demonstrate a statistically significant effect on the primary endpoint, which is NASH resolution without worsening of fibrosis, nor did it achieve the key secondary endpoints. These results led us, after a detailed review of the whole dataset, to initiate the trial termination process for RESOLVE-IT at the end of July 2020, and in September 2020 the termination process for several related trials, including our study in pediatric NASH and our Phase 2 trial on liver fat. Similarly, and for the same reasons, we have decided to discontinue our combination program with elafibranor in NASH.

Following our decision to terminate all development of elafibranor in NASH and to focus our efforts on our two main strategic priorities (development of elafibranor in PBC and development of NIS4 technology for the diagnosis of NASH and fibrosis), we rationalized our pre-clinical research efforts, which led us to continue only those strictly necessary for the purposes of these two priorities. As a result, we decided to discontinue any investment in our TGFTX1 pre-clinical development program and to terminate pre-clinical work related to our development program of combinations with elafibranor in NASH.

Elafibranor is currently being evaluated as a potential treatment for primary biliary cholangitis, or PBC. PBC is an autoimmune disease unrelated to the metabolic origins of NASH and is independent from our evaluation of elafibranor in NASH.

PBC is a chronic, progressive liver disease that leads to inflammation and scarring of the small bile ducts in the liver. Although a relatively rare disease mainly affecting women, PBC can develop into cirrhosis and other serious liver complications. There is currently no cure for PBC, and the two drugs approved for the treatment of PBC are limited by drug intolerance,