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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2020

OR

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

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report

Commission File Number 001-38844

GENFIT S.A.

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

FRANCE
(Jurisdiction of incorporation or organization)

Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France
(Address of principal executive offices)

Pascal Prigent
Chief Executive Officer
GENFIT S.A.
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59120 Loos, France
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Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value €0.25 per share	GNFT	The Nasdaq Global Select Market
Ordinary shares, nominal value €0.25 per share*	*	The Nasdaq Global Select Market*

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

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary shares: 38,888,379 shares outstanding as of December 31, 2020**

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

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

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

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

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

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

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

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

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

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

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

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

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

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INTRODUCTION

Unless otherwise indicated, “GENFIT,” “the company,” “our company,” ‘the group,” “we,” “us” and “our” refer to GENFIT S.A. and its consolidated subsidiaries.

“GENFIT,” the GENFIT logo, “RESOLVE-IT”, “NIS4”, “ELATIVE”, “The NASH Education Program”, “The NASH Epidemiology Institute” and other trademarks or service marks of GENFIT S.A. appearing in this Annual Report on Form 20-F, or annual report, are the property of GENFIT S.A. or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this annual report are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this annual report are the property of their respective owners. We do not intend to use or display other companies’ trademarks and trade names to imply any relationship with, or endorsement or sponsorship of us by, any other companies.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F, or annual report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this annual report, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this annual report, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our plans to develop and commercialize elafibranor, tests powered by our NIS4 technology and our other drug candidates;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, including the timing of availability of data from our clinical trials;
- our ability to successfully expand and advance our pipeline of drug candidates;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals;
- the clinical utility and market acceptance of our drug candidates and tests powered by our NIS4 technology;
- the potential clinical utility of our product candidates and their potential advantages over existing therapies as well as those in development;
- our ability to establish and maintain manufacturing and supply arrangements for our product candidates;
- the ability of third parties with whom we contract to successfully conduct, supervise and monitor clinical trials for our product candidates;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to maintain, protect and enhance our intellectual property rights and proprietary technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- our estimates regarding future revenues, expenses and needs for additional financing;
- the impact of the COVID-19 pandemic on our business and operations; and
- other risks and uncertainties, including those listed in this annual report under the caption "Risk Factors."

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

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

This annual report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this annual report are generally reliable, such information is inherently imprecise.

SUMMARY RISK FACTORS

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

- 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.
- 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.
- 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 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 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.
- 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.
- 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.
- 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.
- 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.
- 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 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.
- 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
- 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.

- 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.
- 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.
- 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
- 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 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 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.
- 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
- The market price of our equity securities is particularly volatile and may decline regardless of our operating performance.
- The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of our ordinary shares and ADSs.
- We are currently the subject of securities class action litigation and may become subject to additional litigation, which could harm our business and financial condition.
- The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

PART I

Item 1.Identity of 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,

inadequate patient response and/or safety issues. Based on our clinical data, we believe elafibranor's unique mechanism of action can provide benefits for patients with PBC without significant side effects, such as the serious liver injury or death and pruritus that have been associated with approved PBC treatments.

Positive results from our Phase 2 clinical trial of elafibranor in PBC, which were presented in April 2019 at the International Liver Congress 2019 organized by EASL (European Association for the Study of the Liver), formed a strong rationale to launch in 2020 the ELATIVE Phase 3 trial for the evaluation of elafibranor in this indication. Both doses of elafibranor met the primary endpoint of our Phase 2 clinical trial, as well as the composite endpoint used for registration of the second line treatment. We also observed a beneficial trend on pruritus – a major symptom of PBC – but this remains to be confirmed in the ongoing ELATIVE Phase 3 trial. In 2019, elafibranor received breakthrough therapy designation from the FDA for the treatment of PBC, and orphan drug designation from both FDA and EMA. The first patient first visit in the ELATIVE trial took place on September 24, 2020 and top-line results of the ELATIVE Phase 3 trial are expected at the beginning of 2023.

The development and commercialization rights in elafibranor for the treatment of both NASH and PBC in Greater China have been granted to Terns Pharmaceuticals through a strategic and license collaboration agreement which we signed in June 2019.

A key differentiator of our growth strategy is our NASH non-invasive biomarker-based diagnostic program based on four biomarkers to identify patients with NASH who may be appropriate candidates for drug therapy.

In January 2019, we entered into a first license agreement with Labcorp to allow Labcorp to develop and commercialize NIS4 in the clinical research space through their drug development subsidiary, Covance. Since then, Covance has made significant progress in the deployment of NIS4 in several clinical trials conducted by leading players in the pharmaceutical industry, although, due to the COVID-19 pandemic, this may have been slowed down due to the delays in the relevant clinical trials.

Moreover, in September 2020, we signed a new and five-year exclusive license agreement with Labcorp to allow them to develop and commercialize an LDT powered by NIS4 technology for use in routine clinical diagnostic testing in the United States and Canada. Unlike IVD tests, which are subject to the same regulations as medical devices and require prior FDA approval before being placed on the market, an LDT does not require such FDA approval but does require that the laboratory performing the test has been certified according to the CLIA standard (which certification our partner Labcorp has obtained). Finally, we continue to explore the possibility of obtaining regulatory approval to commercialize an IVD test powered by NIS4 technology in the United States and European markets.

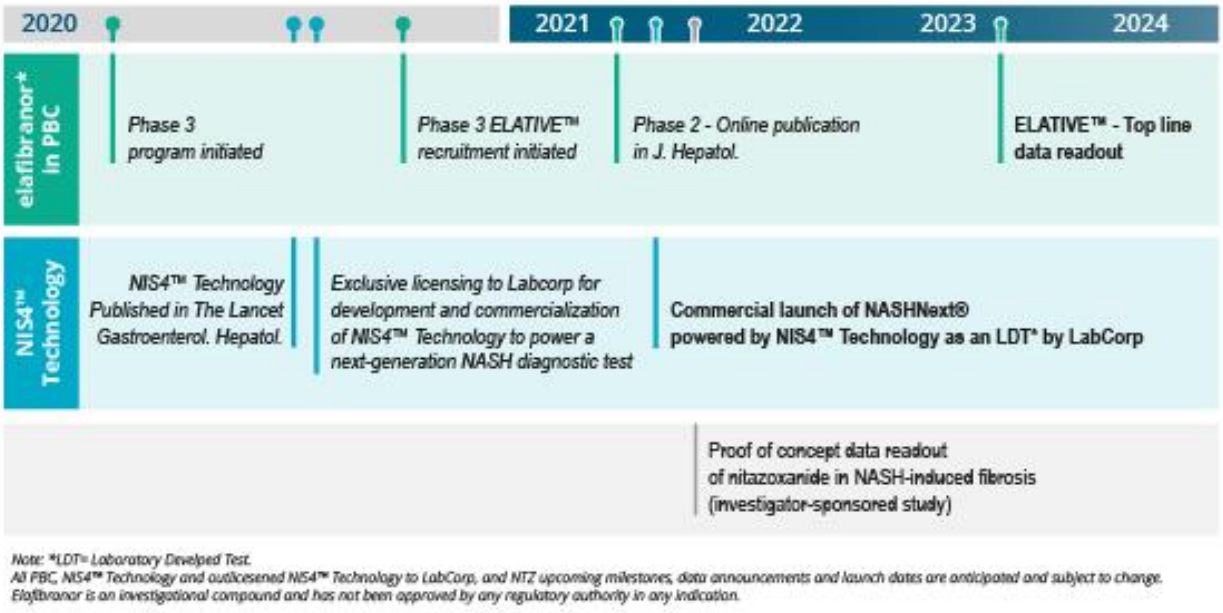
Our scientific and clinical expertise, translational disease-driven approach and strong bioinformatics capabilities have allowed us to build a scientific platform through which we discover and develop our drug candidates and diagnostic tools.

We are also conducting pre-clinical research, notably on NTZ.

NTZ was identified through a phenotypical screening approach combine with the use of a compound database including drugs approved by the FDA. Following this profiling, we believe that NTZ could be repositioned for the treatment of liver fibrosis. In December 2018, a trial was launched at the initiative of Dr. Stephen Harrison, a clinical investigator working with our Company, in order to assess the safety and efficacy of NTZ for patients with NASH-induced stage 2 or 3 fibrosis. The results of this trial are expected in the first half of 2021.

Several other pre-clinical investigations are ongoing in other indications with NTZ, and this program may evolve during the year 2021.

The following table summarizes our drug candidate and diagnostic development pipeline.



Our company was co-founded in 1999 by Jean-François Mouney, now Chairman of the Board of Directors. Our shares have been listed on the Euronext Paris under the symbol “GNFT” since 2006, and we became a dual-listed company in March 2019 after a global offering and U.S. IPO on the Nasdaq Global Select Market, raising gross proceeds totaling $155 million. Our American Depositary Shares, or ADS, are listed on the Nasdaq Global Select Market under the symbol “GNFT”. We are led by an executive team and board of directors with deep experience at leading biotech companies, large pharmaceutical companies and academic institutions. As a consequence of refocusing our efforts on our two main strategic priorities, and following an extensive cost-savings program, including an employment protection plan (*plan de sauvegarde de l’emploi*) in France, our headcount is approximately 125 employees at our offices in Lille and Paris, France and Cambridge, Massachusetts. The chair of our scientific advisory board, Bart Staels, is the other co-founder of our company and a world-renowned expert in nuclear receptors. Our scientific advisory board is comprised of internationally recognized key opinion leaders in the field of metabolic and inflammatory diseases, with a particular focus on the liver and gastroenterology. We believe the expertise of our leadership and the strength of our relationships within the academic and clinical communities are critical to our ability to execute on our mission as we progress our development pipeline.

A note about the evolving COVID-19 pandemic and its potential consequences on our business

The unprecedented spread of COVID-19 – characterized as a pandemic by the World Health Organization on March 11, 2020 – is impacting the global health and business ecosystem, Genfit included. During this evolving crisis, our priorities continue to be to ensure the safety and well-being of our employees, of the patients and healthcare professionals involved in our clinical trials, as well as the integrity of our ongoing clinical trials. We remain committed to ensuring business continuity and have been monitoring the situation closely. In light of our priorities and in accordance with the recently issued guidance documents of the FDA and the EMA, we have worked with our contract research organizations, trial sites and investigators to critically reassess all our existing programs. On March 31, 2020, we announced a series of measures, and have updated our shareholders about the estimated impact on our programs.

As of the date of this Annual Report, and as the result of measures implemented in consultation with the clinical research organization, 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 partners' resources towards the prevention, diagnosis and treatment of COVID-19 patients, to the detriment of other activities, including our programs. While the situation is expected to subside over time, it is still unclear at the time of publication of this Annual Report how long it will last. Therefore, corporate guidance provided in this document may be subject to further adjustments which, by nature, cannot be precisely anticipated. See also Item 3.D Risk Factors – "The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials."

Our Strengths

We believe the following strengths will allow us to successfully continue our activities in drug and diagnostic research and development for metabolic and liver-related diseases:

- **Phase 3 clinical trial ELATIVE in PBC: a priority program with significant potential**

  Robust Phase 2 data

  Positive results from our Phase 2 clinical trial evaluating elafibranor in PBC – published in the Journal of Hepatology in early 2021 and detailed in section "Our Drug Candidates and Diagnostic Development Programs - Elafibranor for the Potential Treatment of PBC"– form a strong rationale for further evaluation of elafibranor in a Phase 3 clinical trial.

  Phase 3 launched, and targeted market with double-digit growth in 2020

  Our Phase 3 clinical trial entered its recruitment phase in September 2020, which means we could, if the trial is successful early 2023 and we receive regulatory approval, provide patients with high unmet medical needs despite existing therapies (UDCA or ursodeoxycholic acid as first line treatment and Ocaliva as second line treatment) with a new therapeutic option. If these results are positive, elafibranor could become the first alternative to Ocaliva on a market estimated to $1 billion in 2025.

  IQVIA, a recognized leader in research and consulting services for the pharmaceutical industry, was commissioned by GENFIT to conduct three comprehensive market research studies evaluating the potential market opportunity, should elafibranor be granted regulatory approval as a second line treatment for PBC. It is estimated that elafibranor could – if approved, and thanks to its efficacy, safety and tolerability profile – achieve $515 million in peak year revenue, as second line treatment for patients with PBC who cannot benefit from the first line therapy.

  A clear regulatory pathway and an accessible commercial roll-out

  There is a clear reference point in PBC in terms of regulatory approval criteria since Ocaliva was approved in this indication in 2016. The placebo response rate in this disease is much more predictable than in other liver diseases. The population to be treated is well defined since the therapeutic approach is a second line treatment, and these patients are easily identified. The price payers are currently willing to pay for the drug is known and is significantly higher than what may have been considered for NASH. A commercial launch in an orphan and specialty pharma indication like PBC typically consumes less resources than that of a mass market launch.

  Low competitive intensity

  The competitive landscape, detailed in section "Competition" in this Item 4.D., is characterized by a limited number of competitors, which is an additional advantage for elafibranor.

- **NIS4 program in NASH Diagnostics: achievements and potential to create value**

  A simple solution already used by KOLs

Our NIS4 technology is designed to identify patients with “at-risk” NASH, i.e., those with NASH and fibrosis, and who therefore may be appropriate candidates for drug intervention. We believe that broad adoption of a blood-based diagnostic test – if validated and authorized for marketing as an IVD or LDT – could help to address the unmet need of under-diagnosed NASH. An LTD or IVD test using our NIS4 technology has the potential to also allow stronger engagement of non-liver specialists such as diabetologists, endocrinologists and primary care physicians in the identification and clinical management of patients with “at risk” NASH. Its use in the clinical research field since 2019 has allowed many KOLs to work and get acquainted with the technology through clinical trials.

Scientific results published in The Lancet

In August 2020, data related to NIS4 published in The Lancet Gastroenterology and Hepatology showcased the robust and consistent performance of NIS4 to identify at-risk NASH, and the improved performance of NIS4 relative to other technologies including commonly used liver fibrosis tests. We believe blood-based diagnostic tests powered by NIS4 technology will play a critical role in the diagnosis and management of patients with NASH. Hence, we believe non-invasive testing will continue to gain importance within healthcare systems given the capability to identify those who may require more aggressive medical intervention with a simple blood draw while maintaining high diagnostic accuracy.

A commercial launch planned for the first half of 2021 targeting an unmet medical need faced by millions of patients

We signed an exclusive licensing agreement in September 2020 with Labcorp, leading global life sciences company that is focused on advancing health and guiding patient care decisions.

As part of the agreement, we anticipate that Labcorp will begin commercialization of or make available a blood-based molecular diagnostic test called NASHnext powered by NIS4 technology throughout the U.S. and Canada enabling widespread access to a large number of healthcare providers including specialty and primary care physicians. Labcorp will leverage its deep experience in commercializing innovative diagnostics to educate providers on NASH and the importance of non-invasive testing.

As a recognized global leader the diagnostics industry, Labcorp has deep experience in the commercial launch of diagnostic tests. Although the market’s growth is tightly linked to the availability of the indication-specific therapies, primary market research conducted by Genfit showed that there is already high unmet medical need despite independent to NASH drug development. These findings from the primary market research are an indicator that clinicians need better non-invasive tools today in order to help stratify the millions of patients with metabolic risk factors including diabetes, prediabetes, obesity or excess weight that may have or are suspected to have “at-risk” NASH. In doing so, patients with oversight from their physician have the potential to make strides towards controlling progression of their disease with the appropriate therapeutic strategy tailored for their needs which may include a combination of future therapeutics, participation in intense lifestyle interventional programs, and long term changes to their nutrition and level of physical activity.

Towards an independent subsidiary

We are exploring the opportunity to establish a dedicated subsidiary for the development of these activities, which should facilitate partnerships in the future.

- **A pioneer in the liver-related diseases field**

Our early move into the liver diseases area gave us the opportunity to develop in-depth regulatory expertise, as well as significant commercial knowledge following the extensive research work carried out with payers and future prescribers. Our network and connections with key experts have grown over time, which we believe represents a major asset. Our long-standing position and the experience acquired over the years could make of GENFIT a valuable partner for any pharmaceutical company willing to develop an ambitious plan, regardless of its development stage and targeted therapeutic area: from the identification of early drug candidates to the design of robust and well-informed commercial strategies, and including the set-up and optimization of relevant regulatory pathways. Practically, we play an active role within The Liver Forum, an international institution bringing together the most prominent stakeholders in the field: representatives from the major regulatory agencies, KOLs, learned societies, or industry leaders. We have also developed strong relationships with most prominent patient associations within our field: Global Liver Institute (GLI), American Liver Foundation, PBC Foundation, etc.

- **An experienced team with industry leaders**

  We believe that the breadth of experience and accomplishments of our management team, board of directors and scientific advisory board, combined with our broad network of established relationships with leaders in the industry and medical community, provide us with unique insights into drug development and commercialization, and have allowed us to bring together top researchers to build interdisciplinary research and development teams.

- **R&D expertise**

  R&D at the heart of our strategy

  Our mission is to develop therapeutic and diagnostic solutions to make them available to patients, we have therefore put together an extended technical platform in our therapeutic areas of expertise, and have established tight collaborations with experts from the academic field or companies specializing in areas that complement our own expertise.

  Our R&D relies on clinical expertise in our therapeutic areas, on a strong knowledge of diseases, precision science in gene and biological mechanisms regulation. Our technical platform allows us to validate new therapeutic targets, to work on preclinical models that can bring proof of the therapeutic significance of a new product, with the establishment of tests and screening cascades, identification of original compounds targeting new mechanisms of action, and the generation of series of small molecules designed to induce specific biological responses.

  We also have the necessary experience to coordinate and manage regulatory preclinical trials and production of active ingredients and finished products all along the drug development path. The robust expertise we have built in these areas allow us to ensure, at each step of the process, the optimized transmission of our know-how to our specialized partners.

  In particular in the nuclear receptor field

  Nuclear receptors are a class of therapeutic targets with a strong potential. Nuclear receptors are intracellular receptors that regulate a number of key biological functions, including inflammation, oxidative stress, and lipid and glucose metabolism, as well as the proliferation and differentiation of certain cell types. Disruption in the normal function of nuclear receptors can lead to certain metabolic diseases, including dyslipidemia and diabetes, inflammatory diseases, and even certain cancers.

  Researchers and industry have actively investigated nuclear receptors for their therapeutic potential in certain diseases for many years. For example, it is estimated that up to 15% of all approved therapies exert all, or part of, their effects through nuclear receptors (e.g., estrogens, glucocorticoids, androgens, vitamin D, and fibrates).

  As a world-leading expert in nuclear receptor pharmacology, GENFIT is focused on development of next-generation therapies which modulate nuclear receptor physiology.

Our Strategy

Our goal is to become a world leader in the development and commercialization of innovative therapies and diagnostics in metabolic and liver-related diseases.

- **A new strategy announced in September 2020**

  In July 2020, following the detailed review of the full RESOLVE-IT interim efficacy dataset we determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the United States and Europe.

  We announced our new corporate strategy, focused on two programs with high unmet medical needs that we believe, represent significant market opportunities with a promising risk profile:

  - The first program is the pursuit of elafibranor’s development as second line treatment for PBC, with a Phase 3 clinical trial (ELATIVE™) currently recruiting since September 2020;

  - The second program aims to develop NIS4 technology’s potential in NASH diagnostics and broaden the range of our solutions and services to complement our existing pipeline.

The development of both of these priority programs is accompanied by a cash burn control plan aiming to reach an annual cash burn of €45 million in 2022, corresponding to a reduction of more than 50% in two years. In parallel, we decided to reduce the amount of our convertible debt (issued in 2017 for a nominal amount of €180 million) and amend its terms to release the financial constraint that was inhibiting our capacity to operate and therefore our development. Our convertible debt was reduced to a nominal amount of €94 million following Shareholders and the Bondholders' Meetings approval in January 2021, and then to a nominal amount of approximately €57 million at April 13, 2021 following subsequent conversions by some bondholders. The convertible debt maturity was also extended to October 2025, compared to 2022 prior to the renegotiation.

The new operational priorities that derive from this new corporate strategy are as follow:

- **Announce top-line data from our Phase 3 clinical trial in Q12023 at the latest**

  Ocaliva, commercialized by Intercept, is currently the only available second line treatment after the prescription of ursodeoxycholic acid (UDCA) as a first line treatment, for the treatment of adult patients with PBC who have had inadequate response to or who are intolerant to UDCA. This market amounted to more than $300 million in 2020, with a double digit growth in 2020. According to estimates from IQVIA, a recognized leader in research and consulting services for the pharmaceutical industry, from a report we commissioned, the total PBC market for second line treatments is estimated to reach $1 billion annually in 2025, by which time we hope to have launched elafibranor in this indication, assuming positive results from the ELATIVE phase 3 trial and provided we obtain regulatory approval. The commercial opportunity is therefore significant in this indication, especially so since the competitive pressure has been described as low, with Ocaliva being the only second line treatment currently approved. The Phase 3 clinical trial for a third molecule developed by another company was stopped prematurely following a safety concern but the sponsor for this clinical trial has announced in late March 2021 that a new Phase 3 trial was ongoing.

  Elafibranor demonstrated promising results in a Phase 2 clinical trial evaluating its efficacy and safety in this indication. These data were published in February 2021 in the Journal of Hepatology. Following 12 weeks of treatment, elafibranor's efficacy on the composite endpoints was significantly superior to what was historically sufficient to obtain regulatory approval. Furthermore, a positive trend on pruritus– that will need to be confirmed in the Phase 3 trial ELATIVE™ – was observed on this major symptom of PBC. If confirmed, this trend could reinforce elafibranor's differentiated potential in this indication. Finally, the abundance of data derived from the RESOLVE-IT trial and the total duration of exposure to the product – which amounts to thousands of patient-years for elafibranor – have shown a favorable safety profile. The topline data for the Phase 3 trial are expected early 2023.

- **Progress our diagnostic program in NASH and expand beyond blood-based diagnostics into digital products and solutions.**

  Identification of NASH patients remains a major challenge. These patients are, for the most, part asymptomatic, and those who do have NASH do not necessarily and systematically require treatment. With "at-risk" NASH, it is important to identify those patients who should receive differential care and may be eligible for future NASH therapeutics. Today, the clinical reference to diagnose NASH and stage fibrosis is a liver biopsy, which is an invasive and costly procedure that may be associated with procedural complications.

  A non-invasive and scalable diagnostic solution optimized for use in NASH remains a high unmet need. And since the goal is to determine which patients may have "at-risk" NASH due to the increased risk of all-cause mortality and liver-related morbidity in this population, we have concentrated our program on identifying this population of patients with a NAFLD activity score (or NAS score) of at least 4, and a fibrosis stage of at least 2.

  Given our extensive knowledge of NASH and insights generated through clinical research programs and market research, we aim to develop innovative digital products and solutions to help identify, evaluate, and monitor patients with NASH. This strategy is based on years of effort in deep-learning and artificial intelligence originally applied to complex scientific and clinical problems. For example, in 2018 at The International Liver Congress in Paris, France, we presented data from a deep-learning algorithm that could accurately identify cell histology patterns consistent with lobular inflammation and

hepatocellular ballooning - markers of disease activity that are essential to establishing the diagnosis and severity of NASH. We believe this underlying core competency can be leveraged to generate new products, services, and solutions in the NASH space.

We reached two major milestones for the NIS4™ program in 2020:

Publication in The Lancet (Gastroenterology & Hepatology) of data describing the derivation and validation of NIS4™: these data showcased the robust and consistent performance of NIS4 to identify at-risk NASH. NIS4 also provided consistent results in critical sub-populations (e.g. diabetic vs. non-diabetic, men vs. women) as compared to other non-invasive tests evaluated in the same individuals. This publication has been a key for the technology need since it demonstrated that NIS4 technology is a potentially scalable and easily integrates into existing care pathways that addresses both aspects of NASH simultaneously (NAS and fibrosis), therefore helping the identification and clinical care of patients.

Signature of an exclusive licensing agreement with Labcorp, paving the way for the potential commercialization of a new diagnostic test powered by our technology NIS4™: this agreement should allow for a large-scale commercial launch of our technology, where its use had remained limited until now to clinical research players. By doing so, NIS4™ technology should become accessible, in late April 2021, to millions of individuals who are at risk of developing severe complications related to the late stages of NASH.

Plans for an independent entity dedicated to developing the potential of our diagnostic program in NASH: Future synergies between GENFIT's priority programs are limited given that one consists in developing a drug to treat a rare disease (PBC) and the other aims at developing diagnostic technologies or solution in liver disease such as NASH. Economic models, target patient population, potential partners, clients, strategies, financing needs and regulatory environments are very different. For these reasons, we have launched plans for a subsidiary dedicated to the diagnostic program, to ensure a more independent steering and a more autonomous growth for the NASH diagnostics activity. This entity would focus on the development of solutions to aid in the identification, evaluation and monitoring of patients with NASH and other diseases. The new organization should facilitate the implementation of future partnerships for NIS4™, but also for other solutions. Its main activity would initially be focused on diagnostics but could well dive into new areas capitalizing on experience and knowledge accumulated over the years, and on its network.

- **Develop our drug-candidates pipeline through organic and external opportunities**

This strategic component is materialized with two parallel workstreams:

Research and Development: this first axis aims at promoting the research conducted on internally developed assets. As an example, we are moving forward with our NTZ repositioning program.

Business Development: this second axis consists in identifying high potential external assets, that we think present a strong potential, with the highest probability of success, and which, according to us, could create value for the company, without the need for a significant cash consumption.

- **Implement a cost-saving plan: to reduce cash burn to €45 million in 2022**

In order to implement its new corporate strategy, we initiated a cost-saving plan aiming to reduce our workforce and its cash burn.

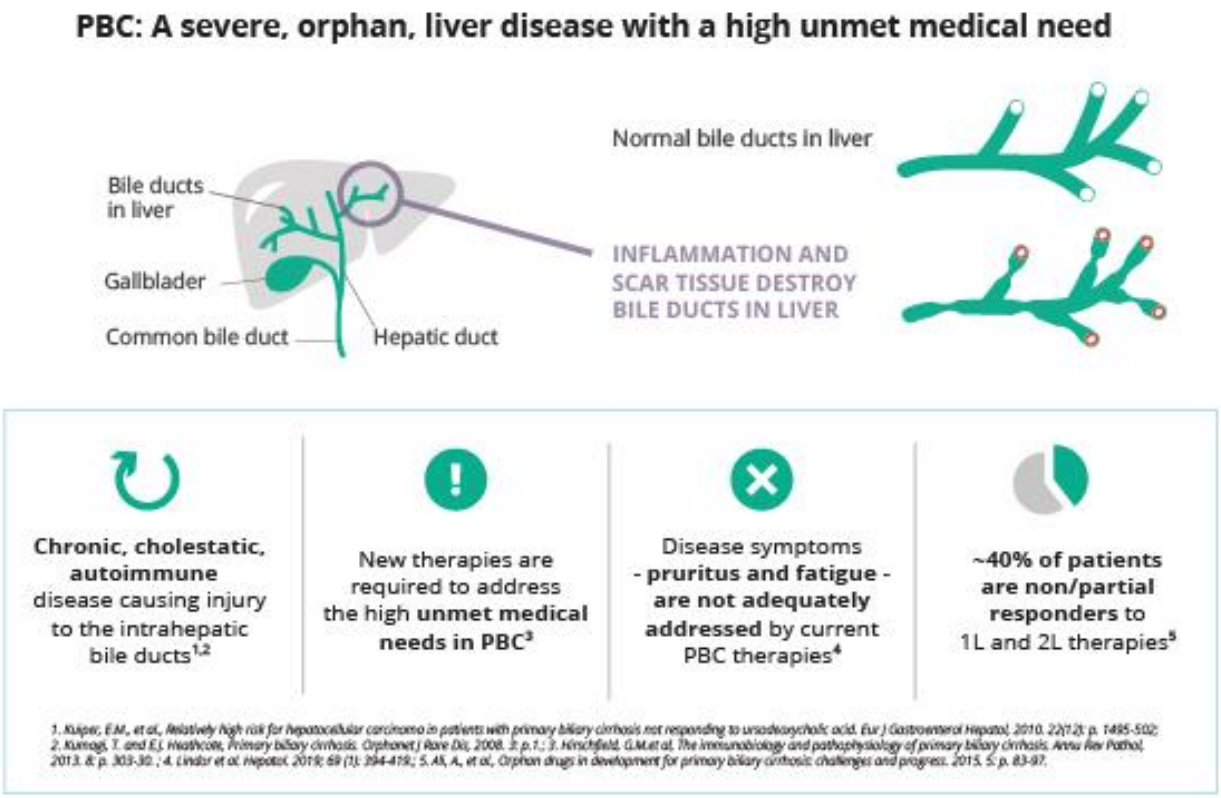
We completed the workforce reduction plan, which reduced the headcount from over 200 mid-May 2020, to less than 125 early 2021. This job preservation plan was executed in accordance with our Works council and reflects the termination of programs and activities announced in September 2020.

We are also working to reduce operational expenses and eliminate non-essential expenses, which is currently ongoing. Our goal is to reduce by half our cash burn by 2022 compared to the cash burn before the RESOLVE-IT data readout. The objective is to go from a cash burn of approximately €110 million annually to €45 million in 2022. 2021 is expected to be a transitional year in terms of operating cash burn. Our goal is to reduce our cash burn to approximately €75 million (excluding cash required for the partial buyback of our OCEANEs for a gross amount of €47.48 million as part of the convertible debt renegotiation), mainly due to expenses related to the termination of the RESOLVE-IT trial and to costs associated with the workforce reduction plan and the renegotiation of our bond debt.

Our Drug Candidates and Diagnostic Development Programs

Elafibranor for the Potential Treatment of PBC

About PBC



PBC is an autoimmune disease resulting from progressive destruction of the small bile ducts inside the liver. When liver bile ducts are destroyed, the bile which normally would travel to the small intestines to aid in digestion and elimination of waste instead accumulates in the liver, contributing to inflammation and fibrosis. PBC is believed to be an autoimmune disease in which a person's immune system is overactive and attacks normal, healthy bile duct cells. The following graphic depicts the distinction between normal bile ducts and those that have been destroyed.

PBC is a disease with a global prevalence of approximately 40 cases per 100,000. However, that prevalence is increasing; in the United States, the prevalence of PBC increased from 21.7 to 39.2 per 100,000 from 2006 through 2014. Women are much more likely to be affected by PBC than men, and the incidence increases after the age of 50.

The initial symptoms of PBC are general fatigue and pruritus, which is itchy skin; other potentially associated symptoms include dry eyes, dry mouth and jaundice. However, approximately 60% of patients are asymptomatic when the disease is diagnosed. PBC is diagnosed based on blood tests revealing the presence of anti-mitochondrial antibodies, or AMAs, and high levels of the liver enzyme ALP (alkaline phosphatase). Cirrhosis is not generally advanced at the time of PBC diagnosis.

Left untreated, PBC typically leads to cirrhosis, liver failure and the need for liver transplantation. In the absence of treatment, the 10-year survival of asymptomatic patients is estimated to be between 50 and 70%, with a median survival of 16 years. Among symptomatic patients, median survival in the absence of treatment is only seven to eight years. PBC is believed to be responsible for 2-3% of deaths by cirrhosis.

Limitations of Current Treatment Options

There is currently no cure for PBC, although there are medications that work to slow its progression. For many years, ursodeoxycholic acid, or UDCA, was the only drug approved by the FDA for the treatment of PBC. UDCA is a naturally occurring bile acid that is normally produced in the liver by healthy cells. UDCA, administered orally, is designed to help move bile through the liver and into the intestines. Although UDCA is effective in more than 50% of patients, up to 40% of patients do not respond or respond poorly to treatment and an additional 5-10% of patients are unable to tolerate the drug.

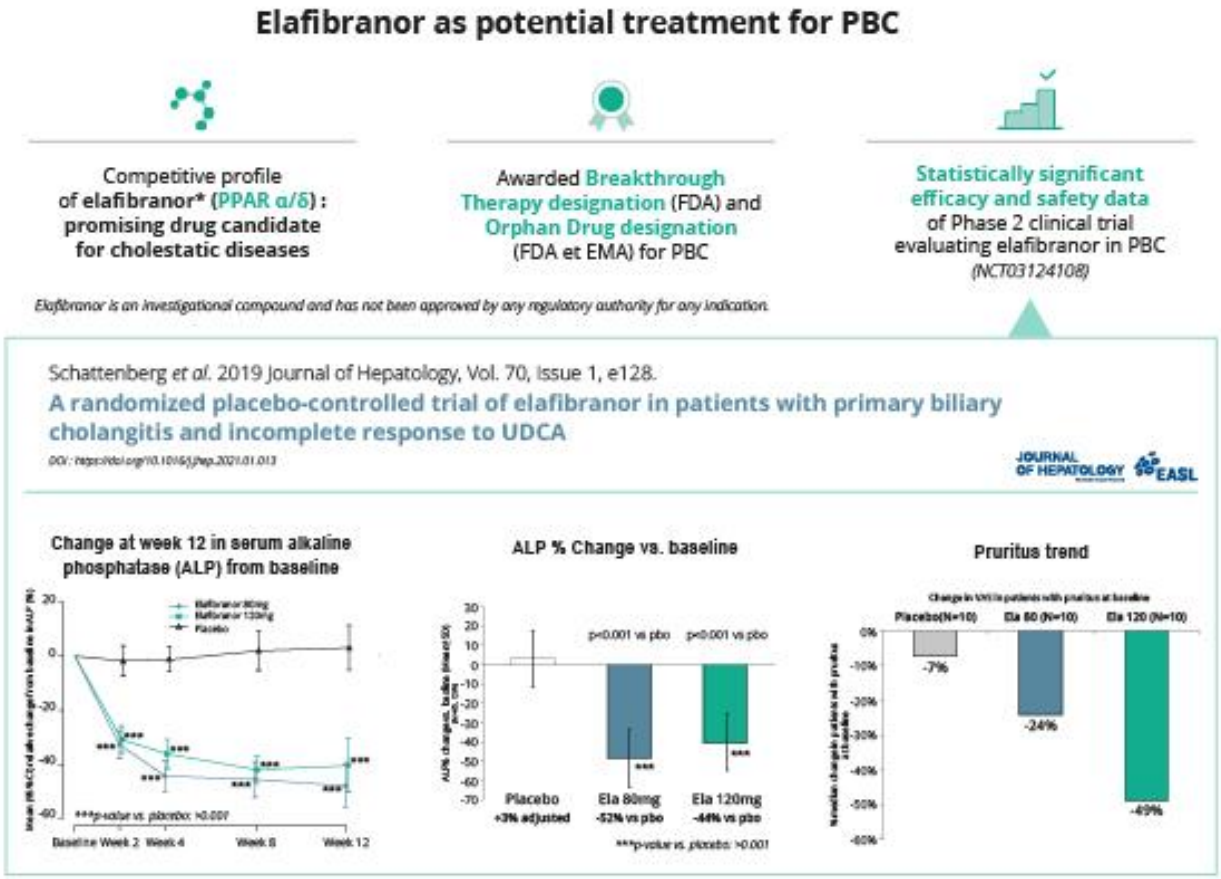
In May 2016, the FDA approved obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, Inc., for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as a single therapy in adults unable to tolerate UDCA. In September 2017, following the death of 19 PBC patients being treated with Ocaliva, the FDA published a safety announcement for Ocaliva, indicating that some patients with moderate to severe decreases in liver function had been incorrectly dosed, resulting in an increased risk of serious liver injury and death. The FDA also indicated that Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. In February 2018, the FDA had a Boxed Warning added to the Ocaliva label, the most severe warning required to be included in labeling by the FDA. Concerns remain over pruritus and serious liver injury or liver death caused by administration of Ocaliva. In its Phase 3 clinical trial, severe pruritus was reported in 23% of patients in the Ocaliva 10 mg dose cohort and in 19% of patients in the Ocaliva titration cohort, in which dosing was initiated at 5 mg and titrated up to 10 mg based on clinical response, compared to 7% of patients in the placebo group.

Accordingly, we believe there is still a significant medical need for new therapies, as current treatments either are ineffective for a large portion of PBC patients, cause significant side effects or include safety risks.

Our Solution: Elafibranor for the Potential Treatment of PBC

We believe that elafibranor has the potential to offer a therapeutic solution that can be effective in treating PBC while also maintaining a favorable tolerability profile and lack of demonstrated safety concerns.

Targeting PPAR receptors has shown multiple beneficial activities, including the reduction of bile acid synthesis, improved detoxification of bile in the bile duct and anti-inflammatory activity. In third-party clinical trials, drugs targeting PPAR receptors resulted in a significant decrease in serum alkaline phosphatase (ALP) and improved biochemical profiles and pruritus in PBC patients. Patients with PBC often have elevated ALP, and studies have shown a correlation between elevated ALP levels and increased risk of adverse patient outcomes. We have observed elafibranor’s effect in lowering ALP levels in our Phase 2 clinical trial in PBC.



Our Clinical Program for Elafibranor in the Treatment of PBC

Phase 3 ELATIVE trial

Positive results from our Phase 2 clinical trial of elafibranor in PBC, which were presented in April 2019 at the International Liver Congress 2019 organized by EASL (European Association for the Study of the Liver), formed a strong rationale to launch the ELATIVE Phase 3 trial for the evaluation of elafibranor in this indication.

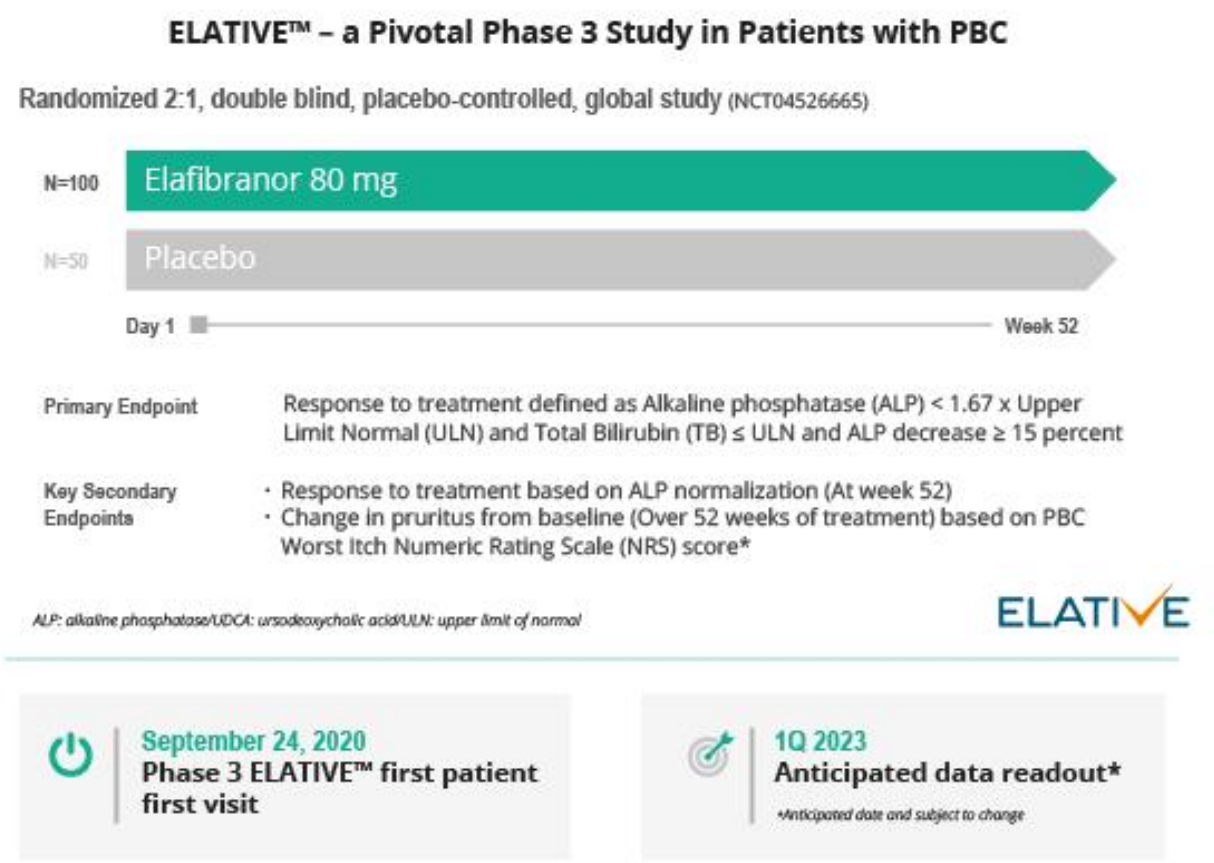
ELATIVE is an international Phase 3 double-blind randomized placebo-controlled study with an open-label LTE evaluating the efficacy and safety of 80 mg elafibranor once daily versus placebo in patients with PBC and inadequate response or intolerance to UDCA. In the double-blind period, patients will be randomized in a 2:1 ratio to receive 80 mg elafibranor (n=100) or placebo (n=50) once daily

After the double-blind period, all patients will receive elafibranor at 80 mg per day for five years at most during the LTE.

The primary endpoint is the response to treatment at week 52 defined as defined by biochemical parameters: ALP < 1.67 x ULN and total bilirubin ≤ ULN and ALP decrease ≥ 15%. Secondary endpoints include response to treatment based on ALP normalization at week 52 and change in pruritus from baseline through week 52 on PBC Worst Itch NRS score.

Due to the COVID-19 pandemic, we announced in March 2020 a delay in the initiation of the ELATIVE trial. In September 2020, we announced the first patient first visit in the ELATIVE trial. Appropriate measures have been implemented, 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 study. Enrollment is continuing, and new clinical research centers have been opened. We expect top-line results of the ELATIVE Phase 3 trial at the beginning of 2023.

In addition to the pivotal phase 3 trial that will be used to support and seek regulatory approval, the program will also include a confirmatory study based on hard clinical endpoints.



Phase 2

In December 2018, we announced positive preliminary results, including achievement of the primary endpoint and the composite endpoint, from our Phase 2 multi-center, double-blind, randomized, placebo-controlled clinical trial to evaluate the efficacy and safety of elafibranor after 12 weeks of treatment in patients with PBC and inadequate response to UDCA. The trial was conducted at multiple clinical centers in the United States and in three European countries and enrolled a total of 45 patients. The patients were randomized into one of three treatment arms, receiving either elafibranor 80 mg, elafibranor 120 mg or placebo.

The primary objective of the trial was to determine the effect of daily oral administration of elafibranor on ALP in these patients, based on relative change from baseline serum ALP levels compared to placebo. In addition to assessing the tolerability and safety of elafibranor in patients with PBC, secondary endpoints included assessment of elafibranor 80 mg and 120 mg as compared to placebo on several outcome measures, including:

- composite endpoint composed of ALP and bilirubin, with response defined as (1) ALP less than 1.67 times the upper limit of normal, or ULN, (2) total bilirubin within normal limits and (3) a reduction of ALP of more than 15%;
- changes in patients' risk scores as measured by several PBC risk scoring systems (Paris I and II, Toronto I and II and UK-PBC);
- change from baseline in pruritus, as measured by a 5-D itch scale and visual analogue scale; and
- change from baseline in quality of life, as measured by PBC-40, a patient-derived questionnaire.

In the preliminary results published in December 2018, we observed that the mean decrease in ALP in both of the elafibranor treatment groups showed statistically significant improvement compared to placebo. In the elafibranor 80 mg and 120 mg treatment groups mean decreases in ALP were 48% (n=15) and 41% (n=14), respectively whereas the mean ALP increased by 3% (n=15) in the placebo group. When adjusted for placebo, the treatment effect of the elafibranor 80 mg and 120 mg treatment groups was a mean decrease in ALP of 52% ($p<0.001$) and 44% ($p<0.001$), respectively. Based on these results, elafibranor achieved the primary endpoint of the trial with high statistical significance.

Elafibranor also achieved high statistical significance on the composite endpoint of ALP and bilirubin, with response defined as (1) ALP less than 1.67 times the upper limit of normal, or ULN, (2) total bilirubin within normal limits and (3) a reduction of ALP of more than 15%. The elafibranor 80 mg and 120 mg treatment groups achieved mean response rates of 67% ($p=0.001$) and 79% ($p<0.001$), respectively, as compared to 6.7% in the placebo group. This composite endpoint was the primary endpoint in the Phase 3 clinical trial of Ocaliva that led to its FDA marketing approval. In a three-month Phase 2 clinical trial of Ocaliva, treatment with Ocaliva 10 mg resulted in a mean response rate of 23%, compared to a placebo response rate of 10%, on this composite endpoint.

Patients treated with elafibranor showed improvement in other PBC markers such as gamma-glutamyl transferase, markers of inflammation, and metabolic markers such as total cholesterol, low-density lipoprotein-C, and triglycerides.

γGT level remained stable throughout the treatment period in placebo treated patients (+0.2±26%), while significant reductions were observed in both elafibranor-treated groups (at week-12: -37.1±25.5%; $p<0.001$ vs placebo with 80 mg and -40.0±24.1%; $p<0.01$ vs placebo with 120 mg). The γGT change over time was similar to the changes in ALP observed in the elafibranor-treated groups. Additionally, a reduction of 5'-nucleotidase at both doses of elafibranor vs placebo was observed at week 12. Finally, significant decreases in the elafibranor-treated groups relative to placebo patients were observed in IgM and inflammatory markers including C-reactive protein and haptoglobin. As expected, patients had features of PBC-related dyslipidemia, notably high HDL-cholesterol at baseline. As compared to placebo, elafibranor-treated groups showed decreases in total cholesterol, LDL-cholesterol and triglycerides. Finally, circulating levels of the bile acid precursor C4 were decreased in the elafibranor-treated groups, but not in the placebo group.

Elafibranor treatment did not induce or exacerbate pruritus. In contrast, a favorable trend was evidenced by a reduction of the virtual analogue scale or VAS score in patients that reported pruritus (VAS ≥0 mm) at baseline. A similar trend was observed in the pruritus domain of the PBC-40 QoL questionnaire with a median change from baseline of -25% and -21% in the 80 mg and 120 mg group, compared to placebo, which remained unchanged. This apparent improvement in pruritus is particularly impressive considering that it was observed in this trial of a duration of 3-months. Considering the burden that pruritus has on the quality of life in a significant proportion of patients with PBC, it will be important to confirm the benefit that elafibranor may have in the phase 3 study, which will be of longer duration.

Treatment with elafibranor was generally well tolerated, with a similar number of patients experiencing adverse events in the drug treatment and placebo arms of the trial, with the most common adverse events being of a gastrointestinal nature and of mild or moderate intensity, and included nausea, fatigue and headache. Two patients experienced serious adverse events, of which only one was considered as possibly drug-related. The latter patient suffered from two preexisting auto-immune diseases (PBC and myasthenia gravis) and during the trial presented with a third auto-immune disease (auto-immune hepatitis, or AIH). This diagnosis was made in a patient with poly-auto-immune diseases, and AIH consecutive to PBC or AIH-PBC overlap syndrome are not uncommon, occurring in up to 2.5% and 14% of PBC patients, respectively. While this factor and/or other concomitant medications could be considered as confounding factors, a causal relationship to study drug could not be excluded. The other patient experienced a serious adverse event or SAE deemed unrelated to treatment with elafibranor and withdrew from the trial after only one daily dose.

In April 2019, the FDA granted elafibranor Breakthrough Therapy Designation, based on the Phase 2 data, for treatment of PBC in adults with inadequate response to UDCA and in July 2019, both the FDA and EMA granted elafibranor Orphan Drug Designation in PBC.

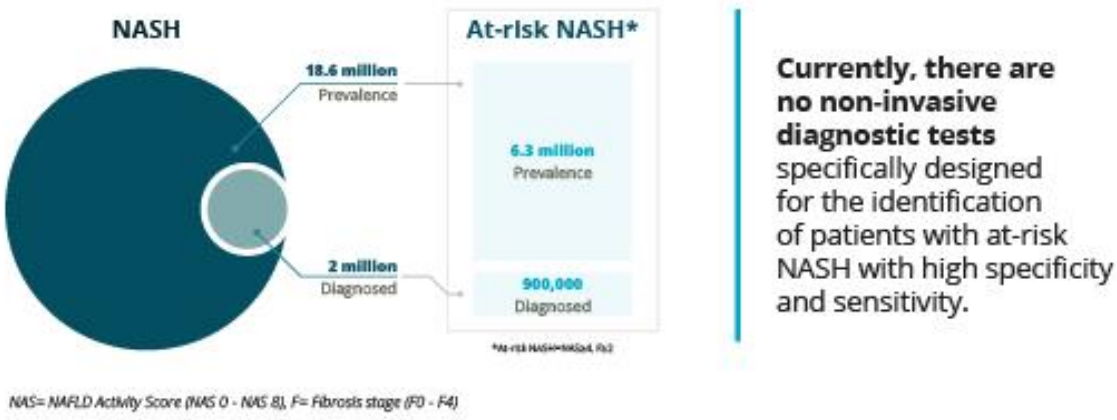
NIS4 Technology to Power the Identification of Patients with NASH and Fibrosis

As part of our strategy to address unmet needs in NASH, we have advanced a diagnostic program based on the identification of specific biomarkers that are expressed at different levels in patients with NASH and significant fibrosis (F≥2) as compared to patients with less severe disease. This discovery kicked off a multi-year effort that has resulted in the development of NIS4, a blood-based molecular technology for the identification of patients with NASH (NAS≥4) and significant fibrosis (F≥2), also referred to as "at-risk" NASH, who are at higher risk of disease progression and may be appropriate candidates for therapeutic intervention. In January 2019, we entered into a license agreement with Labcorp to allow them to develop, market, and sell a test powered by NIS4 in the clinical research space. In September 2020, we signed a five-year exclusive license agreement with Labcorp to allow them to develop and commercialize an LDT powered by NIS4 technology for use in routine clinical diagnostic testing in the United States and Canada.

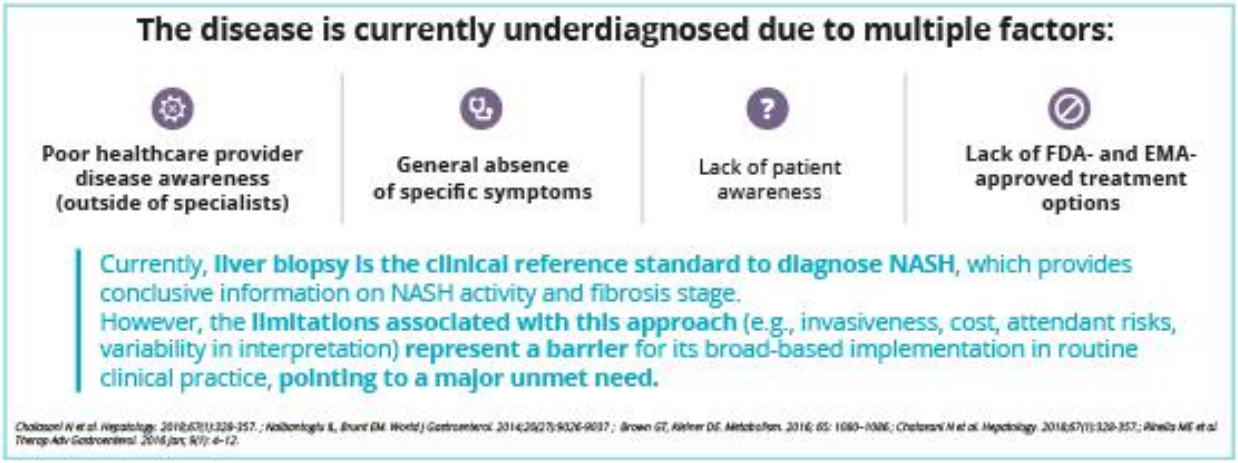
Today's Challenges in Diagnosing NASH

NASH, the most severe form of NAFLD, is characterized by the presence of hepatocyte ballooning and inflammation. NASH can progress silently towards cirrhosis, precluding the opportunity for clinicians to diagnose and intervene therapeutically prior to the development of severe liver complications, and constitutes a growing cause of cirrhosis, liver failure, and hepatocellular carcinoma globally. Furthermore, NASH is projected to become the leading cause of liver transplantation in the United States—it already is the primary cause among women and the secondary cause overall. Given this clinical scenario, there is a pressing need to identify patients at higher risk of disease progression, who could be considered for therapeutic intervention with existing options or potentially promising agents currently in late-stage clinical development obtain regulatory approval is obtained.

The main histological determinants of the risk for long-term severe liver outcomes are NASH activity and fibrosis stage (F). NASH activity is assessed by the NAFLD activity score (NAS), a composite index derived from the sum of the scores for macrovesicular steatosis, hepatocellular injury (i.e., ballooning), and lobular inflammation. In a study with paired liver biopsies, steatohepatitis was associated with liver-related outcomes, and a higher NAS at baseline was associated with a high probability of fibrosis stage increase after ≥1 year, suggesting an association between increased NASH activity and fibrosis progression. Furthermore, a Phase 2b clinical trial in NASH demonstrated higher rates of spontaneous disease regression in both treated and untreated patients with milder NASH severity (NAS=3) compared with patients with higher activity (NAS ≥4) at baseline. Additionally, multiple studies have shown that fibrosis stage reflects the extent of disease progression toward cirrhosis—in particular, that F ≥2 (significant fibrosis) increases the risk of liver-related clinical outcomes. Given that the overall disease state is described by the combination of NASH activity and fibrosis stage, this is the rationale for inclusion of patients with NASH, a NAS ≥4 and a F ≥2 (referred to as "at-risk NASH") in pharmacological intervention clinical trials.



Liver biopsy is the clinical reference standard for the diagnosis of NASH among patients with clinical risk factors for this disease, such as metabolic disorders (with or without abnormal liver biochemistries) in the absence of alternative causes for steatosis. The implementation of this diagnostic approach, however, is limited in routine clinical practice by its invasiveness, cost, attendant risks, variability in interpretation, and the restricted number of professionals able to perform and interpret the test, among other factors. These limitations preclude liver biopsies from being broadly used as the primary diagnostic in such a prevalent disease. Providing a non-invasive alternative to liver biopsy will therefore be critical to facilitate improved patient diagnosis, management, and future treatment access in routine clinical practice, and may eventually reduce the morbidity and mortality associated with this disease.



Currently, there are few non-invasive diagnostics specifically designed to identify at-risk NASH. Existing tests used in a NAFLD or NASH clinical context can be generally characterized as either repurposed or not optimized for the identification of this condition. Multiple algorithm or imaging-based tests used today (e.g., Fibrosis-4 [FIB-4] score, aspartate aminotransferase [AST]-to- Platelet Ratio Index [APRI], Enhanced Liver Fibrosis [ELF] score, vibration-controlled transient elastography ([VCTE] also known as FibroScan) were originally designed for use in mixed liver aetiologies (e.g., hepatitis C virus, hepatitis B virus), and have since been repurposed for use in NAFLD or NASH. Limitations associated with many of these tests have been reported, including performance (area under the receiver operating characteristics curve [AUROC] <0·80) for the identification of NASH or fibrosis stage ≥2, or both, in individuals with type 2 diabetes. Additionally, several NAFLD-focused or NASH-focused tests (e.g., body-mass index [BMI], AST/alanine aminotransferase [ALT] ratio and diabetes [BARD] score, and NAFLD Fibrosis Sore [NFS]) were developed to identify advanced liver fibrosis (i.e., fibrosis stage ≥3), and might therefore not be optimized for the identification of at-risk NASH. Even widely used imaging-based techniques for liver disease management, such as VCTE, have been shown to be influenced by a number of clinical features, including the presence of type 2 diabetes, dyslipidaemia, elevated waist circumference, elevated AST concentrations, and elevated systolic blood pressure at the time of examination. Limitations or confounders of non-invasive tests are of importance to clinicians to help them assess the right NASH diagnostic tests to use in their patients. We aimed to develop and validate a blood-based diagnostic multivariate index test that is specifically designed to rule in and rule out at-risk NASH.

The treatment of NASH being a pressing public health challenge, there is a large unmet need for a widely available, non-invasive tool to identify patients with at-risk NASH as an alternative to liver biopsy. The availability of such a test would help address the under diagnosis of NASH by supporting physicians in identifying patients with at-risk NASH, who are at higher risk for clinical outcomes and would be eligible for therapeutic intervention. We believe a test powered by our NIS4 technology, if validated and approved for marketing, may directly address this clinical gap.

Circulating Biomarkers and miRNA

Biomarkers are characteristics of the body that are objectively measured and have the potential to correlate to a specific biological state or disease condition. Circulating biomarkers are biological molecules, such as proteins, DNA or RNA, found in body fluids such as cerebrospinal fluid, blood or urine that modulate with disease. A single circulating biomarker or a panel of markers has the potential to be used to not only identify but also monitor the progression, regression, or stability of disease.

microRNAs or miRNA represent an emerging class of small non-coding RNA whose principal function is the regulation of the expression of target genes by acting on the stability and the translation of their messenger RNA, or mRNA. miRNAs play an

essential role in many cell functions, such as development, proliferation, differentiation, cell-cycle arrest and apoptosis, or cell death. Multiple studies have shown a close association between circulating levels of miRNA and the development and progression of several cancers and have highlighted an important role for miRNAs in the regulation of human liver development and pathophysiology. Because miRNAs are released from cells in response to stress, they can be detected in most biological fluids, including blood.

Our Solution: NIS4 Technology Comprising Our Proprietary Biomarker Algorithm

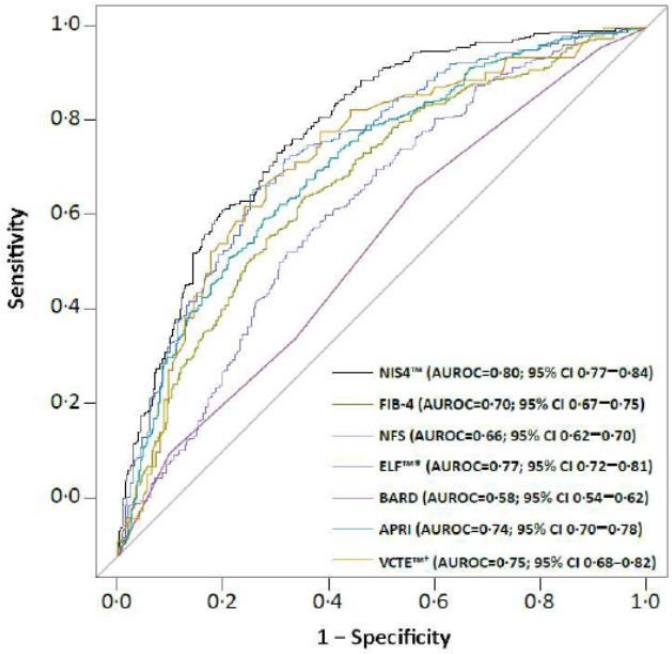
Aware of the challenges associated with diagnosing at-risk NASH, we initiated a research program to combine our technical expertise in informatics, machine learning and molecular biology with access to our extensive NASH clinical biobank, including cohorts from our GOLDEN-505 and RESOLVE-IT clinical trials, in addition to cohorts from academic partnerships, to pursue the discovery of novel biomarkers that may hold the key in developing novel diagnostic tests or technologies in NASH. In 2015, we reached a key milestone with the discovery that two miRNA biomarkers, miR-200a and miR-34a-5p, that were expressed at higher levels in patients with at-risk NASH as compared to patients with less severe disease..

Since then, we have further refined our science which has uncovered four unique biomarkers that we believe provide the best overall diagnostic performance to identify patients with at-risk NASH. Our lead technology, NIS4, integrates the outputs of four independent NASH-associated biomarkers [alpha-2-macroglobulin, YKL-40, hemoglobin A1c, and miR-34a-5p] through an algorithm to produce a single score that can be utilized to rule in and rule out at-risk NASH, while minimizing the number of indeterminate test results. We intend to market an IVD-powered by NIS4 technology, if it receives FDA/CE marketing authorization, as a standalone diagnostic with the potential to enable a non-invasive, accessible and validated alternative to the liver biopsy to benefit patients, improve overall clinical care and greatly reduce barriers to entry for innovative therapies.

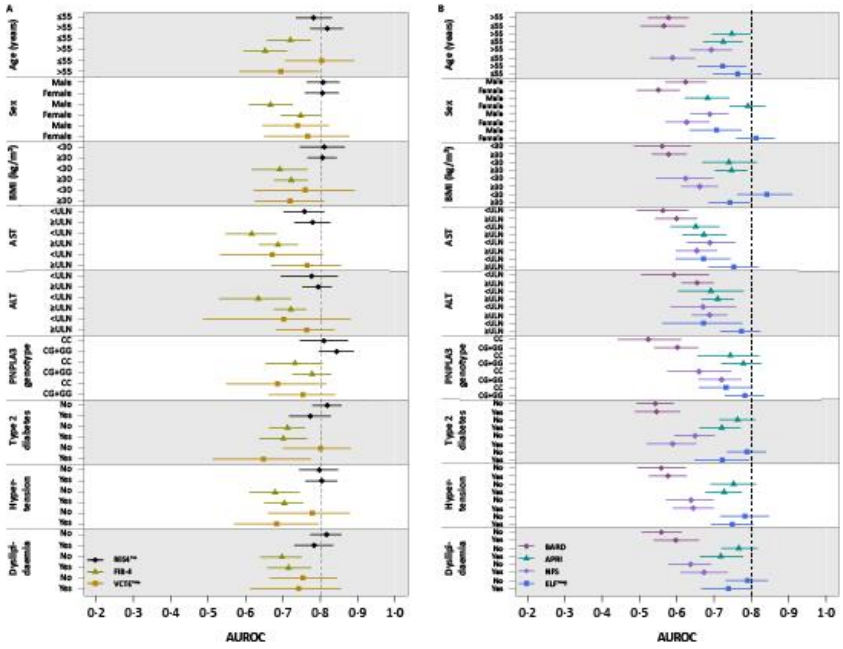
Development and validation of NIS4 technology

Blood samples, clinical data, and liver biopsy results from three independent cohorts with suspected NAFLD were used to develop and validate the NIS4 non-invasive blood-based diagnostic technology. Derivation was done in the discovery cohort, which comprised 239 prospectively recruited patients with biopsy-confirmed NASH (NAFLD NAS ≥3; fibrosis stage 0−3) from the international GOLDEN-505 phase 2b clinical trial. The overall diagnostic performance of NIS4 was externally validated in two independent cohorts: RESOLVE-IT diag and Angers. The RESOLVE-IT diag cohort comprised the first 475 patients screened for potential inclusion into the randomized, double-blind, placebo-controlled, multicenter, international RESOLVE-IT phase 3 clinical trial. ANGERS was a retrospective cohort of 227 prospectively recruited patients with suspected NAFLD and clinical risk factors for NASH or fibrosis stage 2 or more according to abnormal elastography results or abnormal liver biochemistry. Clinical cutoffs were established within the discovery cohort to optimize both rule out and rule in clinical performance while minimizing indeterminate results. NIS4 was validated in the RESOLVE-IT diag cohort (AUROC 0·83, 95% CI 0·79−0·86) and the Angers cohort (AUROC 0·76, 0·69−0·82). The diagnostic performance of NIS4 within the external validation cohorts was not influenced by age, sex, BMI, or aminotransferase concentrations.

In the pooled validation cohort, NIS4 significantly outperformed other non-invasive NASH or fibrosis diagnostics, including FIB-4, NFS, ELF, APRI, and BARD for the identification of “at-risk” NASH (all $p<0·010$, figure below). The overall performance of NIS4 and VCTE was not statistically different. In addition, although NIS4 was not developed to specifically identify the subpopulation of “at-risk” NASH with fibrosis stage ≥3, performance was significantly better than FIB-4, NFS, BARD and APRI (all $p<0·05$), with performance not significantly different to VCTE and ELF.



Subpopulation analyses were done in the pooled validation cohort to assess the overall performance of NIS4 compared with other diagnostics among specific subpopulations of clinical relevance in NASH (figure below). The overall diagnostic performance of NIS4 was the highest across non-invasive tests evaluated, and was neither dependent on (i.e., included as variables in the NIS4 algorithm) nor statistically affected by patient age within the range studied, sex, BMI, or transaminase concentrations. The clinical performance of NFS was significantly better in patients 55 years or older than in those younger than 55 years (AUROC 0·69 vs 0·59; p=0·013), whereas FIB-4 showed higher performance in females than in males (0·75 vs 0·67; p=0·039). Similarly, APRI showed higher performance in females than in males (0·79 vs 0·68; p=0·0040). ELF however showed higher performance in patients with a BMI of 30 kg/m2 or less than in those with a BMI of more than 30 kg/m2 (0·84 vs 0·74; p= 0·029), and in females than in males (0·81 vs 0·71; p= 0·019). BARD showed consistent results across the categories explored, and VCTE— although not significant—had directionally higher performance in patients without type 2 diabetes than in those with type 2 diabetes (AUROC 0·80 vs 0·65; p= 0·056).



We believe that an LDT or IVD powered by NIS4 technology can provide an effective way to noninvasively rule in or rule out at-risk NASH in patients with metabolic risk factors and suspected disease. Use of an LDT or IVD powered by NIS4 in clinical trials or in the clinic has the potential to greatly reduce unnecessary liver biopsies in patients with lower risk of disease progression, achieve straightforward integration into clinical care pathways, and be more cost-effective, accessible, and acceptable for patients than liver biopsy. In doing so, an LDT or IVD powered by NIS4 could also help improve the accuracy of NASH diagnosis in patients with suspected disease, and help healthcare providers identify those most in need of therapeutic intervention.

In August, we announced that pivotal data describing the derivation and validation of NIS4 technology has been accepted for publication by *The Lancet Gastroenterology & Hepatology*. This published study details NIS4 algorithm development and clinical validation against the liver biopsy reference standard in two independent populations comprised of data from over 700 patients. In addition to the high overall performance in identifying patients with at-risk NASH, NIS4 technology also provided consistent results in critical sub-populations (i.e. diabetic vs. non-diabetic, men vs. women) as compared to other non-invasive tests evaluated in the same individuals.

In November 2020, we announced that data relating to the NIS4 technology and the final results of the RESOLVE-IT Phase 3 clinical trial could be consulted on five posters in the context of the *Liver Meeting Digital Experience*, the annual conference of the *American Association for the Study of Liver Diseases*, which was held virtually on 13, 14 and 15 November 2020.

Regulatory and Commercial Strategy

We began communications with the FDA in 2017 to discuss potential regulatory pathways for an IVD powered by NIS4 technology. Based on these discussions, we will be using blood samples and liver biopsy results from non-treated patients enrolled in our clinical trials conducted to date in order to provide support for the potential validation of our test. By calculating NIS4 from a patient's blood sample, and then comparing the test score to that patient's liver biopsy result, we can assess whether an IVD powered byNIS4 is accurate in diagnosing patients with at-risk NASH, who are at higher risk of disease progression and may be considered for therapeutic intervention. We are conducting physician, payer, and patient primary market research to best understand clinical performance goals that would meet the needs of the evolving NASH marketplace. Based on these insights, we will finalize the analytical and clinical study designs, which are required prior to initiating formal validation studies for both the

FDA and Notified Body submissions. We continue to explore the possibility of obtaining regulatory approval to release an IVD powered by NIS4 technology on the US and European markets.

In January 2019, we entered into a license agreement with Labcorp, a global life sciences leader specializing in health improvement and patient treatment decision support, to enable them to further develop and deploy NIS4 in the context of clinical research. We believe this agreement will provide expanded access to, and further validation of an LDT powered by NIS4. Initially, we will enable Labcorp through its subsidiary Covance to market and sell an LDT powered by NIS4 test in the context of clinical research studies. Covance will process samples and provide test results to clinical trial sponsors. Covance is permitted and accredited, and will be responsible for submitting any validation that may be required under applicable state and federal laws. I

In September 2020 we and Labcorp announced the signature of a five-year exclusive license agreement for our NIS4 technology, which seeks to enable easier identification of patients with at-risk NASH. Under the license agreement, Labcorp will commercialize a blood-based molecular test based on NIS4 technology in the United States and Canada, thereby making it more widely accessible to health professionals.

The partnership with Labcorp aims to make this LDT powered by NIS4 available to a large number of specialist and generalist physicians in the United States and Canada. Labcorp will use its vast experience in the commercialization of innovative diagnostic tools to make health professionals more aware of NASH and non-invasive ways of diagnosing NASH.

Other Programs

Repositioning of Nitazoxanide

The identification of NTZ is the result of our research program designed to discover novel anti-fibrotic molecules with a priority given to liver fibrosis. Our strategy to target fibrosis is based on the use of a phenotypic screening approach combined with the use of a compound library composed of FDA-approved drugs. The phenotypic method does not rely on knowledge of the identity of a specific drug target or a hypothesis about its role in a disease, but rather focuses on the modulation of a disease-linked phenotype. In our model, we evaluated the compounds for their capacity to interfere with the activation of quiescent hepatic stellate cells into myofibroblasts, which are the major fibrogenic cell type in the liver.

Following screening of FDA-approved drugs, and investigation of drug candidate profiles in medical literature, we identified NTZ, currently commercialized and prescribed in the United States and in several other countries as an anti-parasitic, as a potent anti-fibrotic agent that we believe can be repurposed for the treatment of fibrosis.

Pre-clinical and Clinical Development Program

As part of our pre-clinical program, we have studied NTZ in disease models and in human fibroblasts from different organs. Fibroblasts are cells in connective tissues that, when activated, play a significant role in the development of fibrosis. In April 2017, we presented the results of this research supporting the potential efficacy of NTZ in two disease models of liver fibrosis at the EASL International Liver Congress. In these two *in vivo* models, we observed that administration of NTZ significantly attenuated liver fibrosis development.

We have also studied NTZ in two mouse models. In the first mouse model, we observed the effect of NTZ administration on mice that had been exposed to a toxin that causes liver damage and fibrosis. The mice were divided into four groups—a group of six mice that received a placebo, a group of nine mice that received the toxin alone, a group of 10 mice that received the toxin plus NTZ at a dose of 32 mg/kg/day and a group of 10 mice that received the toxin plus NTZ at a dose of 104 mg/kg/day. After six weeks, we measured fibrosis by percentage of surface area on a slide from tissue that was fibrotic. The cohort that received NTZ 32 mg/kg/day had their observed liver fibrosis as measured by histological evaluation reduced by an average of 30.3% ($p<0.001$) (ranging from 10% to 53%) and the cohort that received NTZ 104 mg/kg/day had their liver fibrosis reduced by an average of 24.7% ($p<0.01$) (ranging from 1% to 43%), in each case as compared to the cohort that received the toxin alone.

In the second mouse model, we observed the effect of NTZ administration on mice that had been fed a CDAA/c diet. The mice were divided into four groups—a group of four mice that received a “normal” diet as the control group, a group of 12 mice that received the CDAA/c diet alone, a group of eight mice that received the CDAA/c diet plus NTZ at a dose of 26.3 mg/kg/day and a group of eight mice that received the CDAA/c diet plus NTZ at a dose of 78.1 mg/kg/day. After 12 weeks, we measured fibrosis by percentage of surface area on a slide of liver tissue that was fibrotic. The cohort that received NTZ 26.3 mg/kg/day did not have a statistically significant reduction in liver fibrosis as compared to placebo, but the cohort that received NTZ 78.1 mg/kg/day had their liver fibrosis reduced by an average of 27.4% ($p<0.001$) (ranging from –4% to 53%) as compared to placebo. In this same study, we also observed that the cohort that received NTZ 78.1 mg/kg/day had their liver collagen accumulation reduced by 22.9% ($p<0.001$) (ranging from 12% to 34%) compared to the placebo group.

In December 2018, we announced the start of an investigator-initiated single-center, open-label trial to evaluate the safety and efficacy of NTZ in patients with NASH-induced Stage 2 or Stage 3 fibrosis. The primary objective of the study is to evaluate the safety and tolerability of NTZ in patients with NASH-induced stage 2 or stage 3 fibrosis.

Despite the COVID-19 pandemic and due to the implementation of appropriate measures by the clinical investigator leading the study, the recruitment of patients in the clinical trial evaluating NTZ in NASH-induced liver fibrosis continued throughout the year. The results of this trial are expected in the first quarter of 2021.

In parallel, NTZ was tested in a preclinical NASH model, in combination with elafibranor. This study was motivated by the hypothesis that a pure antifibrotic agent, such as NTZ could significantly magnify the therapeutic action of elafibranor in patients with severe NASH and advanced fibrosis. This study was presented at the 53rd annual meeting of the European Association for the Study of the Liver (EASL), in Paris.

The mice in this study were divided into five groups—a group of four mice that received a “normal” diet as the control group, a group of 12 mice that received the NASH-inducing CDAA/c diet alone, a group of 8 mice that received the CDAA/c diet plus NTZ at a dose of 100 mg/kg/day, a group of 8 mice that received the CDAA/c diet plus elafibranor at a dose of 1 mg/kg/day, and a group of 7 mice that received the CDAA/c diet plus NTZ at a dose of 100 mg/kg/day and a dose of elafibranor at a dose of 1 mg/kg/day. After 12 weeks, we measured fibrosis by percentage of surface area on a slide of liver tissue that was fibrotic. The cohort that received NTZ 100 mg/kg/day showed a statistically significant reduction in liver fibrosis of 27% (ranging from -4% to 53%), the cohort that received elafibranor 1 mg/kg/day had their liver fibrosis reduced by an average of 36% ($p<0.001$) (ranging from 18% to 47%) as compared to placebo. The cohort that received both drugs had their liver fibrosis reduced by an average of 52% ($p<0.001$) (ranging from 25% to 63%) as compared to placebo. Fibrosis decrease that was observed in the group that received the combination was statistically superior as compared to the mice that received single drugs.

In parallel, samples from the combination study were used to search for mechanistic explanation of the superior effect of elafibranor /NTZ combination on fibrosis. We have found that elafibranor and NTZ induce complementary and non-redundant signaling pathways that attenuate oxidative damage in the liver. In this respect, elafibranor activates the overexpression of several antioxidant genes, such as SOD1/2, CAT and GPX, whereas NTZ activates the expression of the genes that facilitate the disposal of 4-HNE, the end product of lipid peroxidation, which can directly activate fibrotic actions in stellate cells. These results were presented at the 54th International Liver Congress in Vienna and at the Annual Liver Meeting of the American Association for the Study of Liver Diseases (AASLD) in 2019.

Other preclinical investigations

Several other preclinical investigations are ongoing. As of the date of this Annual Report, we have not published the compounds involved and potential indications while we wait for the results of ongoing tests.

Our Clinical Program for Elafibranor in the Potential Treatment of NASH

RESOLVE-IT—Pivotal Phase 3 Clinical Trial in NASH

In May 2020, we announced the topline results of the interim analysis of the RESOLVE-IT Phase 3 clinical trial evaluating the efficacy of the daily administration of elafibranor 120 mg in adults with NASH.

The RESOLVE-IT Phase 3 clinical trial evaluated the effect of elafibranor compared to placebo in 1,070 patients (ITT population) with biopsy proven NASH as defined by NAFLD activity score (NAS) greater than or equal to 4, fibrosis stage 2 or 3. Patients were randomized 2:1 to receive elafibranor 120mg or placebo once daily, with a follow-up liver biopsy at week 72 to evaluate histologic endpoints (resolution of NASH without worsening of fibrosis or fibrosis improvement of at least one stage).

Resolution of NASH is defined by a ballooning score of 0 and an inflammation score of 0 or 1, and the non-worsening of fibrosis corresponds to a fibrosis score that does not increase.

The trial did not meet the predefined primary endpoint of NASH resolution without worsening of fibrosis in the ITT population. In the ITT population, 19.2% of patients who received elafibranor (N=138) achieved NASH resolution without worsening of fibrosis compared to 14.7% of patients in the placebo arm (N=52) ($p=0.07$).

On the key secondary endpoint of fibrosis improvement of at least one stage, 24.5% of patients who received elafibranor (N=176) achieved fibrosis improvement of at least one stage compared to 22.4% (N=79) in the placebo arm ($p=0.445$).

Baseline characteristics

Patient inclusion criteria for RESOLVE-IT were similar to those in previously conducted late stage trials in patients with non-cirrhotic NASH. The baseline characteristics demonstrated that the trial was well balanced, with 717 patients randomized to elafibranor and 353 randomized to placebo. The mean age of patients was 55 years old, with men representing approximately 60% of the patients and women approximately 40%, which was planned based upon the relatively higher prevalence of NASH in men compared to women. Approximately one-half of enrolled patients had type 2 diabetes. The relative proportion of patients with fibrosis stage F2 and F3 was 47.2% and 52.8%, respectively. The majority of patients enrolled had NAS>6 (approximately 56% in the elafibranor arm and approximately 62% in the placebo arm), indicative of a robust NASH population. The table below summarizes the characteristics of the ITT population of this trial.

		Statistics	Elafibranor	Placebo	Overall
ITT Set (F2-F3)		N	717	353	1070
Age (Years)		Mean (SD)	54.35 (12.06)	55.04 (11.10)	54.58 (11.75)
Sex	Female	N(%)	283 (39.5)	137 (38.8)	420 (39.3)
	Male	N(%)	434 (60.5)	216 (61.2)	650 (60.7)
Fibrosis Stage	Stage 2	N (%)	338 (47.1)	167 (47.3)	505 (47.2)
	Stage 3	N (%)	379 (52.9)	186 (52.7)	565 (52.8)
Type 2 Diabetes	No	N (%)	361 (50.3)	178 (50.4)	539 (50.4)
	Yes	N (%)	356 (49.7)	175 (49.6)	531 (49.6)
NAS	4	N (%)	104 (14.5)	45 (12.7)	149 (13.9)
	5	N (%)	209 (29.1)	90 (25.5)	299 (27.9)
	6	N (%)	239 (33.3)	120 (34.0)	359 (33.6)
	7	N (%)	146 (20.4)	92 (26.1)	238 (22.2)
	8	N (%)	19 (2.6)	6 (1.7)	25 (2.3)

Interim efficacy results at week 72

The primary surrogate efficacy endpoint at week 72 was NASH resolution without worsening of fibrosis, with NASH resolution defined as a ballooning score equal to 0 and an inflammation score equal to 0 or 1 and no worsening of fibrosis defined by a fibrosis score not increasing from baseline. In the ITT population, 19.2% of those treated with elafibranor (N=138) achieved NASH resolution without the worsening of fibrosis compared to 14.7% of patients randomized to placebo (N=52) (p value of p=0.07).

On the key secondary endpoint in the ITT population, 24.5% of patients treated with elafibranor (N=176) achieved fibrosis improvement of at least one stage compared to 22.4% (N=79) of patients randomized to placebo (p value of p=0.445).

The data are summarized in the table below.

ITT (missing biopsy = non-responder)		Elafibranor 120mg		*Placebo*		*P-Value*
		N	%	N	%	
Primary Endpoint	NASH Resolution without worsening of fibrosis	138/717	19.2	52/353	14.7	0.0659
Key secondary Endpoint	Fibrosis improvement of at least one stage	176/717	24.5	79/353	22.4	0.4457

The key secondary metabolic endpoints included triglycerides, non-HDL cholesterol, HDL-cholesterol, LDL-cholesterol, HOMA-IR in nondiabetic patients, and HbA1c in diabetic patients), and statistically significant reductions were seen in triglycerides and non-HDL cholesterol.

Safety and tolerability results

Elafibranor was generally well tolerated over the 72 weeks of exposure, which is consistent with previously conducted studies and with previous DSMB conclusions from their ongoing review of RESOLVE-IT safety data. The safety, including histological assessment, and tolerability profile of elafibranor continues to be supportive of ongoing clinical investigation which is encouraging for the ongoing Phase 3 trial evaluating elafibranor in PBC (see below).

While the topline results do not support an application for accelerated approval of elafibranor for registration in NASH by the FDA under Subpart H or conditional approval by the EMA, we announced in May 2020 our intention to review in detail the full dataset and conduct additional analyses in order to understand why the placebo response rate was higher than what was expected before making a decision regarding the future of the RESOLVE-IT trial.

On July 22, 2020, following the detailed review of the full RESOLVE-IT interim efficacy dataset, we determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the United States and Europe. We also indicated that we are now focusing our efforts on developing our two major programs: elafibranor development in PBC, and the commercial growth of NIS4 technology, for NASH diagnostics.

Pediatric NASH, Phase 2 Trial Addressing Liver Fat and Therapeutic Combination Program with elafibranor in NASH

Due to the COVID-19 pandemic, the Company had announced in late March 2020 that:

- enrollment of patients in the PK/PD trial in pediatric patients with NASH as well as the Phase 2 study addressing liver fat had been put on hold; and
- the initiation of the Phase 2 combination study in NASH with elafibranor had been put on hold.

In September 2020 and following its decision to terminate all development of elafibranor in NASH, due to lack of efficacy, but not due to safety, we decided to initiate the termination process of the PK/PD trial in pediatric NASH, as well as the Phase 2 study on hepatic lipid composition.

Considering that clinical trials in the NASH space involve a large number of patients, are long and very expensive, as well as the fact that the regulatory and competitive landscape in this therapeutic area is in constant evolution, we have considered that the cost in relation to the probability of success was too high to continue development of elafibranor in NASH.

Other Phase 1 trials

We also announced in March 2020, in the context of the COVID-19 pandemic, that all ongoing or upcoming phase 1 trials – which included pharmacokinetic, food effect and bioequivalence studies – had been put on hold. Following the decision to terminate the RESOLVE-IT study, most of these studies were prematurely terminated as it was determined that we had sufficient sample sizes to complete the analyses, the only exception being the bioequivalence section of the bioequivalence and food effect study, which was continued and the results of which are necessary to support a potential elafibranor NDA submission, assuming favorable data from the ongoing pivotal Phase 3 trial in patients with PBC.

Partnering with Terns Pharmaceuticals in NASH and PBC

In June 2019, we announced the signing of a licensing and collaboration agreement with Terns Pharmaceuticals, a global biopharmaceutical company based in the U.S. and China with a focus on developing novel and combination therapies to treat liver disease. Under the agreement, Terns has been granted the exclusive rights to develop, register and commercialize elafibranor in Greater China (mainland China, Hong Kong, Macau, and Taiwan), for the treatment of NASH and PBC.

Under the terms of the license agreement, GENFIT has received an initial payment of $35 million from Terns and may receive up to $193 million in additional payments upon completion of clinical, regulatory and commercial milestones. At commercial launch of elafibranor in Greater China, GENFIT may perceive mid-teen percentage royalties from Terns based on the sales in this territory. As part of the agreement, GENFIT and Terns will also undertake joint R&D projects in liver disease.

The preparation of the inception of clinical trials with elafibranor in PBC in China is underway, and its timeline will be determined by the resolution of the Covid-19 crisis and discussions with regulatory authorities.

This agreement will remain in force until the later of either a 10-year period after the first sale of a licensed product in the territory or the expiration of the last patent concerning such a licensed product in the relevant territory (determined on a per-territory basis). For more information, see Item 10.C – *Collaboration and License Agreement with Terns Pharmaceuticals, Inc.*

Competition

We operate in a highly competitive sector. Several companies are working on technologies, therapeutic targets or drug or biomarker candidates that aim to treat or diagnose the same diseases or identify the same patient population as our product candidates. While we believe that our drug candidates and diagnostic solutions, combined with our expertise and know-how, provide us with competitive advantages, we face potential competition from various sources, including pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions. We anticipate that we will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available.

PBC treatment

UDCA was approved by the FDA to treat PBC in 1997 and remained the only approved treatment for PBC until 2016, when Ocaliva was approved by the FDA and EMA for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Although approved as a second-line treatment, Ocaliva is the subject of continued safety concerns (with respect to pruritus and serious liver injury or death, leading to the FDA issuing a Black Box Warning in 2018).

If approved, elafibranor would compete with these drugs already approved for the treatment of PBC.

The other molecule that could become a direct competitor of elafibranor is seladelpar, developed by the American company CymaBay, which announced at the end of March 2021 that it had commenced recruitment for its new Phase 3 (RESPONSE) trial.

We know that other companies develop other drug candidates to treat PBC, and therefore may also become competitors. The IQVIA report however indicates that these molecules are in relatively early stages of clinical development compared to elafibranor, and would capture together – if approved – less than 20% of market shares.

In addition to these approved drugs and drug candidates in development, we also may compete with approved drugs in other indications which could be used off-label for the treatment of PBC.

NASH Diagnostics

With respect to NIS4™, our technology that uses blood-based biomarkers to identify patients with NASH and fibrosis who we believe could benefit from therapeutic intervention, there are a number of clinical diagnostic tools available for the management of chronic liver disease patients, but none are validated for NASH. If approved by the FDA as an IVD, we believe NIS4™ could become the first of its kind.

Fibrosis

Fibrosis, also known as fibrotic scarring, is a pathological wound healing process for the tissues that exists in several organs: liver, lungs, intestine, etc. So far, no drug has been subject to regulatory approval as a pure anti-fibrotic, regardless of the organ considered. The competitive environment is characterized by several research programs conducted in parallel by several stakeholders. Some of these programs involve pre-fibrotic stages of the disease, and correspond to preventive approaches aiming to prevent patients from progressing to most severe forms of the disease. Other programs focus more on late disease stages such as, for the liver, compensated or decompensated cirrhosis. Addressing late stages presents the advantage of a potentially accelerated approval process from a regulatory standpoint, and such positioning can lead to higher prices. The commercial opportunity is therefore potentially larger, but will depend on upcoming clinical and efficacy results of NTZ. Competitive intensity will ultimately be driven by the number of approved medication in monotherapy, as well as therapeutic approaches retained by experts in terms of combination therapies.

Other considerations

We believe that elafibranor’s differentiated mechanism of action in targeting PPARα and PPARδ, and the favorable tolerability profile observed to date suggest the potential for elafibranor to have competitive advantages over approved drugs and drug candidates in development by our competitors. NTZ also provided encouraging pre-clinical data.

However, many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for their drug candidates and achieving widespread market acceptance and may render our drug candidates, such as elafibranor, obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that we will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available. We expect any drugs that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, delivery, price and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any drugs that we may commercialize. Our competitors also may obtain FDA, EMA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

The same considerations apply in the NASH diagnostic field.

Manufacturing and Supply

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our drug candidates for preclinical and clinical testing, as well as for commercial manufacturing if our drug candidates receive marketing approval.

With respect to our lead drug candidate, elafibranor, we use one supplier for the active ingredient and another manufacturer for the therapeutic units used in our clinical trials. Although we could use a substitute company in the event of failure or breach of these two manufacturers, we may face challenges in finding new suppliers within an acceptable timeframe or under commercially reasonable conditions. To mitigate this risk, we have performed an evaluation of the expected elafibranor manufacturing delays and costs in the event of a disaster at the supplier of the active ingredient or at the manufacturer of therapeutic units. Based on the results of this evaluation, we believe that given the current inventory and drugs in production at various levels of the production chain, which is sufficient to supply our ongoing clinical trials, the short-term failure of one of these manufacturers would not be critical.

With respect to our NIS4 technology, we have entered into two license agreements with Labcorp to further develop and manufacture a test using NIS4 technology for clinical research as well as to allow them to develop and commercialize an LDT powered by our NIS4 technology in routine clinical care in the US and Canada, respectively.

Intellectual Property

Our intellectual property is critical to our business, which we strive to protect by obtaining and maintaining patent protection in territories throughout the world for our drug and biomarker candidates, innovative methods and tools, production methods and other inventions that are important to our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our commercial success depends in part upon obtaining and maintaining patent protection and trade secret protection of our current and future drug and biomarker candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering for sale in the United Sates or importing into the United States, our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we guarantee that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our drug and biomarker candidates, discovery programs and processes from competitors. Furthermore, our patents may be challenged, circumvented, or invalidated by third parties. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by our pending patent applications. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Relating to Our Intellectual Property.”

We monitor our competitors and seek to challenge patent infringements when such infringements would negatively impact our business. We also seek to challenge validity of our competitors' patents when we think that these patents do not fulfill patentability or validity requirements**.**

Patents

As of April 1, 2021, we own or have rights to 35 issued U.S. patents, over 470 issued foreign patents, and 21 pending U.S. applications, and over 283 pending foreign patent applications. Our patent portfolio contains 55 different patent families, which are made up of over 787 patents and patents applications. Twenty-one of our patent families relate to our lead product candidate, elafibranor.

Elafibranor

Our patent portfolio for elafibranor, a molecule synthesized by us, includes issued patents and pending patent applications directed to compositions of matter, manufacturing methods, and methods of use. As of April 1, 2021, we own three U.S. patents directed to the composition of matter of elafibranor, which are expected to expire in 2024, without taking patent term extensions into account. We also have counterpart patents in various countries and regions, including Australia, Brazil, Canada, China, Europe, Israel and Japan.

In addition, we own five U.S. patent applications directed to the treatment of cholestatic diseases, in particular PBC, which, if issued, are expected to expire in 2037 and 2040, without taking patent term extensions into account. We also have counterpart pending patent applications in various countries or regions, including Australia, Canada, Europe, Israel, China, and Japan.

In addition, we own two U.S. patents directed to the method of preparing elafibranor, which are expected to expire in 2024 and 2031. We also have counterpart patents granted in various countries and regions, including Canada, China, Europe, and Israel.

In addition to these patents and pending applications, we are also pursuing additional patents directed to specific forms of elafibranor, and combinations with other pharmaceutical compounds.

Diagnostic Tools and Biomarkers

As of April 1, 2021, we own four U.S. patent applications directed to the diagnosis of NASH, in particular our NIS4 diagnostic technology, using certain biomarkers. The U.S. applications, if issued, would be expected to expire between 2036 and 2038.

In 2020, we also have filed several priority patent applications covering specific aspects of our NIS4 diagnostic technology and on some other research tools.

Other Programs

We are pursuing patent protection directed to our repositioning of nitazoxanide for treating cholestatic and fibrotic disease. As of April 1, 2021 five U.S. patents have been granted to us for the use of NTZ in the treatment of different fibrotic diseases and two U.S. patent applications are pending. These patents and patent applications, if granted, would be expected to expire in 2037 (excluding any patent term extension).

Patent Term Extension (PTE)

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension, or PTE, under the Hatch-Waxman Act as compensation for the reduction of patent monopoly time during the FDA regulatory review process. This extended coverage period, PTE, can only be obtained provided we apply for and receive a marketing authorization for a product. The period of extension may be up to five years beyond the normal expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. In Europe, Supplementary Protection Certificates, or SPCs, may also be available to patents, which would be available by application to the member states. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We will use the procedures established to compensate regulatory delays via Patent Term Extension in the US and via Supplementary Protection Certificates in the EU as soon as Health authorities grant NDA in the US or MA in the EU for our products.

Trademarks

Our candidate products are protected and will be sold around the world under trademarks that we consider to be of material importance.

Our trademarks will help to identify our products and services and will protect the sustainability of our growth.

It is our policy to file and protect our trademarks with a strategy adapted to each product or service, depending on the countries where the product will be commercialized or where the service will be proposed. Basically our trademarks are protected worldwide for our products and services.

We own more than 430 registered or filed trademarks worldwide.

The protection by trademark varies country by country. In most of the countries, trademark right may only be obtained through the filing and registration of a trademark application at the corresponding Patent and Trademark Office. Registrations are granted for a fixed term (usually ten years) and can be renewed indefinitely, unless in certain countries where use of the trademark needs to be demonstrated at renewal time.

In most of the countries, protection of the trademark applies to the products and services designated in the registration certificate.

We monitor our trademarks and defend them against competing trademarks by filing oppositions, observations when appropriate. Similarly, we may enter into coexistence agreement when a third party owns a potentially conflicting or confusing trademark with some of our products or services.

It is also our policy to defend our trademarks against infringement, counterfeiting and/or unfair competition.

Domain names

It is our policy to file domain names for communicating or giving information on our products or services to patients, prescribers or payers. We own today more than 260 domain names.

Know-How and Trade Secrets

In addition to patent protection, we also rely on trade secret protection of our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises (we seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems) and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, that prohibit the disclosure of confidential information, and require disclosure and assignment to us of ideas, developments, discoveries and inventions important to our business.

Government Regulation

Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the European Commission following a positive opinion provided by the EMA through the MAA process for a drug falling within the scope of the Centralized procedure or by a national Competent Authority through other MAA processes (National Procedure, Mutual Recognition or Decentralized procedure) before they may be legally marketed in the European Union. Our drug candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the drug development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal by the FDA to approve applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our drug candidates are governed by extensive regulation by governmental authorities in the United States and other countries. The FDA, under the FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials commence;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication and conducted in accordance with good clinical practices, or GCP;
- preparation and submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA, which might include an Advisory Committee review;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the drug, or components thereof, are made to assess compliance with current good manufacturing practices, or cGMPs;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- agreement for compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Preclinical and Human Clinical Trials in Support of an NDA

Preclinical studies include laboratory evaluations of the drug candidate, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the drug candidate. The conduct of preclinical studies is subject to federal regulations and requirements including GLP regulations. The results of the preclinical studies, together with manufacturing information and analytical data, among other things, are submitted to the FDA as part of the IND, which must become effective before human clinical trials may commence. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time and places a clinical hold on the IND. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. The FDA may nevertheless initiate a clinical hold after the 30 days if, for example, significant public health risks arise.

Clinical trials involve the administration of the drug candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the

IND. Each clinical trial must be reviewed and approved by an IRB at each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap or be combined. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a drug candidate into human subjects, frequently healthy volunteers. In Phase 1, the drug candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the drug candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a drug candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in enforcement action or withdrawal of approval. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Submission and Review of an NDA

The results of preclinical studies and clinical trials, together with detailed information on the drug's manufacture, composition, quality, controls and proposed labeling, among other things, are submitted to the FDA in the form of an NDA, requesting approval to market the drug for one or more indications. The application must be accompanied by a significant user fee payment, which typically increases annually, although waivers may be granted in limited cases. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA has substantial discretion in the approval process and may refuse to file or approve any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

Once an NDA has been accepted for filing, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. This goal date is typically 10 months from the date that the FDA accepts the filing. The review process can be extended by FDA requests for additional information or clarification. The FDA reviews NDAs to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMPs to assure and preserve the drug's identity, strength, quality and purity. Before approving an NDA, the FDA typically will inspect the facilities at which the drug is manufactured and will not approve the drug unless the manufacturing facilities comply with cGMPs. Additionally, the FDA will typically inspect one or more clinical trial sites for compliance with GCP and integrity of the data supporting safety and efficacy.

During the approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the drug. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU 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. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and clinical trial sites, the FDA will issue either an approval of the NDA or a Complete Response Letter, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the

application. Even with submission of this additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new drug, it may limit the approved indications for use of the drug. It may also require that contraindications, warnings or precautions be included in the drug labeling, such as a special warning, known as a boxed warning, to highlight a particular safety risk. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the drug's safety after approval. The agency may also require testing and surveillance programs to monitor the drug after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the drug outweigh the potential risks. The FDA may prevent or limit further marketing of a drug based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved drug, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track and Breakthrough Designations

The FDA is authorized to designate certain drugs for expedited programs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a drug for fast track designation if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track designated drugs, sponsors may have a higher number of interactions with the FDA. In addition, the FDA may review sections of the NDA for a fast track designated drug on a rolling basis before the complete application is submitted.

The FDA may designate a drug for breakthrough designation if the drug is intended to treat a serious condition and that preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. The feature of this program allows the same advantages of the fast track designation, but also intensive FDA guidance to promote efficient development and FDA organizational commitment.

Accelerated Approval Pathway

The FDA may grant accelerated approval, under Subpart H of 21 CFR Part 314, to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the drug has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. The benefit of accelerated approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is

subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the drug. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Requirements

In additional to the post-approval requirements specific to an accelerated approval pathway, there are other post-approval requirements whatever the registration pathway.

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by 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 labeling 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.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance programs to further assess and monitor the drug's safety and effectiveness after commercialization. The FDA may also require a REMS, which could involve requirements for, among other things, medication guides, special trainings for prescribers and dispensers, patient registries, and elements to assure safe use.

In addition, entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA has promulgated specific requirements for drug cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an 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 events or AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the 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, labeling, 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 investigation by federal and state authorities. 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.

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of drugs previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-

Waxman Amendments. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product. As such, under Section 505(b)(2), the FDA may rely, for approval of an NDA, on data not developed by the applicant. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for the new indication sought by the 505(b)(2) applicant.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

FDA Regulation of In Vitro Diagnostics

Under the FDCA, *in vitro* diagnostics are regulated as medical devices. In the United States, 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, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA; however, other devices may be commercialized after the FDA grants a *de novo* request.

Device Classification

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and post market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k)

premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to either:

- a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- another commercially available, similar device that was cleared through the 510(k) process.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence.

After a 510(k) notice is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

The PMA Process

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is classified into Class III by operation of law, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA process, or seek classification of the device through the *de novo* process by submitting a *de novo* request. A manufacturer can also submit a direct *de novo* request if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. In response to a *de novo* request, FDA may classify the device into class I or II. When FDA grants a *de novo* request, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, including for 510(k)s.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical study data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer.

Laboratory-developed Tests

LDTs have generally been considered to be tests that are intended for clinical use and that are designed, manufactured and used within a single laboratory. The FDA takes the position that it has the authority to regulate such tests as devices under the FDCA. The FDA has historically exercised enforcement discretion, meaning FDA has not enforced premarket review or other applicable FDA requirements with respect to LDTs. In addition, the New York State Department of Health, or NYSDOH, separately approves certain LDTs offered to New York State patients. The laboratory partner to whom we license our technology will be responsible for obtaining the requisite approvals for our LDT in New York, and maintaining CLIA-certification and state clinical laboratory licenses, where applicable.

On October 3, 2014, the FDA issued two draft guidance documents regarding oversight of LDTs. These draft guidance documents proposed more active oversight over LDTs. The draft guidance documents have been the subject of considerable controversy, and in November 2016, the FDA announced that it would not be finalizing the 2014 draft guidance documents. On January 13, 2017, the FDA issued a discussion paper which laid out elements of a possible revised future LDT regulatory framework, but did not establish any regulatory requirements. The FDA's efforts to regulate LDTs have prompted the drafting of legislation governing diagnostic products and services, including LDTs. Congress or FDA may still act to provide further direction on the regulation of LDTs.

European Union Regulation for Drug Development and Registration

Pre-clinical and Clinical Development

In the European Union, our drug candidates are also subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. Although the Regulation entered into force on June 16, 2014, it will not be applicable until six months after the full functionality of the IT portal and database envisaged in the Regulation is confirmed. This is not expected to occur until later in 2020. Until then the Clinical Trials Directive 2001/20/EC will still apply.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

European Union Drug Review and Approval

In the European Economic Area, or EEA (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Marketing Authorizations may be granted either centrally (EU MA) or nationally (National MA).

The EU MA is issued centrally by the European Commission through the Centralized Procedure, based on the opinion of the CHMP of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs are issued nationally by the competent authorities of the Member States of the EEA and only cover their respective territory. National MAs are available for products not falling within the mandatory scope of the Centralized Procedure. We do not foresee that any of our current drug candidates will be suitable for a National MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, our drug candidates should be approved through EU MAs.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. The EMA may give a positive opinion for conditional marketing authorization based on interim clinical data for a medicinal product for human use if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

Also, pursuant to Regulation (EC) No 1901/2006, all applications for marketing authorization for new medicines must include the results of studies as described in a pediatric investigation plan agreed between regulatory authorities and the applicant, unless the medicine is exempt because of a deferral or waiver. Before the EMA is able to begin its assessment of an EU MA application, it will validate that the applicant has complied with the agreed pediatric investigation plan. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its marketing authorization application and to conduct additional non-clinical and clinical studies.

Orphan Drugs

In the European Union, Regulation (EC) No 141/2000, as amended, states that a drug will be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug but before filing of a MA application. A MA for an orphan drug may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, as a separate MA has to be sought.

If an EU MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of usually 10 years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. The exclusivity period may increase to 12 years if, among other things, the MAA includes the results of studies from an agreed pediatric investigation plan. Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority’. Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan drug designation does not shorten the duration of the regulatory review and approval process.

In Vitro Diagnostics

The regulations on IVDs are currently harmonized through the Directive 98/79/EC on in vitro diagnostic medical devices (the IVD Directive). The IVD Directive requires a conformity assessment by the person placing the product on the market under its name (the legal manufacturer), confirming the performance of an IVD. The IVD Directive will be replaced by Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). The IVDR shall apply from May 26, 2022, with certain exceptions for earlier application and transitional periods for later application. The IVDR in many instances results in an upclassification of IVD, which means that the conformity assessment previously carried out by the legal manufacturer may have to be confirmed by a notified body. Notified bodies are companies designated by competent authorities of a EU Member State to review and confirm an IVD conformity assessment. The rules for the conformity assessment are tightened themselves. Furthermore, a Unique Device Identification (UDI) will be required, as well as a performance evaluation report and tightened vigilance and market surveillance requirements.

Other European Regulatory Matters

French Regulatory Framework on Clinical Trials

In the European Union, the regulation governing clinical trials is currently based on Directive 2001/20/EC of April 4, 2001 relative to the implementation of good clinical practices in the conduct of clinical trials on medicinal products for human use. Each Member State of the European Union had to transpose this Directive into national law, which resulted in Member States adapting it to their own regulatory framework.

In France, for example, Directive No. 2001/20/EC has been implemented by Act Law 2004-806 of August 9, 2004 regarding the public health policy and Decree 2006-477 of April 26, 2006, modifying the section of the Public Health Code, or PHC, on biomedical research. Law No. 2012-300 of March 5, 2012, or the “Loi Jardé,” related to biomedical research involving human

subjects, and French Order No. 2016-800 related to clinical trials of medicinal products for human use have recently adapted French law to the new provisions of Regulation No. 536/2014 of the European Parliament and of the Council of April 16, 2014 related to clinical trials of medicinal products for human use, which repealed Directive 2001/20/EC. Law 2004-806 abolishes the prior notification procedure introduced by the Law Huriet-Sérusclat of December 20, 1988.

The framework imposed by Directive 2001/20/EC is in the process of being replaced by a new framework set forth in Regulation No. 536/2014 of the European Parliament and of the Council of April 16, 2014 related to clinical trials of medicinal products for human use, which repealed Directive 2001/20/EC. For practical purposes, full implementation of Regulation No. 536/2014 depends on the development of a fully functional EU clinical trials portal and database, which is currently estimated to start operating in 2020.

In France, the main legislative and regulatory texts relating to the conduct of clinical trials are mainly codified in the French Public Health Code (Articles L. 1121-1 to L. 1126-12 and Articles R. 1121-1 to R. 1125-26). In addition, other regulations apply to such clinical trials such as Data Protection regulations.

In France, Article L. 1121-4 of the Public Health Code establishes a system of prior authorization for interventional clinical trial on human beings. This authorization is granted by the French Medicines Agency, or ANSM, provided that the competent Ethics Committee issued a favorable opinion. In addition, clinical trials require a prior favorable opinion from an ethics committee. Non-interventional clinical trials are only subject to approval by the competent ethic committee.

Under Article L. 1123-7 of the Public Health Code, the Ethics Committee shall assess whether the conditions in which the trial will be conducted are valid. This assessment should be based on whether: adequate protection is offered to individuals, in particular to participants; adequate information is provided to the participants and appropriate procedure is in place to obtain their informed consent; the project is relevant; the benefits/risks assessment is satisfactory; the objectives of the trial are adequate to the means implemented; the qualification of the investigator(s) is satisfactory; the conditions and amount of patients' indemnification is appropriate; and the method for recruiting participants is adequate.

The ANSM, after submission of the complete file containing not only information on the clinical protocol, but also specific product data and its quality control, as well as results of preclinical studies, may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of its research project and submit this amended or supplemented request to the ANSM; this procedure may not, however, be applied more than once. If the sponsor does not alter the content of its request, the request is considered rejected. Under Article R. 1123-38 of the Public Health Code, the time limit for the examination of a request for authorization cannot exceed 60 days from the receipt of the complete file. As of October 15, 2018, sponsors of clinical trials may volunteer for a Fast Track procedure, established by ANSM, to obtain expedite processing of their application, which may reduce the examination to a maximum of 40 days (for innovative treatments) or a maximum of 25 days (for known molecules).

Finally, under Article L. 1123-11, in the event of risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the Public Health Code, it may at any time request changes to procedures for the realization of research, and suspend or ban this research. The decision of November 24, 2006 sets the rules for Good Clinical Practice, or GCPs, for clinical trials on medicines for human use as referred to in Article L. 1121-3 of the Public Health Code. GCPs aim to ensure both the reliability of data arising from clinical trials and the protection of the persons participating in these clinical trials. GCPs apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers as well as Phase 2 to Phase 4 clinical trials.

Protection of Clinical Trial Subjects in France

Under French law, a clinical trial may be undertaken only if (1) it is based on the latest stage of scientific knowledge and on sufficient preclinical testing, (2) the foreseeable risk incurred by the subjects is outweighed by the benefit expected for these persons or the interest of the research, (3) it aims at expanding scientific knowledge and the means possible to improve the human condition and (4) the research was designed to reduce the pain, inconveniences, fear and other predictable inconvenience connected to the disease or to the research, by taking into account in particular the degree of maturity of minors and the capacity of understanding of adults unable to express an informed consent. All these conditions must be fulfilled in order to start a clinical trial. A clinical trial may be undertaken under the following technical conditions: (a) under the direction and the supervision of a qualified physician and (b) under adapted material and technical conditions, compatible with the rigorous imperatives of science and the safety of the clinical trial subjects. Two documents must be provided to clinical trial subjects before the conduct of the trial. First, the patient must receive a patient information sheet which must contain in particular a description of the objective, the methodology and the time period of the research, as well as a description of the alternative treatments, the number of subjects expected to take part in the study, the anticipated benefits, the constraints and the foreseeable risks resulting from the

administration of the products that are the object of the clinical trials but also the favorable opinion of the ethics committee and the authorization of the ANSM, and information on processing of personal data. The information communicated must be summarized in a written document delivered to the patient prior to any administration of products by the investigator or a physician. Second, the patient must confirm his or her agreement to participate in the clinical study by signing an informed consent form. For each study, patient information must include a right to refuse to participate and to withdraw consent at any time and by any means without further consequences or prejudice. A clinical trial on a minor may be undertaken only if, in particular, the informed consent of the parents or legal representative has been obtained. Furthermore, a clinical trial on adults under guardianship requires the informed consent of the adult's legal representative.

In addition, personal data collected during clinical trials should be declared in simplified form to the French Data Protection Agency (*Commission Nationale de l'Informatique et des Libertés*, or *CNIL*) pursuant to a reference methodology (MR-001 for interventional studies where the consent of the patient is necessary and MR-003 for certain non-interventional studies where the information of the patient is required). As a principle, patients have a right to access and rectify their personal data pursuant to Law 78-17 of January 6, 1978 on Personal Data, as amended.

The sponsor of a clinical trial is also responsible for subscribing to a mandatory insurance policy, in order to provide for the indemnification of all unfavorable consequences of the clinical trial on the patients subject to such trials, pursuant to Article L. 1121-10 of the Public Health Code. The guaranties cannot amount to less than EUR 1.000.000 per victim and EUR 6.000.000 per research protocol.

Transfer of Values to Health Care Professionals

The French Public Health Code provides for two sets of requirements regarding the transfer of values by health care companies to health care professionals:

- The Transparency or Sunshine regime, set out by Article L.1453-1 of the Public Health Code, requires companies manufacturing or marketing health care products (medicinal products, medical devices, etc.) in France to publicly disclose (mainly on a specific public website available at: https://www.entreprises-transparence.sante.gouv.fr) the advantages and fees paid to healthcare professionals amounting to 10 euros or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.).

The Anti-Gift regime, regarding the general prohibition of payments from pharmaceutical and device manufacturers to healthcare professionals (Article L.1453-3 of the French Public Health Code), except in certain circumstances in particular scientific research, speaker fees and hospitality provided in the course of scientific event. The Anti-Gift regime is in the process of being modified by the implementation of the provisions of Ordinance n° 2017-49 of January 19, 2017 through regulations which are scheduled to be adopted by the end of 2018. The new regime will include a prior declaration or prior authorization procedure for the transfers of values which do not fall under the above-mentioned prohibition.

Reimbursement

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

To secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate.

These costs are in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our drug candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable us to realize an appropriate return on our investment in product development.

In January 2019, we entered into a license agreement with Labcorp to enable them to further develop and deploy NIS4 in the context of clinical research. Initially, we will enable Labcorp through its subsidiary Covance to market and sell an LDT powered by NIS4t in the context of clinical research studies. Covance will not seek or receive third-party insurance reimbursement because clinical trial sponsors will directly cover testing costs. In September 2020, we signed a five-year exclusive license agreement with Labcorp to allow them to develop and commercialize an LDT powered by NIS4 technology for use in routine clinical diagnostic testing in the United States and Canada.

As an LDT, the laboratory partner will be responsible for marketing the product to healthcare providers and will make every reasonable effort to seek coverage and reimbursement from third party payors, including Medicare and Medicaid. We will separately seek FDA marketing authorization for a kit-based IVD powered by NIS4 to allow us to commercialize the test within the United States as a medical device. In parallel, we intend to progress towards submitting a data package to a European Notified Body to enable CE marking and associated marketing approval in key European markets in 2021. In Europe, we are still finalizing our plans but are considering, if approved, selling the IVD powered by NIS4 through a distributor or commercial partner to independent, smaller laboratories, as there are fewer large central laboratories in these regions. We, or our collaborators, will be required to obtain coverage and reimbursement for this test separate and apart from the coverage and reimbursement we plan to seek for our product candidates, once approved. There is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement in some or all commercial territories for this test for the same reasons applicable to our product candidates.

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

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country.

The complexity of this process explains why, there can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our drug candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, enacted in the United States in March 2010, has already had, and is expected to continue to have, a significant impact on the healthcare industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program.

There have been judicial and Congressional challenges as well as challenges by the executive branch to certain aspects of the ACA. For example, President Trump signed 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 has considered legislation that would 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, eliminating 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. For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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, even though we do not know when a decision will be made nor how the Supreme Court will rule. Despite the US Supreme Court not having ruled yet on the constitutionality of the ACA, President Biden signed an Executive Order on January 28, 2021 to establish a Special Enrollment Period from February 15, 2021 to May 15, 2021 to seek health insurance coverage through the ACA marketplace. The Executive Order also requires that some government agencies review and reconsider their current policies and practices that may undermine access to health care, including, among others, the review of Medicaid demonstration and waiver policies including work requirements, and policies that may present unnecessary barriers to accessing health care, Medicaid or ACA coverage. We do not know how the Supreme Court decision, other similar litigations, or the Biden administration may impact the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013 and which, due to subsequent legislative amendments, including the BBA, will stay in effect through 2029 unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. A new bill further extending the suspension until December 31, 2021 is currently moving through Congress. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA. The ATRA, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement

methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement a reform of drug pricing, notably through federal budget proposals, executive orders and political initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing, which attempted to implement several of the administration's proposals. The FDA also issued a rule, in force as of November 30, 2020, implementing part of the Executive Order on Prescription Drug Importation, providing guidance to the States to prepare and submit importation plans for drugs from Canada. Besides, on November 20, 2020, the Department of Health and Human Services issued a final rule for the removal of safe harbor protection for rebates involving prescription pharmaceuticals to plan sponsors under Medicare part D, either directly or through the certain pharmacy benefit managers, unless the rebate is required by law. The implementation of the rule has been postponed by the Biden administration from January 1, 2022 to January 1, 2023, in response to ongoing litigation. The rule also created a new safe harbor protection for rebates reflected at the point of sale, as well as a new safe harbor protection for certain fixed fees that manufacturers pay to pharmacy benefit managers for services rendered, of which the implementation has also been postponed until January 1, 2023. On November 20, 2020, the Center for Medicare and Medicaid Services issued an interim final rule implementing the Most Favored Nation Executive Order signed by President Trump, which would closely align payments for some Medicare Part B drugs administered by physicians to the lowest cost paid in other economically advanced countries as of January 1, 2021. On December 28, 2020, the US District Court of Northern California issued a preliminary injunction on a federal level against the implementation of the interim final rule. However, it is not clear whether the Biden administration will work to revert these measures or pursue similar initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Moreover, it is possible that additional governmental measures will be taken in response to the Covid-19 pandemic.

Other U.S. Healthcare Laws and Compliance Requirements

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, which can be enforced by private individuals through civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibits individuals and entities from, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians, as defined by such law, and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members. As of 2022, the aforementioned manufacturers will also be required to declare information regarding payments and other transfers provided during the

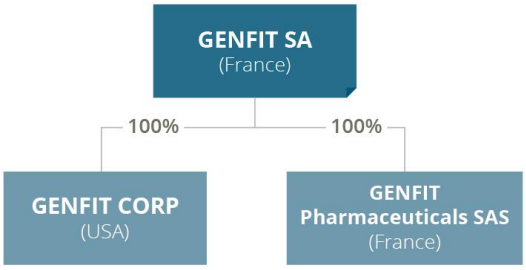
previous years to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes certain requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their business associates, which are individuals and entities that perform functions or activities on behalf of covered entities that involve protected health information, relating to the privacy, security and transmission of protected health information; and
- State and foreign equivalents of each of the above federal laws and regulations, such as: state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; and state and/or foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

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

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws involves substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, for example, significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government funded healthcare programs.

C. Organizational Structure



As part of our new corporate strategy, we expect to distinguish our pharmaceutical and diagnostic technologies activities, in order to ensure more independent management and growth:

-one entity will be dedicated to the development of specialty indications, starting with the execution of the ELATIVE Phase 3 program in PBC; and

-the second entity would house diagnostic technologies, including all programs related to the identification, evaluation and monitoring of patients with NASH. This independent structure would facilitate future partnerships for NIS4.

D. Property, Plants and Equipment

Our corporate headquarters are located in Loos., France. To date, the total surface occupied is approximately 5,500 square meters of office space. The lease for our Loos headquarters continues through March 2029. We also lease office space in Paris, France and, for our U.S. subsidiary, Genfit Corp., in Cambridge, Massachusetts.

Item 4A.Unresolved Staff Comments.

Not applicable.

Item 5.Operating and Financial Review and Prospects.

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 almost two decades. Since 2016, we had been evaluating our most advanced drug candidate, elafibranor, in a pivotal Phase 3 clinical trial (the RESOLVE-IT trial) as a potential treatment for nonalcoholic steatohepatitis, or NASH. , On May 11, 2020, we published the topline data from the interim analysis of the RESOLVE-IT trial. In these interim results, elafibranor did not demonstrate a statistically significant effect on the primary surrogate endpoint which was 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.

Elafibranor is also 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. Our phase 3 trial of elafibranor in PBC, ELATIVE, began in 2020. The first patient first visit in the ELATIVE trial took place on September 24, 2020 and top-line results of the ELATIVE Phase 3 trial are expected at the beginning of 2023.

The development and commercialization rights in elafibranor for the treatment of both NASH and PBC in Greater China have been granted to Terns Pharmaceuticals through a strategic and license collaboration agreement which we signed in June 2019.

A key differentiator of our development strategy is our NASH biomarker-based diagnostic program, called NIS4, a technology which we are developing to power a new *in vitro* diagnostic, or IVD, test to identify patients with NASH who may be appropriate candidates for drug therapy. In January 2019, we entered into a first license agreement with LabCorp to allow LabCorp to develop and commercialize NIS4 ™ in the clinical research space through their drug development subsidiary, Covance. Since then, Covance has made significant progress in the deployment of NIS4 in several clinical trials conducted by leading players in the pharmaceutical industry, although, due to the COVID-19 pandemic, this may have been slowed down due to the delays in the relevant clinical trials.

Moreover, in September 2020, we signed a new and exclusive license agreement with LabCorp to allow them to develop and commercialize an LDT powered by NIS4 technology for use in routine clinical diagnostic testing in the United States and Canada. Our scientific and clinical expertise, translational disease-driven approach and strong bioinformatics capabilities have allowed us to build a scientific platform through which we discover and develop our drug candidates and diagnostic tools.

Although we recorded revenue in 2019 from the receipt of an upfront payment under our collaboration and license agreement with Terns Pharmaceuticals for the development of elafibranor in Greater China, we have never generated significant revenues from product sales. We do not expect to generate material revenue from product sales unless and until we successfully complete clinical development of, obtain marketing approval for and commercialize our drug candidates and IVD test. Clinical development, regulatory approval and commercial launch of a product candidate can take several years and are subject to significant uncertainty. Historically, we have financed our operations and growth through issuances of share capital and convertible bonds, through conditional advances and subsidies from BPI France and from research tax credits. In 2006, we completed the initial public offering of our ordinary shares on the Alternext market of Euronext in Paris and transferred to the Euronext Paris in April 2014. Between 2010 and 2016, we raised a total of over €220 million in gross proceeds from the issuance of ordinary shares. In October 2017, we issued €180 million in convertible bonds. In March 2019, we completed a global offering consisting of an initial public offering of our American Depositary Shares, or ADSs, in the United States, and a private placement of our ordinary shares in Europe and other countries outside the United States, including France. We refer to this transaction herein as the “global offering” or the “March 2019 global offering.” Aggregate gross proceeds from the global offering, before deducting underwriting discounts and commissions and offering expenses payable by us, were approximately $155.4 million.

Since our inception, we have incurred significant operating losses. Our net loss was €101.2 million for the year ended December 31, 2020. Following the results of the phase 3 RESOLVE-IT trial, we implemented a cost savings plan to reduce operational expenses, including a workforce reduction plan and eliminate non-essential expenses, which is currently ongoing. Our goal is to go from a cash burn of approximately €110 million annually (pre-RESOLVE-IT readout) to €45 million in 2022. 2021 is expected to be a transition year with a cash burn of approximately €75 million (excluding a partial buyback of our convertible bonds in January 2021 for a gross amount of €47.48 million) mainly due to expenses related to the termination of the RESOLVE-IT trial and to costs associated with the workforce reduction plan. We expect that our research and development expenses will remain lower than during the year 2020 for the foreseeable future. Nevertheless, we will continue to incur significant expenses and substantial operating losses over the next several years as we continue our operational efforts and advance the clinical development of our drug candidates and the development of our diagnostic test.

Financial Operations Overview

Revenue and Other Income

For the year ended December 31, 2019, our revenue was €30.8 million primarily due to the recognition in revenue of the upfront payment received under the Terns licensing agreement with Terns Pharmaceuticals, or Terns. For the year ended December 31, 2020, our revenue was €0.8 million, mainly due to a one-time transaction as well as the income recognized within the scope of our license agreements with Labcorp.

In 2019, we entered into two licensing agreements, one with Terns with respect to development and commercialization of elafibranor in Greater China, and one with Covance, Labcorp's drug development business, with respect to the development and deployment of a test powered by NIS4 technology in the clinical research space. Pursuant to our agreement with Terns, we received an upfront payment of $35 million in 2019, and are eligible for up to $193 million in clinical, regulatory and commercial milestone payments, as well as mid-teen percentage royalties (For more information see Note 4.4.1 to our consolidated financial statements). In September 2020, we entered into a second agreement with Labcorp, for a five-year exclusive licensing agreement with Labcorp to develop and commercialize an LDT powered by NIS4 in the clinical diagnostic market. Other than pursuant to these two agreements, we do not expect to receive any revenue from any of our product candidates until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates.

Our other income results principally from the research tax credits. We expect to continue to be eligible for these tax credits and subsidies for so long as we incur eligible expenses.

CIR Research Tax Credit

We benefit from a tax credit known as *Crédit d'Impôt Recherche*, or CIR, which is granted by French tax authorities to encourage companies to conduct technical and scientific research. Companies demonstrating that they have expenses that meet the required criteria, including research expenses located in France or within the European Union or in another state that is a party to the agreement in the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause, receive a tax credit that can be used against the payment of French corporate income tax due for the fiscal year in which the expenses were incurred and the three fiscal years thereafter, or, as applicable, can be reimbursed for the excess portion. The expenses taken into account for the calculation of the CIR only involve certain eligible research and development expenses. The subcontracting expenses are limited to an amount equal to €10 million.

The main characteristics of the CIR are the following:

- the CIR results in a cash inflow from the tax authorities paid to us as we are not subject to corporate income tax;
- a company's corporate income tax liability does not limit the amount of the CIR—a company which meets certain criteria in terms of sales, headcount or assets to be considered a small/mid size company and that does not pay any corporate income tax can request cash payment of the research tax credit; and
- the CIR is not included in the determination of the corporate income tax.

We have concluded that the CIR meets the definition of a government grant as defined in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, and, as a result, it has been classified as other income within operating income in our statement of operations.

CICE Tax Credit

We also recognize income relating to the *Crédit d'impôt pour la compétitivité et l'emploi*, or CICE, which is a tax credit implemented by French tax authorities to enhance the competitiveness of businesses through the promotion of certain activities and employment. The CICE was discontinued on January 1, 2019.

Exchange Gain on trade receivables and liabilities

We also recognize in other operating income within "other income" the exchange gains on trade receivables because we determined that they are attributable to the related revenue and other income initial recognized.

Operating Expenses

Research and Development Expenses

We engage in substantial research and development (R&D) efforts to develop our drug and diagnostic candidates. Research and development expenses include:

- raw materials and consumables, such as lab supplies, used in research and development activities;
- fees and costs paid to third parties, such as clinical research organizations and scientific advisors, for clinical trial and other research and development activities, including services subcontracted to research partners for technical or regulatory reasons;
- employee-related costs and costs related to external employees seconded to us for clinical development, biometrics and information technology;
- intellectual property fees related to the filing of patents.
- The provision recognized in 2019 due to the research tax credit dispute with the French revenue services and reversed in 2020

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, such as the RESOLVE-IT and ELATIVE trials. We expect that our research and development expenses will be at a lower level than in 2020 for the foreseeable future. Nevertheless, we will continue to incur significant expenses and substantial operating losses over the next several years as we continue our operational efforts and advance the clinical development of our drug candidates and the development of our diagnostic test. Moreover, the RESOLVE-IT study in NASH will continue to impact our 2021 results insofar as the residual amount for termination costs is estimated to be between €8 and 10 million in 2021.

We generally do not track our research and development expenses by product candidate. However, the substantial majority of our direct expenses incurred, such as for contract research organizations, or CROs, and other contracted research and development activities, as well as raw materials, relate to elafibranor, our lead drug candidate.

General and Administrative Expenses

General and administrative expenses include:

- employee-related costs for executive, intellectual property, finance, legal and human resources and communications functions;
- facility-related costs;
- grants to The NASH Epidemiology Institute (formerly The NASH Education Program) for 2018 and 2019, primarily to finance International NASH Day;
- fees for third-party providers of administrative services, including legal, audit and accounting, press relations and communication services, security and reception and recruiting; and
- intellectual property fees for the registration and maintenance of our patents.

We anticipate that the cost-saving plan initiated in September 2020 will lead to a decrease in general and administrative expenses over 2021. However, they will remain significant due to expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and SEC requirements, director and officer insurance premiums, investor relations and litigation costs. In particular, we will continue to incur additional expenses associated with accounting and internal control over financial reporting to comply with the Sarbanes-Oxley Act of 2002 in the United States.

Marketing and Market Access Expenses

Marketing and market access expenses include:

- employee-related costs for marketing, and business development functions;
- facility-related costs; and
- fees for third-party providers of marketing and pre commercialization services including market surveys, brand strategy, medical communication and market access services.

The cost-saving plan initiated in the summer of 2020 has allowed us to initiate a decrease in our marketing and market access expenses in 2020, which will continue in 2021.

Reorganization and restructuring expenses include:

- the accruals and provisions recognized within the scope of the reduction in force plan;
- the extraordinary amortization, loss of value and impairment of fixed assets recognized within the scope of the reorganization of GENFIT;
- the impairment of the right of use of the leased equipment and premises,
- the portion of the OCEANE renegotiation expenses recognized in 2020;
- the provision recognized for some of the costs of the closing process for the RESOLVE-IT study, which, after detailed analysis, do not have any future economic advantage for the PBC program.
- The remainder of the OCEANE renegotiation expenses will be reflected in the 2021 financial statements.

Financial Income (Expense)

Financial income relates primarily to interest income received from cash and cash equivalents deposits. Our cash and cash equivalents have been deposited primarily in cash accounts and term deposit accounts with short maturities, as well as medium term notes or UCITS and therefore generate only a modest amount of interest income.

Financial expense relates primarily to interest expense on our outstanding convertible bonds as well as interest expense for bank loans and for leases . We also incur foreign exchange losses related to our purchases of services in U.S. dollars, which amounts are recorded as financial expense and interest expenses due to leases in application of IFRS16.

A. Operating Results

Our results of operations for the years ended December 31, 2018, 2019 and 2020 are summarized in the table below.

	Year ended		
(in € thousands, except earnings per share data)	**2018/12/31**	**2019/12/31**	**2020/12/31**
Revenues and other income			
Revenue	69	30,839	765
Other income	7,425	10,122	6,993
Revenues and other income	7,494	40,961	7,758
Operating expenses and other operating income (expenses)	—	—	—
Research and development expenses	(67,024)	(66,170)	(59,097)
General and administrative expenses	(9,076)	(17,265)	(14,270)
Marketing and market access expenses	(717)	(13,708)	(11,216)
Reorganization and restructuring expenses	—	—	(5,308)
Other operating income (expenses)	(162)	(1,649)	(764)
Operating income (loss)	(69,484)	(57,832)	(82,897)
Financial income	728	5,221	6,544
Financial expenses	(11,118)	(13,110)	(25,296)
Financial profit (loss)	(10,391)	(7,889)	(18,752)
Net profit (loss) before tax	(79,875)	(65,721)	(101,649)
Income tax benefit (expense)	354	576	428
Net profit (loss)	**(79,521)**	**(65,144)**	**(101,221)**

(*) IFRS16 was adopted on January 1, 2019 using the modified retrospective method and 2018 has not been restated.

Comparisons for the Years Ended December 31, 2019 and 2020

Revenue

Revenue of €30.8 million during the year ended December 31, 2019 related to the recognition of the revenue related to the license transferred to Terns under the Terns licensing agreement, after deduction of deferred revenue. Deferred revenue amounted to €0.1 million, which corresponds to our expected revenue in relation with the costs to be incurred to assist Terns under the Terns licensing agreement.

Revenue of €0.8 million during the year ended December 31, 2020 was the result of a one-time transaction and the recognition of the revenue under the Labcorp licensing agreements. The decrease in revenue compared to 2019 is due to the one-time nature of the payment for a licensing agreement with Terns recognized in 2019.

Other Income

Other income for the years ended December 31, 2019 and 2020 consisted of the following:

Other income	**Year ended**	
(in € thousands)	**2019/12/31**	**2020/12/31**
CIR tax credit	8,125	6,020
Other operating income (including CICE tax credit)	1,992	968
Government grants and subsidies	5	5
TOTAL	**10,122**	**6,993**

During the year ended December 31, 2019 we had foreign exchange gains linked to trade receivables linked to services denominated in U.S. dollars, which amounted to €1.985 and are recorded as Other operating income (see table above).

During the year ended December 31, 2020, other income amounted to €7.0 million. The decrease compared to the previous year is mainly due to:

- the effect of the expense recorded in 2020 related to the end of the research tax credit dispute for 2010, 2011, 2012 and 2014. This expense was balanced with the reversal of the provision recognized in 2019. The research tax credit for the year 2020 amounted to €7.9 million; and
- the decrease in foreign exchange gains related to trade receivables, which amounted to €0.9 million and are recorded as Other operating income.

Operating Expenses

The tables below summarize our operating expenses for the years ended December 31, 2019 and 2020.

Operating Expenses for the Year Ended December 31, 2020

		Of which:					
Operating expenses and other operating income (expenses) (in € thousands)	**Year ended 2020/12/31**	**Raw materials and consumables used**	**Contracted research and development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes…)**	**Depreciation, amortization and impairment charges**	**Gain / (loss) on disposal of property, plant and equipment**
Research and development expenses	(59,097)	(1,876)	(39,216)	(11,554)	(5,465)	(985)	—
General and administrative expenses	(14,270)	(202)	(92)	(6,936)	(6,545)	(495)	—
Marketing and market access expenses	(11,216)	(7)	(2)	(1,298)	(9,818)	(90)	—
Reorganization and restructuring expenses	(5,308)	—	—	8	(2,141)	(3,175)	—
Other operating income (expenses)	(764)	—	—	—	(684)	—	(80)
TOTAL	**(90,655)**	**(2,085)**	**(39,310)**	**(19,779)**	**(24,655)**	**(4,746)**	**(80)**

Operating Expenses for the Year Ended December 31, 2019

		Of which:					
Operating expenses and other operating income (expenses) (in € thousands)	**Year ended 2019/12/31**	**Raw materials and consumables used**	**Contracted research and development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes…)**	**Depreciation, amortization and impairment charges**	**Gain / (loss) on disposal of property, plant and equipment**
Research and development expenses	(66,170)	(2,017)	(41,509)	(11,740)	(6,188)	(4,716)	—
General and administrative expenses	(17,265)	(177)	(59)	(7,598)	(8,972)	(458)	—
Marketing and market access expenses	(13,708)	(8)	(0)	(1,645)	(11,979)	(76)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(1,649)	—	—	—	(1,668)	—	19
TOTAL	**(98,793)**	**(2,202)**	**(41,568)**	**(20,984)**	**(28,807)**	**(5,251)**	**19**

Research and Development Expenses

Research and development expenses totaled €66.2 million, or 67% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €43.5 million in contracted research and development conducted by third parties, the substantial majority of which were incurred in connection with the progression of our RESOLVE-IT Phase 3 trial. The clinical development costs related to the RESOLVE-IT Phase 3 trial, were lower in 2019 than in 2018 due in particular to a revised estimate of expensed yet unbilled investigator costs which led a decrease in costs of €7.0 million. To a lesser extent, the development costs related to the PBC and NTZ programs also generated subcontracting costs in 2019.

We also incurred €11.7 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development functions and patents. This increase of €2.3 million of employee-related expenses over the prior year was primarily due to changes in seniority, increase in headcount, wage increases and bonuses for our workforce in the research and development functions. Other expenses of €6.2 million consisted primarily of maintenance and other facility costs, as well as employee travel expenses and third-party fees incurred for seconded employees in research and development functions.

The depreciation, amortization and impairment charges totaled €4.7 million, consisting of a provision of €1.9 million with respect to the research tax credit (more information is provided in Note 24 of our consolidated financial statements), and due to additional depreciation due to the adoption of IFRS 16.

Research and development expenses totaled €59.1 million, or 65% of our total operating expenses, for the year ended December 31, 2020. These expenses consisted primarily of €41.1 million in contracted research and development conducted by third parties and consumables. The clinical development costs related to the RESOLVE-IT Phase 3 trial evaluating elafibranor in NASH remained high notwithstanding the decision made in July 2020 to terminate the study. The suspension or termination of some Phase 1 and Phase 2 trials related to NASH contributed to the decrease in contracting costs for 2020. To a lesser extent, the development costs related to the PBC and NTZ programs also generated contracting costs in 2020, but those were much less significant than the aforementioned trials.

We also incurred €11.6 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development functions. The changes in employee expenses for employees in research and development are mainly due to the reduction in force (82 vs. 127 employees) balanced with the change in employee profile, noting that bonuses granted to these employees for their involvement in the development of the Group affected these expenses in 2019 and such bonuses were not granted in 2020.

The changes in depreciation, amortization and impairment charges is mainly related to the provision of €1.9 million recognized in 2019 due to the research tax credit dispute with the French revenue services and reversed in 2020, and to the consequence of the application of IFRS16 in 2019, while in 2020, the amortization impacted the results for up to €2.9 million.

We expect our research and development expenses to decrease in the foreseeable future compared to 2020 . They will nonetheless remain significant and may increase depending on the next steps initiated in the clinical development of our drug candidates and progress in the development of our diagnostic test. Moreover, the RESOLVE-IT study in NASH will continue to impact our 2021 results insofar as the residual amount for termination costs is estimated to be between €8 and 10 million in 2021.

General and Administrative Expenses

General and administrative expenses totaled €17.3 million, or 17% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €9.0 million of other expenses, in particular, related to the insurance costs and audit and communication costs and third-party fees incurred for seconded employees in general and administrative functions. This increase compared to 2018 of €3.5 million was primarily due to an increase related to the insurance costs and costs following the listing on NASDAQ .We also incurred €7.6 million in employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative functions. This increase compared to 2018 of €3.8 million was primarily due to an increase in headcount, changes in seniority, wage increases and to the bonuses paid to employees in those functions.

General and administrative expenses totaled €14.3 million, or 15.7% of our total operating expenses, for the year ended December 31, 2020. These expenses consisted primarily in employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative function for €7.0 million, as well as €6.6 million in other expenses. The reduction in non-R&D and marketing employee expenses was mainly due to the reduction in force (43 vs. 60 employees), and the reduction in compensation as bonuses granted to these employees for their involvement in the development of the Group which affected these expenses in 2019 and such bonuses were not granted in 2020, with the impact being partly balanced with the change in profile of these employees.

The impact of the insurance specific to the year of the IPO and costs following the listing on NASDAQ in 2019 mainly explain the relative decrease of general and administrative expenses in operational expenses for 2020.

We anticipate that the cost-saving plan initiated in September 2020 will lead to a decrease in general and administrative expenses over 2021. However, they will remain significant due to expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and SEC requirements, director and officer insurance premiums, investor relations and litigation costs. In particular, we will continue to incur additional accounting expenses to comply with the Sarbanes-Oxley Act of 2002 in the United States.

Marketing and Market Access Expenses

Marketing and market access expenses totaled €13.7 million, or 14% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €12.0 million of other expenses, in particular, related to preparation for the potential marketing of elafibranor and NIS4 in NASH. The services performed include market surveys, brand strategy, medical communication and market access services. We also incurred €1.6 million in employee-related expenses, consisting of wages, salaries, social security and pension costs paid to employees in marketing and business development functions. This increase of €1.2 million was primarily due to an increase in headcount, changes in seniority, wage increases.

Marketing and market access expenses totaled €11.2 million, or 12% of our total operating expenses, for the year ended December 31, 2020. These expenses consisted primarily of €10 million of other expenses, in particular, related to preparation for the potential marketing of elafibranor and NIS4 in NASH. The services performed include market surveys, brand strategy, medical communication and market access services. We also incurred €1.3 million in employee-related expenses, consisting of wages, salaries, social security and pension costs paid to employees in marketing and business development functions. This decrease of €1.5 million was primarily due to the cost saving plan linked to the termination of the development program of elafibranor in NASH.

We expect that the decrease in our marketing and market access costs initiated in the summer of 2020 with our cost-saving plan will continue in 2021.

Reorganization and Restructuration Expenses

Reorganization and restructuration expenses included mainly expenses and accruals related to employees within the scope of the reduction in force (*Plan de Sauvegarde de l'Emploi* or *PSE)* of €1.9 million, the part of renegotiation fees for the OCEANE recognized in 2020 for €0.8 million, the amortization and impairment loss of fixed assets recognized following the reorganization, the impairment of rights of use of leased premises and leased equipment notably for €2.2 million, and the provision of €0.4 million recognized for some termination costs of the RESOLVE-IT study.

Financial Income (Expense)

Our net financial income (expense) for the year ended December 31, 2019 was €(7.9) million, consisting primarily of €11.3 million of interest expense on our convertible bonds, and €1.7 million of foreign exchange losses, offset partially by € 2.3 million in foreign exchange gain on cash and cash equivalents and €2.6 million in interest income. The increase in financial income is due to the increase in interest on term accounts as we keep some of our cash in US dollars. Interest rates received on investments in US dollars were higher than for investments in euros.

Our net financial expense for the year ended December 31, 2020 was €18.7 million, consisting primarily of €11.6 million of interest expense on our convertible bonds, and €13.5 million of foreign exchange losses, offset partially by € 5 million in foreign exchange gain on cash and cash equivalents and €1.4 million in interest income. The exchange result was a loss of €8.5 million and is notably related to the exchange rate fluctuations on the cash held in US dollars, as the Company made the decision to keep part of its cash in US dollars. These cash holdings in US dollars are to be used to pay directly expenses in US dollars (natural currency hedge).

Comparison for the Years Ended December 31, 2018 and 2019

Revenue

Revenue of €69,000 during the year ended December 31, 2018, was primarily the result of our subleasing a part of our corporate headquarters in Loos, France.

Revenue of €30.8 million during the year ended December 31, 2019 related to the recognition of the revenue related to the license transferred to Terns under the Terns licensing agreement, after deduction of deferred revenue. Deferred revenue amounted to €0.1 million, which corresponds to our expected revenue in relation with the costs to be incurred to assist Terns under the Terns licensing agreement. We also incurred €9.4 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development functions and patents. Other expenses of €6.5 million consisted primarily of maintenance and other facility costs, as well as employee travel expenses and third-party fees incurred for seconded employees in research and development functions.

Other Income

Other income for the years ended December 31, 2018 and 2019 consisted of the following:

Other income	**Year ended**	
(in € thousands)	**2018/12/31**	**2019/12/31**
CIR tax credit	7,295	8,125
Other operating income (including CICE tax credit)	130	1,992
Government grants and subsidies	—	5
TOTAL	**7,425**	**10,122**

Increase in the CIR between the years ended December 31, 2018 and 2019, respectively, was primarily the result of the increase of our research expenditures that met the required CIR criteria.

Operating Expenses

The tables below summarize our operating expenses for the years ended December 31, 2018 and 2019.

Operating Expenses for the Year Ended December 31, 2018

		Of which:					
Operating expenses and other operating income (expenses) (in € thousands)	**Year ended 2018/12/31**	**Raw materials and consumables used**	**Contracted research and development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes…)**	**Depreciation, amortization and impairment charges**	**Gain / (loss) on disposal of property, plant and equipment**
Research and development expenses	(67,024)	(1,724)	(47,659)	(9,431)	(6,502)	(1,707)	—
General and administrative expenses	(9,076)	(126)	(2)	(3,778)	(5,451)	283	—
Marketing and market access expenses	(717)	(4)	—	(416)	(287)	(11)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
TOTAL	**(76,979)**	**(1,855)**	**(47,662)**	**(13,625)**	**(12,403)**	**(1,435)**	**2**

Operating Expenses for the Year Ended December 31, 2019

		Of which:					
Operating expenses and other operating income (expenses) (in € thousands)	**Year ended 2019/12/31**	**Raw materials and consumables used**	**Contracted research and development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes…)**	**Depreciation, amortization and impairment charges**	**Gain / (loss) on disposal of property, plant and equipment**
Research and development expenses	(66,170)	(2,017)	(41,509)	(11,740)	(6,188)	(4,716)	—
General and administrative expenses	(17,265)	(177)	(59)	(7,598)	(8,972)	(458)	—
Marketing and market access expenses	(13,708)	(8)	(0)	(1,645)	(11,979)	(76)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(1,649)	—	—	—	(1,668)	—	19
TOTAL	**(98,793)**	**(2,202)**	**(41,568)**	**(20,984)**	**(28,807)**	**(5,251)**	**19**

Research and Development Expenses

Research and development expenses totaled €67.0 million, or 87% of our total operating expenses, for the year ended December 31, 2018. These expenses consisted primarily of €47.7 million in contracted research and development conducted by third parties, the substantial majority of which were incurred in connection with the progression of our RESOLVE-IT Phase 3 clinical trial of elafibranor for the treatment of NASH and the increase in contracted research and development expenses resulting from the progression of the research and development program pipeline, of which the majority related to expenses for the Phase 3 elafibranor trial in NASH, and to a lesser extent, the Phase 2 trial of elafibranor in PBC and the launch of the Phase 2 trial of NTZ. The increase of €12.6 million over the prior year reflects the advancement of these clinical trials. We also incurred €9.4 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development functions and patents. This increase of €1.5 million of employee-related expenses over the prior year was primarily due to the expansion of our workforce in the research and development functions. Other expenses of €6.5 million consisted primarily of maintenance and other facility costs, as well as employee travel expenses and third-party fees incurred for seconded employees in research and development functions. The decrease of €1.5 million from the prior year was primarily the result of our contribution to The NASH Education Program in 2018 being classified as general and administrative expense instead of research and development expense.

Research and development expenses totaled €66.2 million, or 67% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €41.5 million in contracted research and development conducted by third parties, the substantial majority of which were incurred in connection with the progression of our RESOLVE-IT Phase 3 trial. The clinical development costs related to the RESOLVE-IT Phase 3 trial, were lower in 2019 than in 2018 due in particular to a revised estimate of expensed yet unbilled investigator costs which led a decrease in costs of €7.0 million. To a lesser extent, the development costs related to the PBC and NTZ programs also generated subcontracting costs in 2019 and 2018.

We also incurred €11.7 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in research and development functions and patents. This increase of €2.3 million of employee-related expenses over the prior year was primarily due to changes in seniority, increase in headcount, wage increases and bonuses for our workforce in the research and development functions. Other expenses of €6.2 million consisted primarily of maintenance and other facility costs, as well as employee travel expenses and third-party fees incurred for seconded employees in research and development functions.

The depreciation, amortization and impairment charges totaled €4.7 million, consisting of a provision of €1.8 million with respect to the research tax credit (more information is provided in Note 24 of our consolidated financial statements), and due to additional depreciation due to the adoption of IFRS 16.

General and Administrative Expenses

General and administrative expenses totaled €9.1 million, or 12% of our total operating expenses, for the year ended December 31, 2018. These expenses consisted primarily of €5.4 million of costs and fees for third-party service providers, as well as €3.8 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative functions. The increase of €2.1 million in other expenses was primarily the result of increases and fees and expenses in communication expenses, including the support to the creation of the first International NASH Day in conjunction with The NASH Education Program and expenses related to maintenance of equipment at our corporate headquarters. During the year ended December 31, 2018, we also donated €1 million to The NASH Education Program. The decrease of €1.7 million in employee-related expenses over the prior year period was primarily due to the exceptional 2017 bonuses not replicated in 2018.

General and administrative expenses totaled €17.3 million, or 17% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €9.0 million of other expenses, in particular, related to the insurance costs and audit and communication costs and third-party fees incurred for seconded employees in general and administrative functions. This increase of €3.5 million was primarily due to an increase related to the insurance costs and costs following the listing on NASDAQ .We also incurred €7.6 million in employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative functions. This increase of €3.8 million was primarily due to an increase in headcount, changes in seniority, wage increases and to the bonuses paid to employees in those functions.

Marketing and Market Access Expenses

Marketing and market access expenses totaled €0.7 million, or 1% of our total operating expenses, for the year ended December 31, 2018. These expenses consisted primarily of €0.4 million of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in marketing and business development functions. These expenses were primarily the result of costs incurred in the preparation for the commercialization of elafibranor in NASH.

Marketing and market access expenses totaled €13.7 million, or 14% of our total operating expenses, for the year ended December 31, 2019. These expenses consisted primarily of €12.0 million of expenses, in particular, related to preparation for the potential marketing of elafibranor and NIS4 in NASH. The services performed include market surveys, brand strategy, medical communication and market access services. We also incurred €1.6 million in employee-related expenses, consisting of wages, salaries, social security and pension costs paid to employees in marketing and business development functions. This increase of €1.2 million was primarily due to an increase in headcount, changes in seniority, wage increases.

Financial Income (Expense)

Our net financial income (expense) for the year ended December 31, 2018 was €(10.4) million, consisting primarily of €11 million of interest expense on our convertible bonds and bank loans, offset partially by €0.4 million in other financial income and €0.2 million in interest income. The increase in interest expense was due to our convertible bonds, issued in October 2017, having been outstanding for the full year ended December 31, 2018. The change in financial expenses is related to the interest on the OCEANEs, mainly due to interest payments at a rate of 3.5% and the accretion of the discounting of the bond debt at an effective interest rate of 7.29%. The accretion of bond debt consists of bringing the amount of the debt component of the bond issue to the amount that will be repaid (or converted) at maturity, by the recognition of a theoretical annual interest expense resulting from the accretion over the period of an amount equivalent to the equity component at an effective interest rate.

Our net financial income (expense) for the year ended December 31, 2019 was €(7.9) million, consisting primarily of €11.3 million of interest expense on our convertible bonds, and €1.7 million of foreign exchange losses, offset partially by € 2.3 million in foreign exchange gain on cash and cash equivalents and €2.6 million in interest income. The increase in financial income is due to the increase in interest on term accounts as we keep some of our cash in US dollars .The interest rates received on investments in US dollars were higher than for investments in euros.

B. Liquidity and Capital Resources

Overview

As of December 31, 2018, 2019 and 2020, we had €207.2 million, €276.7 million and €171.0 million, respectively, in cash and cash equivalents.

Since our inception, we have financed our operations primarily through the issuance of new ordinary shares and bonds convertible into new ordinary shares in public offerings and private financing transactions. In 2006, we completed the initial public offering of our ordinary shares on the Alternext market of Euronext in Paris. The listing of our ordinary shares was transferred to the regulated market of Euronext Paris in 2014. Between 2010 and 2016, we raised a total of over €220.0 million in

gross proceeds from the issuance of additional ordinary shares for cash. In October 2017, we issued €180.0 million in bonds convertible into new ordinary shares or exchangeable for existing ordinary shares. In March 2019, we completed a global offering consisting of an initial public offering of our American Depositary Shares, or ADSs, in the United States, and a private placement of our ordinary shares in Europe and other countries outside the United States, including France. Aggregate gross proceeds from the global offering, before deducting underwriting discounts and commissions and offering expenses paid by us, were approximately $155.4 million.

We also financed our operations through historical collaborative research alliances, as well as research tax credits and subsidies granted by various public institutions, such as BPI France Institutions. We also entered into conditional and repayable advances agreements with governmental entities and had a liability of €3.2 million, €3.2 million and €3.2 million associated with these types of arrangements as of December 31, 2018, 2019 and 2020, respectively. Additional information is provided in the note 12 to our consolidated financial statements under the captions “Subsidies and Refundable and Conditional Advances” and “Loans and Borrowings”. We also entered into loans with commercial banks and had an outstanding balance of €4.0 million, €2.6 million and €1.5 million in bank loans as of December 31, 2018, 2019 and 2020, respectively.

In 2019, our cash and cash equivalents were also increased by an upfront payment of $35 million, of which $34.9 million was recognized as revenue in 2019, pursuant to a licensing and collaboration agreement with Terns.

Following the results of the phase 3 RESOLVE-IT trial, we implemented a cost savings plan to reduce operational expenses, including a workforce reduction plan and eliminate non-essential expenses, which is currently ongoing. Our goal is to go from a cash burn of approximately €110 million annually (pre-RESOLVE-IT readout) to €45 million in 2022. 2021 is expected to be a transition year with a cash burn of approximately €75 million (excluding a partial buyback of our convertible bonds in January 2021 for a gross amount of €47.48 million) mainly due to expenses related to the termination of the RESOLVE-IT trial, unbilled payables pertaining to this study, costs associated with the workforce reduction plan and expenses for the renegotiation of the OCEANEs.

In light of this, we will likely continue relying on some or all of these sources of financing, as well as potential milestone payments and royalties that may result from licensing agreements for our drug candidates, diagnostic solutions and results of our research programs, such as our agreements with LabCorp and Terns, as well as the financing opportunities offered by the French government in the context of the COVID-19 pandemic.

Cash Flows

The table below summarizes our cash flows for the years ended December 31, 2018, 2019 and 2020:

(in € thousands)	**Year ended 2018/12/31 (*)**	**Year ended 2019/12/31**	**Year ended 2020/12/31**
Cash flows provided by (used in) operating activities	(56,081)	(47,680)	(96,371)
Cash flows provided by (used in) investment activities	(3,986)	327	(966)
Cash flows provided by (used in) financing activities	(6,514)	116,860	(8,256)
	(66,580)	**69,508**	**(105,593)**

(*)IFRS16 “leases” was adopted on January 1, 2019 using modified retrospective method and 2018 has not been restated.

Operating Activities

Cash used in operating activities was €56.1 million, €47.7 million and €96.4 million for the years ended December 31, 2018, 2019 and 2020, respectively.

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With respect to the 2018 period, this amount primarily resulted from our net loss of €79.5 million, again driven largely by our significant research and development efforts as we progressed our Phase 3 clinical trial of elafibranor in NASH and our Phase 2 clinical trial of elafibranor in PBC, adjusted by €13.0 million in non-cash expenses and other adjustments of €10.3 million in net cash flows from changes in working capital.

With respect to the 2019 period, this amount primarily resulted from our net loss of €65.1 million largely the result of our significant research and development efforts as we progressed our Phase 3 clinical trial of elafibranor in NASH and prepared for the potential commercialization of elafibranor in NASH, adjusted by €17.8 million in non-cash expenses and other adjustments of (€0.3) million.

With respect to the 2020 period, this amount primarily resulted from our net loss of €101.2 million largely the result of our significant research and development efforts as we incurred significant costs for RESOLVE-IT, our Phase 3 clinical trial of elafibranor in NASH, and before implementing the cost saving plan during the summer 2020, for the preparation for the potential commercialization of elafibranor in NASH, adjusted by €16 million in non-cash expenses and other adjustments of (€11.1) million.

Investing Activities

Cash used in investing activities was €4.0 million and €0.3 million for the years ended December 31, 2018 and 2019, respectively, and consisted primarily of equipment, acquisition of financial instruments and other capital purchases and in 2019,due to the reimbursement by the landlord of the costs associated with the expansion of our corporate headquarters when construction was completed in April 2019 . Cash used in investing activities was €1 million for the year ended December 31, 2020 consisted primarily of equipment (more information is provided in Note 8 of our consolidated financial statements, included in this report).

Financing Activities

For the 2018 period, cash used in financing activities was €6.5 million, which consisted primarily of €6.4 million in interest paid on our convertible bonds and €2.0 million in repayments of loans and borrowings, partially offset by €1.8 million in proceeds from new loans and borrowings.

For the 2019 period, cash provided by financing activities was €116.9 million and primarily consisted of €125.3 million in net proceeds from the March 2019 global offering, partially offset by the repayment of loans and borrowings and including the impact of lease payments due to the implementation of IFRS16 on January 1, 2019.

For the 2020 period, cash used in financing activities was €9.7 million, which consisted primarily of €7.8 million in interest paid on our convertible bonds and €2.1 million in repayments of loans and lease repayments.

Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. Our net loss was €79.5 million, €65.1 million and €101.2 million for the years ended December 31, 2018,, 2019 and 2020, respectively. While we expect expenses related to the development of our products to decrease significantly over the next two years, we expect to incur significant expenses and operating losses over the next several years as we continue our research and development efforts and advance the clinical development and prepare for the potential commercialization of NIS4 and our other drug candidates, in the United States, Europe and elsewhere. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We anticipate that our expenses will remain significant in connection with our ongoing activities, as we:

- initiate and conduct our planned preclinical studies and clinical trials of our drug candidates, including the ELATIVE trial of elafibranor for the treatment of PBC;
- proceed with the termination of the RESOLVE-IT trial;
- continue and complete the validation and development of NIS4 for NASH;
- continue the research and development of our other drug candidates, including planned and future preclinical studies and clinical trials;
- seek to discover and develop additional drug candidates and explore combination therapies for our existing drug candidates;
- seek regulatory approval for an IVD powered by NIS4 and any drug candidates that successfully complete clinical trials;
- assist with the scale-up of our subcontractors' manufacturing capabilities in order to support the launch of additional clinical trials and the commercialization of our drug candidates, if approved;
- establish a sales and marketing infrastructure for the commercialization of our drug candidates and diagnostic candidates, if approved, in certain geographies, either on our own or in partnership with a third party;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and our operations as a public company listed in the United States.

Our present and future funding requirements will depend on many factors, including, among other things:

- the size, progress, timing and completion of our clinical trials of elafibranor and our other current or future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of elafibranor and our other current or future product candidates, including other product candidates in preclinical development, together with the costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly, or in the form of royalty payments from any future potential collaboration agreements.

For more information as to the risks associated with our future funding needs, see the section of this annual report titled "Risk Factors."

Until such time that we can generate substantial revenue from product sales, we expect to finance these expenses and our operating activities through a combination of our existing liquidity. If we are unable to generate revenue from product sales in accordance with our expected timeframes, we will need to raise additional capital through the issuance of our shares, through other equity or debt financings or through collaborations with other companies. However, we may be unable to raise additional funds or enter into other funding arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant others rights to develop or market drug candidates that we would otherwise prefer to develop and market ourselves. Our ability to successfully transition to profitability will be dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents as of December 31, 2020 will be sufficient to fund our operations for at least the next 12 months.
Our equity fell below half of the share capital at December 31, 2020. As a result, under French law, our Board of Directors must convene an extraordinary shareholders' meeting within four months after approval of the financial statements showing the loss, in order to comply with the provisions of article L.225-248 of the French Commercial Code. See the risk factor "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".

C. Research and Development

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

D. Trend Information

For a discussion of trends, see "Item 4.B—Business Overview," "Item 5.1—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

E. Off-Balance Sheet Arrangements

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

F. Tabular Disclosure of Contractual Obligations

Contractual obligations are disclosed in Note 12.4 – "Maturities of Financial Liabilities" of the Notes to the consolidated financial statements. We enter into contracts in the normal course of business with CROs and contract manufacturing organizations, or CMOs, for clinical trials, preclinical studies and clinical manufacturing, and with vendors for pre-commercial activities, research and development activities, research supplies and other services and products for operating purposes. These contracts generally provide for termination upon notice. Such agreements may be terminated at will.

We also made donations to The NASH Epidemiology Institute (formerly, The NASH Education Program), the endowment fund of which we are a sponsor. Such donations were at our discretion, and we were not contractually obligated to make any such donation. In 2020, the board of GENFIT decided to cease the activity of the endowment fund.

Although for the year ended December 31, 2019, our board of directors approved a maximum grant of €0.2 million our actual contribution was limited to €45 thousand to The NASH Epidemiology Institute during the year.

Subsidies and Refundable and Conditional Advances

We have received financial assistance from Banque Publique d'Investissement, or BPI France, and other governmental organizations in connection with the development of our product candidates. BPI France's mission is to provide assistance and

support to emerging French enterprises to facilitate the development and commercialization of innovative technologies. Such funding, in the form of refundable and conditional advances, is intended to finance our research and development efforts and the recruitment of specific personnel.

We account for non-refundable subsidies as other income ratably over the duration of the funded project. Funds received in the form of refundable advances are recognized as financial liabilities, as we are obligated to reimburse BPI France for such refundable advances in cash based on a repayment schedule if specified conditions are met.

As of December 31, 2018, December 31, 2019, and as of December 31, 2020 respectively, we had one outstanding repayable advance from BPI France with an aggregate remaining balance of €3.2 million. This advance, in an amount of €3.2 million, is a conditional advance we received in our capacity as leader of a research consortium initiated in 2008 called IT-DIAB to follow patients at risk for type 2 diabetes. The program ended on December 31, 2014. The conditional advance is not refundable except that in the event of success. In the event of technical or commercial success of the consortium's activities, defined as the sale of related drugs or diagnostic devices developed using research results, we would be required to repay the advance, plus an additional specified amount, based on a percentage of any revenues generated from the licensing of such products over a 10-year period. The maximum amount that we would be required to pay under this arrangement is €14.8 million, inclusive of the €3.2 million advance to be repaid. As provided in the contract, we sent a letter to BPI in December 2019 in order to notify it of our LabCorp and Terns contracts while indicating that elafibranor was now aimed at treating hepatic diseases and no longer type 2 diabetes as provided for in the contract. We proposed to BPI to acknowledge the failure of the IT DIAB project. Following this letter, the parties met in March 2020 for the presentation of our arguments, and were in contact again in June 2020 following the results of the RESOLVE IT trial. We sent another letter in November 2020. We are awaiting a proposal from BPI on new financial terms related to this situation and a draft amendment to the repayable advance agreement.

Convertible Bonds

In October 2017, we issued convertible bonds for gross proceeds of €180.0 million. The convertible bonds carry a fixed interest rate of 3.5%, with an effective interest rate of 7.2%, payable semi-annually in arrears in April and October.

On November 23, 2020, we presented to all OCEANE bondholders a two-prong renegotiation offer:

- A partial buyback of the outstanding OCEANEs for a maximum amount of 3,048,780 OCEANEs at €16.40 per bond; and
- An amendment of the terms of the remaining OCEANEs to extend their maturity (by 3 years) and increase the conversion ratio (to 5.5 shares per bond).

At the Shareholders' and Bondholders' Meetings on January 25, 2021, the shareholders and bondholders approved this renegotiation offer.

Following the shareholders' and bondholders' decisions, GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. The settlement operations occurred on January 29, 2021. The repurchased OCEANEs were then cancelled by GENFIT.

The fees related to this renegotiation (including financial advising, counsel fees and meeting costs) are estimated at €2.4 million of which €0.7 were incurred in 2020 and recognized in 2020. The other fees incurred in January 2021 will be recognized in the 2021 period.

Following conversion of the OCEANEs into shares up until April 13, 2021, which led to the creation of 6,886,871 new shares, the residual nominal convertible debt, initially reduced to a nominal amount of €94.3 million through the partial buyback transaction, was further reduced by a nominal amount of €37.1 million, with approximately €57.2 million nominal amount outstanding as of April 13, 2021.

For more information please see Notes 2.3 “Renegotiation of the convertible bond debt (OCEANEs)” and 12.1 “Breakdown of convertible loan” in the Notes to the consolidated financial statements.

Bank Loans

At December 31, 2018, 2019 and 2020, we had borrowed under multiple bank loans primarily intended to finance the acquisition of scientific and information technology equipment for total principal amount outstanding of €4.0 million, €2.6 million and €1.5 million , respectively. These bank loans carry fixed interest rates of between 0.36% and 2.0% and are generally payable over periods ranging from three to five years from the original date of the loan.

Operating Leases

Operating leases consist of real estate leases for our offices located in Loos and Paris, France and in Cambridge, Massachusetts and lease agreements for scientific equipment.

Pension and Employee Benefits

French law requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement. Benefits do not vest prior to retirement. The amount presented in the table included in Note 12.4 – “Maturities of Financial Liabilities” in the Notes to the consolidated financial statements represents the present value of estimated future benefits to be paid, applying a number of assumptions, including dates of expected retirement, life expectancies, salary growth rates and a discount rate.

Critical Accounting Policies and Judgements and Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by IASB. Some of the accounting methods and policies used in preparing our consolidated financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable with respect to the circumstances. The actual value of our assets, liabilities and shareholder’s equity and of our accumulated deficit could differ from the value derived from these estimates if conditions change and these changes had an impact on the assumptions adopted. See note 4 to our consolidated financial statements for a description of our significant accounting policies

G. Safe Harbor

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Special Note Regarding Forward-Looking Statements.”

Item 6.Directors, Senior Management and Employees.

A. Directors and Senior Management

At the June 11, 2020 Shareholders' Meeting, the shareholders approved the nomination of Mrs. Katherine Kalin and Mr. Eric Baclet, to the Board of Directors, both independent directors who bring significant experience in the pharmaceutical and diagnostic industries.

In January 2021, we announced the appointment to the Executive Committee of Pascal Caisey, Chief Commercial Officer, as well as Philippe Motté, as Chief Regulatory and Quality Officer. On February 26, 2021, the Board of Directors appointed Jean-François Tiné to replace Philippe Moons who resigned from his position as member of the Board. This appointment is subject to ratification by the shareholders at the Shareholders Meeting that will be called to approve the financial statements for the year ended December 31, 2020.

On March 11, 2021, the Board of Directors, in accordance with Article 24 of our by-laws, appointed Philippe Moons as board observer until the Shareholders' Meeting called to approve the financial statements for the year ended December 31, 2021. Until that date, his role will be to provide an advisory opinion on questions that may arise with respect to the application of our by-laws, the Charter of the Board of Directors, with a view to supporting good corporate governance; in a particular context where three new directors have joined the Board of Directors since June 2020.

Although the board observer is not a director and is prohibited from interfering in any way in the management of the Company, the observer is invited to participate in all meetings of the Board of Directors and is subject to the Board charter in particular with respect to confidentiality and duties of loyalty.

Finally, on April 21, 2021, we announced the appointment of Thomas Baetz as Chief Financial Officer, as well as Stefanie Magner as Chief Compliance Officer, and their appointment to the Executive Committee.

The following table sets forth information concerning our senior management and directors as of April 23, 2021. Unless otherwise stated, the address for our senior management and directors is c/o GENFIT S.A., Parc Eurasanté, 885 avenue Eugène Avinée, 59120 Loos, France.

Name	Age	Position(s)
Senior Management		
Pascal Prigent	53	Chief Executive Officer
Carol Addy, M.D.	61	Chief Medical Officer
Thomas Baetz	47	Chief Financial Officer
Pascal Caisey	53	Chief Commercial Officer
Suneil Hosmane, Ph.D	39	Head of Global Diagnostics
Nathalie Huitorel	59	Executive Vice President Finance
Dean Hum, Ph.D	58	Chief Operating Officer
Laurent Lannoo	51	Corporate Secretary, Director of Legal Affairs
Stefanie Magner, J.D.	40	Chief Compliance Officer, VP International Legal Affairs
Jean-Christophe Marcoux	44	Chief Strategy Officer
Philippe Motté	61	Chief Regulatory and Quality Officer
Non-Employee Directors		
Jean-François Mouney (1)(6)	65	Chairman of the Board
Xavier Guille des Buttes (2)(3)(7)	79	Vice-Chairman of the Board
Eric Baclet (2)	61	Director
Frédéric Desdouits-(7)	54	Director
Katherine Kalin (7)	58	Director
Catherine Larue, Ph.D (1)	65	Director
Anne-Hélène Monsellato (4)	53	Director
Philippe Moons (8)	67	Board observer (*censeur*)r
Florence Séjourné (5)	49	Director
Jean-François Tiné (7)	64	Director

(1) Member of the Nomination and Compensation Committee.

(2) Member of the Audit Committee.

(3) Chairman of the Nomination and Compensation Committee.

(4) Chair of the Audit Committee.

(5) As representative of Biotech Avenir SAS, the legal entity that holds this board seat.

(6) Chairman of the Strategy and Alliances Committee

(7) Member of the Strategy and Alliances Committee

(8) Resigned as Director of the Board of Directors on February 26, 2021.

Senior Management

Pascal Prigent has served as our Chief Executive Officer since September 2019. He served as our Executive Vice President, Marketing and Development from May 2018 to September 2019. Prior to that, he served as Vice President of Marketing—U.S. Vaccines for GlaxoSmithKline USA from April 2014 to November 2017. Prior to this, he was Vice President and General Manager of GlaxoSmithKline Romania from January 2011 to March 2014. He also served in various roles at Eli Lilly and its affiliates from 1996 through January 2011. Mr. Prigent is a graduate of Reims Management School, now known as NEOMA Business School, in Reims, France and earned his MBA from INSEAD in Fontainebleau, France.

Carol Addy has served as our Chief Medical Officer since September 2019. Prior to this, Dr. Addy held various leadership roles, including most recently, Chief Medical Officer at Health Management Resources, a subsidiary of Merck & Co., from November 2013 to August 2019, and as Associate Director, Director and Senior Principal Scientist at Merck Research Laboratories from June 2003 to November 2013. In addition to an M.D. degree, she holds a Masters of Medical Science from Harvard Medical School, and has also been an endocrinology consultant for MIT Medical.

Thomas Baetz has served as our Chief Financial Officer since April 1, 2021. He has extensive global finance experience across the investment banking and biotech industries. Prior to joining our company, Mr. Baetz was a Healthcare Director at Dragon Financial Partners, where he specialized in licensing agreements and fundraising consultancy for European biotechs. Before that, he was Group Chief Financial Officer and Head of Asia-Pacific for four years at Impeto Medical, a medtech company based in Hong-Kong and Paris, where he oversaw the corporate and business development in China until 2017. Prior to moving to Asia, he held key senior management positions, specializing in mergers and acquisitions, financial control, and consultancy among other areas. M. Baetz earned his MSc. in Finance and Actuarial Science from ENSAE and his BA from ESCP Europe.

Pascal Caisey has served as Chief Commercial Officer in January 2021 and joined GENFIT in September 2019 as Executive Vice President of Commercial Development. He has vast pharmaceutical business experience, holding roles with GSK, BMS, Pfizer, Schering Plough and most recently Boehringer Ingelheim, where he oversaw, as the European Business Manager, the commercial launch of empagliflozin in Europe. Pascal is a registered nurse and holds an MBA from École des Hautes Études Commerciales (HEC) in Paris.

Suneil Hosmane has served as our Head of Global Diagnostics since October 2019. Prior to that Suneil served as the Executive Vice President of Strategic Development at GENFIT Corp., which he joined at the end of 2017. He has had a leadership role on multiple strategic initiatives that span across GENFIT's therapeutic and diagnostic programs. Prior to joining GENFIT, he held positions of increasing responsibility at Becton Dickinson Diagnostics, Intercept Pharmaceuticals, and EchoSens. Suneil holds a Ph.D. in Biomedical Engineering from the Johns Hopkins University School of Medicine and a BSc/MSc in Electrical Engineering from the University of Illinois at Urbana-Champaign.

Nathalie Huitorel has served as our Executive Vice President Finance since October 2007 and was a member of our former Executive Board until the change in management and administration in June 2017. From 1997 to 2007, she was Chief Financial and Administrative Officer for MS Composites, a company specializing in high-performance composite materials. She is a graduate of the SKEMA Business School (School of Management in Lille, France). At Genfit, she oversees the financial management controls, purchasing, human resources department and general services. She is also a member of the board of directors of our wholly owned subsidiary, Genfit Corp. and of the Management Committee of Genfit Pharmaceuticals SAS.

Dean Hum, Ph.D has served as our Chief Operating Officer since September 2018 and prior to that served as our Chief Scientific Officer since 2000 and as a member of our former Executive Board from May 2014 until the change in management and administration in June 2017. He earned a Ph.D in Biochemistry from McGill University in Montreal in 1990. He is an expert in the regulation of gene expression and nuclear receptors associated with endocrine and cardiometabolic diseases. Prior to becoming a Professor at Laval University in Quebec from 1994 to 2000, Dr. Hum held a research position at the University of California in San Francisco from 1990 to 1994. Dr. Hum coordinates our research and development activities with our Chief Executive Officer and in close collaboration with our other scientific officers and project managers. He is also a president and member of the board of directors of our wholly owned subsidiary, Genfit Corp., and a member of the Management Committee of our wholly owned subsidiary Genfit Pharmaceuticals SAS.

Laurent Lannoo has served as our Corporate Secretary and Director of Legal Affairs since 2008. From 2005 to 2008, he served in various roles at the Coeur et Artères foundation, including as chairman of its executive board from 2007 to 2008 and as corporate secretary from 2005 to 2006. Prior to that, from 1996 to 2005, he was in charge of finance and administration for Eurasanté, the public agency for the economic development of healthcare activities in the Nord-Pas de Calais region of France. He began his professional career at M&M, a consulting firm, in 1994, becoming partner in 1996. Mr. Lannoo graduated from Lille Law School with a degree in Business Law.

Stefanie Magner has served as our Chief Compliance Officer and VP International Legal Affairs since March 1, 2021, after joining our company in 2016 as Deputy Director of Legal Affairs. Prior to joining Genfit, she spent nearly 10 years at the Paris offices of the global U.S. law firm, Jones Day advising issuers, many in the biotech space, and banks on a variety of corporate, cross-border securities and M&A transactions, including several U.S. IPOs. She is admitted to practice law in New York and is a former member of the Paris Bar. She graduated from the University of Pennsylvania with a Bachelor of Arts in International Relations and French, as well as an international diploma from Sciences-Po Paris. She received her U.S. law degree from Washington College of Law at the American University in Washington D.C. and holds a Masters of Business Litigation from the Université de Paris X – Nanterre.

Jean-Christophe Marcoux has served as our Chief Strategy Officer since 2016, after joining our company in 2015 to play a cross-disciplinary role regarding tactical, strategic and operational matters. He is an engineer and graduated from INSA Lyon in France, having spent part of his time at the University of Leeds in England. In addition, he also holds a degree in Strategic Management and Economic Intelligence from EGE in France. From 2000 to 2015, he led international projects and programs in a variety of industrial sectors, in particular in Europe and Asia, and with clients and colleagues in the United States. In 2012, he joined IQVIA (formerly known as IMS Health, and later Quintiles IMS), a global information and technology services company for clients in the healthcare industry, where he led projects in healthcare systems, such as patient longitudinal studies, forecasting, targeting, profiling, prospective analyses, digital healthcare and innovation.

Philippe Motté has served as Chief Regulatory and Quality Officer since January 2021 after joining GENFIT in June 2020 as Senior Vice President of Global Regulatory Affairs. Philippe’s previous commercial and regulatory roles include positions with Sanofi, GSK, Roche, Ipsen, and AbbVie. Prior to joining GENFIT, he was Vice President of Global Regulatory Affairs and Chief Access Officer (safety, quality, regulatory, and market access) at MedDay Pharmaceuticals. Philippe holds a PharmD from the Paris-Descartes University and a PhD in Human Biology (major Experimental Oncology) from the Paris-Sud University, completed Postdoctoral Research at Harvard Medical School and the Massachusetts General Hospital Cancer Center, earned an MBA from the ESCP-EAP European School of Management (Paris), and is certified as a Pharmacien Responsable.

Non-Employee Directors

Jean-François Mouney has served as Chairman of our board of directors since June 2017. Mr. Mouney also served as our Chief Executive Officer from September 1999 to September 2019. Mr. Mouney served as Chairman of our Executive Board from September 1999 to June 2017, when we changed our management structure. He co-founded Genfit in 1999 after having been actively involved in the incubation of the company since 1997. Prior to this, he founded, managed and developed several companies specializing in high-performance materials, particularly in the aeronautical industry. In 1992, he founded M&M, a consultancy firm specializing in health economics. He was responsible for carrying out a feasibility study for the economic development agency, Eurasanté, within the field of health and biology in Nord-Pas-de-Calais region of France and was appointed Chief Executive Officer of this agency. He has continued to serve in this role since its launch in 1995. Mr. Mouney has also served as Deputy Chairman of the "Nutrition, Health and Longevity" research hub between 2008 and 2016 and as an Advisor to the Banque de France since 2008. Mr. Mouney is a graduate of ESCP-Europe Business School, and holds a masters degree in Economics from the University of Lille.

Xavier Guille des Buttes served as member of our former Supervisory Board since 2006 and has served as a member of our board of directors since June 2017. Mr. Guille des Buttes was educated at the Ecole Supérieure des Sciences Commerciales d'Angers, the Institut de gestion prévisionnelle et de contrôle de gestion, and has spent his entire career in the pharmaceutical industry. He has held a number of executive positions for more than 30 years, particularly in the French subsidiary of the German Group Schering AG, where, from 1974 to 2006, he successively held the positions of Marketing Director, General Manager of the Pharmaceutical Division and Chairman of the board of directors. As a member of our former Supervisory Board from October 2006, he chaired the Supervisory Board from April 2008 to June 2017, when he became Vice-Chairman of our Board of Directors following the change in administration and management. In addition to his responsibilities at Genfit, he also serves as director of several private companies. Mr. Guille des Buttes also chairs the Foundation of the Catholic University of Lille.

Eric Baclet joined our board of directors in 2020. In 1987, he began his extensive experience in the pharmaceutical industry with Eli Lilly and since the late 1990s until 2017, held executive or corporate officer positions in various countries where Eli Lilly and Company has a presence (North Africa, Belgium, the United States, China and Italy). From 2009 to 2013, Mr. Baclet was President and General Manager of Lilly China and most recently from 2014 to 2017, President of Lilly Italy and General Manager of Lilly Italian Hub. He is a seasoned executive with extensive experience gleaned from senior executive positions, having built and managed diverse and multicultural teams involved in the biopharmaceutical value chain throughout the world. From this background Mr. Eric Baclet has acquired extensive experience in international management from initial clinical development to final commercialization. Mr. Baclet has been responsible for portfolio strategies, international brand development, global marketing projects, global sales operations and the management of various geographic areas and countries. Mr. Baclet holds a Pharmacy degree from the University René Descartes.

Frédéric Desdouits served as member of our former Supervisory Board since 2014 and has served as a member of our board of directors since our change in management and administration in June 2017. Mr. Desdouits was Managing Director of Seqens CDMO Business Unit until June 30, 2020 (Ecully, France) and served as CEO for PCAS SA until March 23, 2020 (Ecully, France) a publicly listed affiliate of Seqens. Prior to joining Seqens (former Novacap) in October 2017, he was head of Business Development, Acquisition and Market Intelligence at Pierre Fabre Group since 2011, and North American Pharma Director from January 2016. He was also a member of the pharmaceuticals executive board and of the development products board. Prior to joining Pierre Fabre, from 2004 to 2011, Mr. Desdouits was Managing Partner at Bionest Partners, a consulting and transaction firm based in Paris and New York specializing in healthcare and biotechnology. From 2007 to 2011, he was the founding Managing Partner of Bionest Partners Finance, a boutique specialized in value strategy and fund raising for emerging bio-companies. Between 1997 and 2004, Mr. Desdouits was a partner in charge of Pharmaceutical and Biotechnology sectors at Exane BNP-Paribas, an investment company. Prior to that, Mr. Desdouits worked in research from 1996 to 1997 at GlaxoWellcome in France (now GSK), as a consultant for Hoechst in the USA from 1995 to 1997 and was a Ph.D student from 1992 to 1995 with a grant from Rhône-Poulenc in France (now Sanofi). Between 2010 and 2011, he was a member of the Pre-Phase III DPU Blood & Vessels board at Sanofi Aventis (now Sanofi) in Chilly-Mazarin, France. He is currently a member of the strategic committee of Treefrog Therapeutics. Mr. Desdouits was a member of the supervisory board of CiToxLab (now Charles River). Between 2008 and 2011, Mr. Desdouits was a board member at Exonhit Therapeutics (now Eurobio Scientific) and member of the Mergers and Acquisitions subcommittee, and from 2015 to 2017, was an observer on the Orphelia Pharma Board of Directors. Mr. Desdouits graduated from Ecole Polytechnique (Palaiseau, France), obtained a M.S. in pharmacology and a Ph.D in Neurosciences at University Paris VI and Collège de France and studied from 1994 to 1996 at the Rockefeller University in New York. He is a CEFA (Certified European Financial Analyst) and Certified in Global Management from INSEAD.

Katherine Kalin joined our board of directors in 2020. She brings more than 25 years of experience as a senior executive in healthcare and professional services, most recently at Celgene Corporation, where she led corporate strategy from 2012 to 2017 and Johnson & Johnson, where she held leadership roles in marketing, sales and new business development from 2002 to 2011. Prior to that, she was a partner in the global healthcare practice of McKinsey & Company from 1990 to 2002. Her healthcare industry experience spans diagnostics, medical devices, pharmaceuticals and digital health. She began her career as an investment banker in Corporate Finance at Nomura in Tokyo, Japan and London, UK. Ms. Kalin currently serves as a non-executive director on the board of Athersys, a publicly-traded, US biopharmaceutical company, and as a member of the board of directors of Brown Advisory LLC, an independent investment and strategic advisory firm and Clinical Genomics Technologies, a biotech company dedicated to improving patient outcomes through early detection of colorectal cancer. She is also a member of the Advisory Board of Stardog, an enterprise data company, and a board member of PRIMARI Analytics, an artificial intelligence startup. She has a B.A. from Durham University, U.K., and an M.B.A. from Harvard Business School.

Catherine Larue, Ph.D has served as a member of our board of directors since 2017. Since September 2020, she is an independent consultant in the biotechnology and diagnostic fields. From 2012 to 2020, Dr. Larue was CEO of the Integrated Biobank of Luxembourg (IBBL), where she led the development of the biobanking strategy and new initiatives in the field of personalized medicine. During this period, she also served as interim CEO of the Luxembourg Institute of Health (LIH), a biomedical research institute, between 2016 and 2017. Prior to joining the IBBL, Dr. Larue piloted Genfit's biomarker program until 2012. Dr. Larue began her career as team leader at Sanofi at the Montpellier, France based research and development center in the cardiovascular research department. She later joined Sanofi Diagnostics Pasteur, as Director of Research and Development and then spent 11 years at the Bio-Rad group, holding different management positions. She participated in the discovery of several innovative biomarkers and the commercialization of dozens of diagnostic products. Dr. Larue holds a doctorate in experimental biology and an accreditation to direct research (Habilitation à Diriger la Recherche, or HDR) from the University of Rouen, a university degree in clinical oncology from the University of Paris VI and an executive MBA from St. John's University (New York).

Anne-Hélène Monsellato has served as a member of our board of directors and the chair of our Audit Committee since 2017. Since May 2015, she has been an independent member of the Supervisory Committee and the Chairman of the Audit and Risk Committee of Euronav, a Belgian crude oil tanker company listed on the New York Stock Exchange and Euronext Brussels. In addition, she serves as the Vice President and Treasurer of the American Center for Art and Culture, a U.S. private foundation based in New York, which operates the American cultural center in Paris, France. From 2005 until 2013, Ms. Monsellato served as a Partner with Ernst & Young (now EY), Paris, after having served as Auditor/Senior, Manager and Senior Manager for the firm starting in 1990. During her time at EY, she gained extensive experience in cross border listing transactions, in particular with the United States, internal control and risk management, and was involved with several companies in the pharmaceutical and biotechnology sector. Ms. Monsellato is an active member of the French association of Directors (IFA) since 2013 in particular with the Club of Audit Chairs, the ESG Committee and the European Confederation of Directors' Association. She is also a member of the Consultative Working Group for the ESMA Corporate Reporting Standing Committee since 2019. Ms. Monsellato has been a Certified Public Accountant in France since 2008 and received a board member certification from IFA Sciences Po in 2014. She graduated from EM Lyon in 1990 with a degree in Business Management.

Philippe Moons served as member of our former supervisory board since 2015 and has served as a member of our board of directors since June 2017. In February 2021, he resigned from his position as director on the Board of Directors, but will remain as a board observer. Mr. Moons graduated from the Institut Catholique des Arts et Métiers de Lille and received an MBA from the Ecole des Hautes Etudes Commerciales du Nord (EDHEC), and began his career as a business engineer at Delattre Leviver, part of the Creusot-Loire Group, a French industrial Group. In 1989, he joined Finorpa, a venture capital and growth capital company, operating under the aegis of the Group "Charbonnage de France" in the Nord-Pas-de-Calais region of France. Between 2006 and 2015, he was in charge at Finorpa of supporting and financing several companies in their early-stage activities or development phases, in particular in the fields of biology and health. Mr. Moons was a member of the executive board of Finovam, a regional venture capital company, established in 2014 to strengthen the emergence and provide seed capital to innovative businesses, primarily technological projects in the Nord-Pas-de-Calais region, until 2015.

Florence Séjourné has served as a member of our board of directors since June 2017 as representative of SAS Biotech Avenir. She was a member of our former Supervisory Board from 1999 until the change in our management and administration in June 2017. Ms. Séjourné co-founded our company and served as our chief operating officer, business development director, industrial alliances coordinator and member of our former Executive Board from 1999 to 2008. Since 2008, she has been the Chairwoman and CEO of Da Volterra, a clinical-stage biotechnology company developing novel Microbiota Protective therapies for protection against antibiotics residues, in particular in cancer and blood disorders. From 1997 to 1999, she was in charge of the

biopharmaceutical sector for Eurasanté, the economic development agency. Ms. Séjourné graduated from the Ecole des Mines of Paris with a degree in Biotechnology and holds a master's degree in Pharmacy from the University of Illinois in Chicago.

Jean-François Tiné joined the Board of Directors in 2021. He is a seasoned senior investment banking executive, having most recently served since 2017 as Chairman of Equity Capital Markets at Natixis Corporate & Investment Banking after joining Natixis in 2005 as Global Head of Equity Capital Markets. He began his career in various sales, trading and syndication positions in the London and Paris capital markets at Union Bancaire Privée, Crédit Suisse, First Boston and Bank of America. In 1993, he became an associate at MC Securities in London, before being appointed three years later as Global Head of Equity Syndicate at Société Générale in Paris.

Family Arrangements and Selection Arrangements

Except as described below, there are no family relationships between any of the members of our senior management or board of directors, nor are there any arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any member of our senior management or board of directors was selected as such.

Our Executive Vice President, Finance and our Corporate Secretary and Director of Legal Affairs, are civil partners recognized under the French civil partnership regime *Pacte civil de solidarité.*

B. Compensation

Director Compensation

At our general meeting of shareholders held on June 30, 2020, shareholders set the total annual attendance fees (*jetons de présence*) to be distributed among non-employee directors at €600,000 for the period beginning with the shareholders' general meeting of June 30, 2020 until the next shareholders' general meeting. The following table sets forth information regarding the compensation earned by our non-employee directors for service on our board of directors during the year ended December 31, 2020, which consisted solely of attendance fees, with the exception of our Chairman, Jean-François Mouney.

NAME	(€)
Jean-François Mouney(1)	242,933
Eric Baclet	20,165
Xavier Guille des Buttes	85,020
Frédéric Desdouits	53,360
Katherine Kalin	15,805
Catherine Larue, Ph.D.	43,600
Anne-Hélène Monsellato	50,140
Philippe Moons	45,780
Florence Séjourné, as representative of SAS Biotech Avenir	-_

(1) Mr. Mouney's compensation includes his fixed compensation, directors' fees and social security charges. See below "Chairman of the Board Compensation" for more details.

We compensate all the members of the Board of Directors, with the exception of the permanent representative of Biotech Avenir, a shareholder of the Company and a non-independent member of the Board of Directors. Director compensation includes a fixed part for each director and a variable part depending on their attendance. The fixed part varies according to:

•the role played by each director on the Board of Directors and the Committees;

•the function of Vice-Chairman of the Board of Directors or Chairman of a specialized committee, which is more remunerative.

Given the frequency of meetings observed in recent years, the variable portion linked to attendance is greater than the fixed portion.

Directors fees are allocated as follows:

(in euros)	**Annual fixed amount (1)**	**Variable amount (per director and per meeting)**
Board member	10,000	2,500
Board committee member	2,500	2,500
Vice-Chairman of the Board of Directors	10,000	-
Chairman of a Board committee	5,000	-

(1)For Board members joining during the course of the fiscal year, calculated pro-rata to number of months spent on the Board of Directors. Amounts may be cumulative.

The Board of Directors may also compensate members on an exceptional basis for special assignments, within the meaning of article L.225-84 of the French Commercial Code. To date, no special assignments have been given to any of the board members.

Chairman of the Board Compensation – Jean-François Mouney

The various components of the overall annual compensation of Mr. Mouney for his duties within the Genfit group during the fiscal year ended December 31, 2020 are summarized below:

- gross fixed compensation under article L.225-47 of the French Commercial Code;
- attendance fees for participation in the work of the committees of the Board of Directors (as a member and/or chairman), according to the distribution decided by the Board of Directors
- other benefits related to his position including use of a company vehicle and eligibility for the Group’s life insurance and health insurance benefits.

Fixed Compensation

Mr. Mouney received a gross fixed compensation of €192,996.

Attendance Fees

Mr. Mouney also received gross compensation of €49,937 as Chairman of the Board of Directors, which amount includes directors' fees for his participation in certain Board committees (Compensation and Nominations Committee and Strategy and Alliances Committee).

Other Compensation

The benefits in kind granted to Mr. Mouney for the year ended December 31, 2020 consisted of the use of a company car valued at €7,200 and eligibility for the Group's life insurance and health insurance benefits .

Chief Executive Officer Compensation – Pascal Prigent

Our only executive officer under French law is our chief executive officer. The following table sets forth information regarding compensation earned during the year ended December 31, 2020 by Mr. Prigent.

NAME AND PRINCIPAL POSITION	FIXED COMPENSATION (€)	VARIABLE COMPENSATION (€)	EQUITY AWARDS (€)	ALL OTHER COMPENSATION (€)	TOTAL (€)
Pascal Prigent, Chief Executive Officer	325,008	70,770(1)	40,600	18,805	384,413

(1) Variable compensation subject to "Say-on-Pay" approval of the Shareholders' Meeting to be called to approve the financial statements for the year ended December 31, 2020.

The various components of the overall annual compensation of Mr. Prigent for his duties as Chief Executive Officer of the Genfit group during the fiscal year ended December 31, 2020 are summarized below:

Fixed Compensation

Through his executive officer contract (*contrat de mandat social*), Mr. Prigent received a gross fixed compensation of €325,008.

Variable Compensation

Even though the Board found that almost all of the CEO's objectives had been achieved in 2020, on the proposal of the Nominations and Compensation Committee, and taking into account the multi-year savings plan we implemented in 2020, which included reducing variable compensation for all employees, the Board of Directors determined that the CEO's variable compensation would be €70,770.49, i.e. 43% of what could have been his maximum variable compensation (i.e., €162,504, representing 50% of his fixed compensation). Variable compensation is subject to approval at the upcoming Shareholders' Meeting called to approve the financial statements for the year ended December 31, 2020.

Equity Awards

During the year ended December 31, 2020, Mr. Prigent received a grant of 35,000 stock options (SO 2020) with vesting subject to performance conditions.

Other Compensation

Mr. Prigent received use of a company car valued at €6,602, was eligible for the Group's life insurance and healthcare plans and the payment of premiums for unemployment insurance Social Security for Business Managers (GSC) whose purpose is to guarantee the payment of compensation in the event of unemployment (up to 55% of net professional tax income for the uncapped share for 12 months following the loss of the position) given that corporate officers are not eligible for standard French unemployment benefits, valued at €12,203.

Change of Control and Severance Benefits

Mr. Prigent also benefits from a severance payment falling within the scope of Article L.225-42-1 of the French Commercial Code equal to 12 months' gross compensation, calculated on the basis of the last 12 months, increased, where applicable, by the

amount of annual variable compensation due for the previous fiscal year and it would be paid if, and only if, one of the following three performance conditions is achieved at the time that his post is terminated:

- elafibranor has been granted marketing authorization by the FDA or EMA in NASH or PBC or that NIS4 has been granted FDA approval or obtained CE marking in Europe;
- a license agreement for elafibranor or NTZ has been signed for the US market and / or for at least two of the five major European markets (Germany, France, Italy, United Kingdom, Spain and / or for Japan); or
- we have merged with or into a biopharmaceutical group with a transaction value at least equal to our market capitalization.

Mr. Prigent also benefits from a non-compete indemnity equal to 12 months of gross fixed compensation, calculated on the basis of the gross amounts due for the past twelve months end, and where applicable, by the amount of the annual variable compensation due for the previous year. The amounts which he may receive under a non-compete indemnity are not cumulative with his severance payment and vice-versa.

Limitations on Liability and Indemnification Matters

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

We have liability insurance for our directors and officers and insurance coverage for liability under the Securities Act. We have also entered into agreements with our directors and senior management to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements will provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified directors and members of senior management.

Certain of our non-employee directors may, through their relationships with their employers or partnerships, be insured against certain liabilities in their capacity as members of our board of directors.

These agreements may discourage shareholders from bringing a lawsuit against our directors and senior management for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and senior management, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these insurance agreements.

Equity Incentives

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best available personnel for positions of substantial responsibility, provides additional incentives to our employees, senior management and directors and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted several different equity incentive instruments to our directors, senior management, employees and other service providers, including:

- redeemable share warrants (otherwise known as *bons de souscription et/ou d'acquisition d'actions remboursables*, or BSAAR);
- share warrants (otherwise known as *bons de souscription d'actions*, or BSA), which have historically only been granted to non-employee directors;
- restricted, or free, shares (otherwise known as *actions gratuites*, or AGA); and
- stock options (otherwise known as *options de souscription et/ou d'achat d'actions*, or SO).

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

We have three outstanding share-based compensation plans for our senior management, directors and employees, the BSA plan, the AGA plan and the SO plan. In general, share warrants no longer continue to vest following termination of the employment, office or service of the holder and all vested shares must be exercised within post-termination exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants.

As of April 13, 2021, share warrants, stock options and free shares were outstanding allowing for the purchase and/or free allocation of an aggregate of 563,942 ordinary shares.

Redeemable Share Warrants (BSAAR)

Redeemable share warrants had historically been granted to our executives and employees, including Mr. Mouney and the two other members of the former executive board (*directoire*) who were corporate officers at the time of their subscription. Exercise of the BSAAR is subject to the effective presence of the beneficiary in our company or one of our French or foreign subsidiaries as an employee, officer, or through a consulting agreement at the date of receipt of the exercise request accompanied by the payment of the exercise price.

Pursuant to authorizations granted by the shareholders meetings on April 2, 2014 and February 24, 2015, we put in place in September 2014 and July 2016, two share warrant plans (BSAAR 2014 and BSAAR 2016) for members of the executive board (including the current Chairman and Chief Executive Officer) and non-corporate officer employees.

In July 2020, the BSSAR 2016 plans lapsed without having been exercised. There are no longer any BSSAR plans.

The main terms of the BSAAR plans were as follows:

Plan title	BSAAR 2014-A	BSAAR 2014-B	BSAAR 2014-C	BSAAR 2016-A	BSAAR 2016-B
Meeting date	April 2, 2014	April 2, 2014	April 2, 2014	February 24, 2015	February 24, 2015
Dates of allocation	September 15, 2014	September 15, 2014	September 15, 2014	July 22, 2016	July 22, 2016
Exercise conditions(1)			1 warrant / 1.03 shares		
Subscription periods	From September 19, 2014 to October 15, 2014	From May 7, 2015 to May 29, 2014	From July 6, 2015 to July 31, 2015	From July 25, 2016 to July 27, 2016	From July 25, 2016 to July 27, 2016
Total number of BSAARs granted	15,200	23,238	24,279	7,200	3,600
Start date for the exercise of the BSAARs	September 15, 2015	September 15, 2015	September 15, 2015	January 1, 2018	August 1, 2019
BSAAR expiry date	September 15, 2018	May 4, 2019	July 1, 2019	July 27, 2020	July 27, 2020
BSAAR issuance price	€ 5.61	€ 5.61	€ 5.61	€ 4.60	€ 4.60
BSAAR exercise price per share	€ 23.50	€ 23.50	€ 23.50	€ 23.50	€ 23.50
Number of shares subscribed as of December 31, 2020	833	0	400	0	0
BSAAR cancelled or lapsed	14,367	23,238	23,879	0	0
BSAAR remaining as of December 31, 2020	0	0	0	0	0

(1) Exercisable in tranches of 1/3 of the BSAAR owned by the beneficiary.

Share Warrants (BSA)

Share warrants have been granted to the independent members of the former supervisory board and of the board of directors and scientific consultants. Similar to options, share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary

share on the date of grant. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants.

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

As of December 31, 2020, we have two outstanding share warrants plans as follows:

Plan title	BSA 2017-A	BSA 2017-B	BSA 2019
Meeting date	June 16, 2017	June 16, 2017	June 15, 2018
Dates of allocation	November 21, 2017	November 21, 2017	October 31, 2019
Exercise conditions(1)	1 warrant / 1 share		1 warrant / 1 share
Subscription periods	From December 11, 2017 to December 26, 2017	From July 1, 2018 to July 15, 2018	From October 31, 2019 to November 30, 2019
Total number of BSAs granted	18,345	18,345	35,070
Start date for the exercise of the BSAs	July 1, 2018	July 16, 2018	July 1, 2019
BSA expiry date	June 30, 2022	July 15, 2022	May 31, 2024
BSA issuance price	€ 2.00	€ 2.00	€ 1.23
BSA exercise price per share	€ 19.97	€ 19.97	€ 12.32
Number of shares subscribed as of December 31, 2020	0	0	0
Warrants cancelled or lapsed	0	0	0
Warrants remaining as of December 31, 2020	18,345	18,345	35,070

(1) Exercisable by tranches of a minimum of 2,000 BSA, or a multiple thereof, except for outstanding balance under 2,000.

Free Shares (AGA)

Free shares may be granted to any individual employed by us or by any affiliated company. Free shares may also be granted to our chairman of the board of directors, chief executive officer (*directeur général*) and deputy executive officers (*directeurs général délégué*). During the year ended December 31, 2020, neither Mr. Mouney our chairman of our board, nor Mr. Prigent, our chief executive officer received any free shares grants. . We currently do not have any deputy executive officers. However, under French law, the maximum number of shares that may be granted shall not exceed 10% of the share capital as at the date of grant of the free shares (30% if the allocation benefits all employees).

No free shares were granted in 2020.

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

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

The free shares granted under our AGA plans will be definitively acquired at the end of the vesting period as set by our board of directors subject to performance conditions and continued service during the vesting period, except if the board releases a given beneficiary from this condition upon termination of his or her employment contract. At the end of the vesting period, the beneficiary will be the owner of the shares. However, the shares may not be sold, transferred or pledged during the holding period. In the event of disability before the end of the vesting period, the free shares shall be definitively acquired by the beneficiary on the date of disability. In the event the beneficiary dies during the vesting period, the free shares shall be definitively acquired at the date of the request of allocation made by his or her beneficiaries in the framework of the inheritance provided that such request is made within six months from the date of death.

As of December 31, 2020, an aggregate of 144,499 free shares have been granted under the free shares plans which will vest, subject to performance conditions and continued employment, as follows:

	MEETING DATE	DATE OF ALLOCATION	NUMBER OF FREE SHARES GRANTED	VESTING DATE (SUBJECT TO CONDITIONS)(1)	STOCK PRICE ON ALLOCATION DATE	FREE SHARES VESTED
AGA D and S 2016-1	June 21, 2016	December 15, 2016	20,520	December 16, 2019	€ 20.79	17,484
AGA D and S 2016-2	June 21, 2016	December 15, 2016	10,189	December 16, 2019	€ 20.79	7,796
AGA D and S 2017-1	June 16, 2017	December 21, 2017	27,472	January 1, 2021	€ 21.95	19,400
AGA D and S 2017-2	June 16, 2017	December 21, 2017	13,730	January 1, 2021	€ 21.95	8,021
AGA D and S 2018	June 15, 2018	November 22, 2018	35,800	January 1, 2021	€ 20.02	21,741
AGA D and S 2019	June 15, 2018	July 18, 2019	36,788	September 17, 2022	€ 17.06	0

(1) Subject to meeting performance conditions and continued employment with us.

Stock Options (SO)

Stock options may be granted to any individual employed by us or by any affiliated company. Stock options may also be granted to our chairman of the board of directors, chief executive officer (*directeur général*) and deputy executive officers (*directeurs général délégué*). In addition, incentive stock options may not be granted to owners of shares possessing 10% or more of the share capital of our company.

Since 2016, the board of directors, using the authorizations granted to them by the extraordinary shareholders' meeting, has granted stock options to the CEO and certain senior managers. These stock options were put in place as motivation and retention instruments for the current teams, to recruit new talents interested in participating in our future development and include them in obtaining operational and financial objectives.

These stock options allow us to continue to offer to new employees competitive packages compared to other companies in our sector, in particular U.S. companies; substantiate in shares a portion of the total profit-sharing of our employees, this contributing to the alignment of their interests with those of shareholders; and motivate the employees to achieve long-term objectives, and particularly to retain some of them by establishing a direct link between their level of profit sharing and the evolution of the stock price.

Stock options issued pursuant to these plans provide the holder with the right to purchase a specified number of ordinary shares from us at a fixed exercise price payable at the time the stock option is exercised, as determined by our board of directors. The plans generally provide that the exercise price for any stock option will be no less than 80% of the volume weighted average price of the 20 market trading days prior to the day of the board of directors' decision to grant the options. The vesting of the stock options is subject to performance conditions and the continued presence in our Company. These conditions are evaluated over a period of three years and reflect our mid-term objectives. Incentive stock options and non-statutory stock options may be granted under the SO plans.

Our board of directors, and in certain cases our CEO, has the authority to administer and interpret the SO plans. Subject to the terms and conditions of the stock option plan, our board of directors determines the recipients, dates of grant, exercise price, number of stock options to be granted and the terms and conditions of the stock options, including the length of their vesting schedules. Our board of directors is not required to grant stock options with vesting and exercise terms that are the same for every participant. The term of each stock option granted under the SO plans will generally be 10 years from the date of grant. Further, stock options will generally terminate on the earlier of when the beneficiary ceases to be an employee of our Company or upon certain transactions involving our Company.

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

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

beneficiary's estate or any recipient by inheritance or bequest may exercise any portion of the stock option vested at the time of the beneficiary's death within the six months following the date of death, but in any event no later than the expiration of the maximum term of the applicable stock options.

The main terms of the SO plans are as follows:

Plan title	SO 2016-1	SO 2016-2	SO 2017-1	SO 2017-2	SO 2018	SO 2019	SO US 2019-2	SO 2020
Meeting date	June 21, 2016	June 21, 2016	June 16, 2017	June 16, 2017	June 15, 2018	June 15, 2018	November 27, 2019	November 27, 2019
Dates of allocation	December 15, 2016	December 15, 2016	November 21, 2017	November 21, 2017	November 7, 2018	July 18, 2019	November 27, 2019	December 11, 2020
Exercise conditions(1)	1 option / 1 share							
Total number of SOs granted	48,917	24,458	72,830	36,420	139,500	138,500	13,350	187,500
Start date for the exercise of the SOs	December 16, 2019	December 16, 2019	January 1, 2021	January 1, 2021	January 1, 2022	September 17, 2022	January 17, 2023	January 1, 2024
SO expiry date	December 16, 2026	December 16, 2026	December 31, 2027	December 31, 2027	December 31, 2028	September 17, 2029	January 17, 2030	January 1, 2031
SO exercise price per share	€15.79/€21.12(2)	€15.79/€21.12	€17.91/€22.54(3)	€17.91/€22.54	€16.00/€21.65(4)	€13.99/€16.90(5)	€14.31	€4.52(6)
Number of SO exercised as of December 31, 2020	0	0	0	0	0	0	0	0
SO voided or lapsed	14,519	9,150	29,619	18,655	58,109	20,350	4,450	0
SO vested as of December 31, 2020	34,398	15,308	43,212	17,765	81,391	0	13,350	
SO remaining to vest as of December 31, 2020	0	0	0	0		118,150	8,900	187,500

(1) Exercisable by 1/3 of the number of options held by each beneficiary.

(2) Exercise price at €15.79 for SO 2016-1 and SO 2016-2 and €21.12 for SO US 2016-1 and SO US 2016-2.

(3) Exercise price at €17.91 for SO 2016-1 and SO 2016-2 and €22.54 for SO US 2016-1 and SO US 2016-2.

(4) Exercise price at €16.00 for SO 2018 and €21.65 for SO US 2018.

(5) Exercise price at €13.99 for the SO 2019 and €16.90 for the SO US 2019.

(6) Exercise price at €3.50 for the SO 2020, €4.52 for the SO US 2020, and €4.38 for the SO 2020 granted to Pascal Prigent.

Until 2020, all of our stock option plans (SO and SO US) and our AGA D free share plans were subject to internal performance conditions related to our R&D programs, and to external performance conditions related to our stock price. The other free share plans (AGA S) are subject only to internal performance conditions, as further described below.

In 2020, the Board of Directors decided that the 2020 stock option plans would only be subject to internal performance conditions, with the exception of the plan dedicated to the CEO, which would have both internal and external performance conditions.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2017-2 SO US 2017-2 AGA D 2017-2	12/31/2020	66 2/3% of the instruments will be exercisable or definitively allocated, regardless of the evolution of the stock market price if at least one of the three following conditions is met: (i) if an application for marketing authorization for a product (elafibranor for NASH) is examined by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA); or (ii) if the launch of at least one clinical trial among the following is authorized by the EMA or the FDA, either: • Phase III clinical trials of or which aim to record a new product (NTZ program) or a new indication for Elafibranor (PBC); • Clinical trials with a product in Phase II (Elafibranor) within a NASH subpopulation; or (iii) if we enter into at least one licensing agreement for our product candidates in one or several territories.
		Nature of external conditions
		33 1/3% of the instruments will be exercisable or definitively allocated in proportion to the evolution of the stock market price, as follows: (i) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0; (ii) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number exercisable or definitively allocated is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of instruments; or (iii) if the Final Price is equal to or higher than the Ceiling Price, the number exercisable or definitively allocated is equal to the entire one-third of the instruments granted.

Plans	Evaluation date for performance conditions	Nature of internal conditions
AGA S 2017-2	12/31/2020	The free shares will be definitively allocated upon the same internal performance conditions as the SO 2017-2, SO US 2017-2 and AGA D 2017-2 plans.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2018 SO US 2018 AGA D 2018	12/31/2021	66 2/3 % of the instruments will be exercisable or definitively vested, and 100% of the free shares for the AGA S 2018 will be vested, regardless of the variation of the stock market price, if one of the three following conditions is met: (i) if an application for marketing authorization for elafibranor for the treatment of NASH is submitted to the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA); or (ii) if authorization to launch at least one new clinical trial among the following trials is obtained: • Phase III or Phase II/III clinical trial evaluating a new product (NTZ); • Phase III or Phase II/III clinical trial evaluating elafibranor in PBC • Phase III clinical trial evaluating elafibranor in a NASH subpopulation; or (iii) if we enter into at least one licensing agreement for our product candidates in one or several territories.
		Nature of external conditions
		33 1/3% of the Stock Options will be exercisable in proportion to the variation of our stock market price as per the following breakdown: (i) if the Final Price is strictly lower than the Initial Price, the number of the Stock Options exercisable is equal to 0; (iii) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number of Stock Options exercisable is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of Stock Options; or (iii) if the Final Price is equal to or higher than the Ceiling Price, the number of Stock Options exercisable is equal to the entire one-third of the Stock Options allocated.

Plans	Evaluation date for performance conditions	Nature of internal conditions
AGA S 2018	12/31/2021	The free shares will be definitively allocated upon the same internal performance conditions as the SO 2018, SO US 2018 and AGA D 2018 plans.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2019 SO US 2019 AGA D 2019	07/31/2022	66 2/3% of the instruments will be exercisable or definitively vested, and 100% of the free shares for the AGA S 2019 will be vested, regardless of the variation of the stock market price of our shares, if at least one of the three following conditions is fulfilled: (i) if a marketing authorization is granted or an application for marketing authorization is examined: • by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA) for elafibranor for NASH; or: • by the U.S. Food and Drug Administration (FDA)/the competent European authorities in the field of IVD for NIS4 for NASH; or: (ii) if at least two of the four clinical trial among the following trials have delivered their principal results or are ongoing: • Phase III clinical trials for elafibranor for PBC; or • clinical trial evaluating elafibranor's efficacy in NASH pediatric patients; or • Phase IIb clinical trial or clinical trial aimed at registration for NTZ in fibrosis; or • Clinical trial evaluating elafibranor or NTZ in combination therapy for NASH or for hepatic fibrosis; or: (iii) if we enter into at least one new licensing agreement for our product candidates in one or several territories.
		Nature of external conditions
		33 1/3 % of the instruments will be exercisable or definitively vested, in proportion to the variation of our stock market price as per the following breakdown: (i) if the Final Price is strictly lower than the Initial Price, the number of the Stock Options exercisable is equal to 0; (ii) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number of Stock Options exercisable is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of Stock Options; or (iii) if the Final Price is equal to or higher than the Ceiling Price, the number of Stock Options exercisable is equal to the entire one-third of the Stock Options allocated.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO US 2019-2	01/09/2023	66 2/3 % of the instruments will be exercisable if at least if at least one of the three following conditions is fulfilled: (i) if elafibranor has been granted marketing authorization by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA) in NASH or PBC or NIS4 has been authorized by FDA or received CE marking from the EMA; (ii) a licensing agreement pertaining to elafibranor or NTZ has been signed for the U.S. market and/or for at least two of the five major European markets (Germany, France, Italy, United Kingdom, Spain) and/or Japan; or (iii) at least two clinical trials for drug registration are underway.
		Nature of external conditions
		33 1/3 % of the instruments will be exercisable, in proportion to the variation of our stock market price as per the following breakdown: (i) if the Final Price is strictly lower than the Initial Price, the number of the Stock Options exercisable is equal to 0; (ii) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number of Stock Options exercisable is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of Stock Options; or (iii) if the Final Price is equal to or higher than the Ceiling Price, the number of Stock Options exercisable is equal to the entire one-third of the Stock Options allocated.

Plans	Evaluation date for performance conditions	Nature of internal conditions
AGA S 2019	07/31/2022	The free shares will definitively vest upon the same internal performance conditions as the SO 2019, SO US 2019 and AGA D 2019 plans.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2020 SO US 2020	12/21/2023	50% of the Stock Options will be exercisable if at least one of the following three conditions relating to PBC and ELATIVE is fulfilled: i.“Last Patient Visit” in ELATIVE in the fourth quarter of 2022 or earlier; ii.If the results of ELATIVE are released to the market before or during the first half of 2023; iii.if a registration request is filed for elafibranor in PBS with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in 2023. 25% of the Stock Options will be exercisable if at least one of the following two conditions relating to the NIS 4 diagnostic is fulfilled: i.if a research and development partnership agreement with at least one major NASH player (“big pharma”, biotech company, institution, etc.) is entered into by the Company; ii.the NIS 4 diagnostic is used in at least 20 clinical studies. 25% of the Stock Options will be exercisable if at least one of the following two conditions relating to the product pipeline of the Company is fulfilled: i.initiation of a clinical study for a new indication with elafibranor or NTZ; ii.if the Company develops or acquires the rights to a new molecule.

C. Board Practices

Board Composition

Until June 2017, our company had a two-tier corporate governance system: an executive board (*directoire*) was responsible for managing the company and a supervisory board (*conseil de surveillance*) oversaw and advised the executive board. We have now established a board of directors. Our board of directors currently consists of seven members, none of which are citizens or residents of the United States. As permitted by French law, one of our directors, SAS Biotech Avenir, is a legal entity. This entity has designated an individual, Florence Séjourné, to represent it and to act on its behalf at meetings of our board of directors. Ms. Séjourné has the same responsibilities to us and to our shareholders as she would have if she had been elected to our board of directors in her individual capacity. None of our directors serve pursuant to a service contract providing benefits upon termination of service as a director.

Under French law and our bylaws, our board of directors must be comprised of between three and 18 members. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied within six months of this appointment will be null and void. Within these limits, the number of directors is determined by our shareholders. Directors are appointed, reappointed to their position, or removed by the company's ordinary general meeting, and in particular, any appointment which remedies a violation of the 40% gender limit must be ratified by our shareholders at the next ordinary general meeting. Their term of office, in accordance with our bylaws, is five years. Directors chosen or appointed to fill a vacancy must be elected by our board of directors for the remaining duration of the current term of the vacant director. The appointment must then be ratified at the next shareholders' general meeting. In the event the board of directors would be comprised of less than three directors as a result of a vacancy or removal, the remaining directors shall immediately convene a shareholders' general meeting to elect one or several new directors so there are at least three directors serving on the board of directors, in accordance with French law.

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

	CURRENT POSITION	YEAR OF INITIAL APPOINTMENT	TERM EXPIRATION YEAR
Jean-François Mouney	Chairman	1999(1)	2022
Xavier Guille des Buttes	Vice Chairman	2006(2)	2022
Eric Baclet	Director	2020	2025
Frédéric Desdouits	Director	2014(3)	2022
Katherine Kalin	Director	2020	2025
Catherine Larue	Director	2017	2022
Anne-Hélène Monsellato	Director	2017	2022
Philippe Moons	Observer	2015(4)	2022
SAS Biotech Avenir represented by Florence Séjourné	Director	2010(5)	2022
Jean-François Tiné	Director	2020(6)	2022

(1) As member of the former executive board of our company and was subsequently appointed as a member of our board of directors at our combined general meeting in June 2017 and elected as chairman and chief executive officer of our company. Mr. Mouney resigned as chief executive officer of our company in September 2019 but continues to serve as chairman of our board of directors.

(2) As member of the former supervisory board and was subsequently appointed as a member of our board of directors at our combined general meeting in June 2017 and elected as vice chairman.

(3) As member of the former supervisory board and was subsequently appointed as a member of our board of directors at our combined general meeting in June 2017.

(4) As member of the former supervisory board and was subsequently appointed as a member of our board of directors at our combined general meeting in June 2017. He resigned as a director on February 26, 2021 but will remain as an observer on the Board of Directors until the 2022 Shareholders Meeting.

(5) Biotech Avenir SAS was appointed to the former supervisory board for the first time on incorporation of the company on September 15, 1999. Ms. Séjourné has been its permanent representative since 2010, first to the former supervisory board and later to the board of directors of our company.

(6) Appointed by the Board of Directors on February 26, 2021 to replace Philippe Moons on the Board of Directors. His appointment is subject to approval by the Shareholders' Meeting to be convened to approve the financial statements for the period ended December 31, 2020 and if approved, he will serve out the remainder of the term of Philippe Moons which will end at the shareholders meeting called to approve the financial statements for the year ended December 31, 2021 to be held in 2022.

In 2020, the Board of Directors met 14 times, with an average participation rate of 98 % of Board members.

The average participation rates for each Board member at Board of Directors' meetings was:

Mr. Jean-François Mouney : 100 % ;

Mr. Xavier Guille des Buttes: 100 % ;

Mr. Eric Baclet : 100%

SAS Biotech Avenir (represented by Ms. Florence Séjourné) : 100 % ;

Mr. Frédéric Desdouits : 100% ;

Ms. Katherine Kalin: 100%

Ms. Catherine Larue : 93 % ;

Ms. Anne-Hélène Monsellato : 100 % ;

Mr. Philippe Moons : 100 %.

Director Independence

As a foreign private issuer, under the listing requirements and rules of the Nasdaq Global Select Market, we are not required to have independent directors on our board of directors, except to the extent that our audit committee is required to consist of independent directors. Nevertheless, our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from, and provided by, each director concerning such director's background, employment and affiliations, including family relationships, our board of directors determined that all of our directors, except for Jean-François Mouney who previously served as our CEO, and Florence Séjourné, as representative of Biotech Avenir, qualify as "independent directors" as defined under applicable rules of the Nasdaq Global Select Market and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our ordinary shares by each non-employee director and his or her affiliated entities (if any).

Role of the Board in Risk Oversight

Our board of directors is primarily responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. The audit committee also monitors our system of disclosure controls and procedures and internal control over financial reporting and reviews contingent financial liabilities. The audit committee, among other things, examines our balance sheet commitments and risks and the relevance of risk monitoring procedures. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Corporate Governance Practices

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

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least 33 1/3% of the outstanding shares of the company's voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Board Committees

The board of directors has established an audit committee and a remuneration and appointments committee, which operate pursuant to rules of procedure adopted by our board of directors. The board of directors also established in September 2017 a strategy and alliances committee to analyze potential business and corporate development opportunities that may be available to us. Subject to available exemptions, the composition and functioning of all of our committees complies with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq Global Select Market and SEC rules and regulations.

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

Audit Committee. Our audit committee assists our board of directors in its oversight of our corporate accounting and financial reporting and submits the selection of our statutory auditors, their remuneration and independence for approval. Ms. Anne-Hélène Monsellato, Mr. Xavier Guille de Buttes and Mr. Eric Baclet (who replaced Mr. Philippe Moons starting February 26, 2021) currently serve on our audit committee. Ms. Monsellato is the chairperson of our audit committee. Our board has determined that each member is independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our board of directors has further determined that Ms. Monsellato is an "audit committee financial expert" as defined by SEC rules and regulations and that each of the members qualifies as financially sophisticated under the applicable Nasdaq listing rules. The principal responsibility of our audit committee is to monitor the existence and efficacy of the company's financial audit and risk control procedures on an ongoing basis.

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

- monitoring the financial reporting process provided by the company. In this respect, it examines in particular the consistency and the relevance of the accounting standards and methods used by the company, and the advisability of any

modification of the accounting methods. Special attention is paid by the audit committee to reviewing the accounting policies used for the valuation of significant or unusual transactions. The audit committee may make recommendations, in particular to ensure the integrity of the financial reporting process provided by the company, control the integrity of the financial information provided by the company and, in particular, review the consistency and relevance of the accounting standards and methods retained by the company;

- monitoring of the effectiveness of the internal control and risk management systems, as well as of the internal audit, as regards the procedures relating to the preparation and processing of accounting and financial information, without it undermining its independence. If necessary, it alerts the board of directors in the event of an irregularity or anomaly identified in the company's financial statements or control procedures. The audit committee assists the board of directors in drafting the report on internal control;
- monitoring the appointment and renewal process of the statutory auditors. For this purpose, and in accordance with the regulations, the audit committee issues a recommendation to the board of directors on the statutory auditors proposed for appointment and / or renewal by the shareholders' general meeting;
- monitoring of the performance by the Statutory Auditors of their mission, taking into account, where appropriate, the findings and conclusions of the *Haut conseil du commissariat aux comptes* following the audits carried out, in accordance with the regulations;
- monitoring by the statutory auditors of the conditions of independence under the conditions and in the manner provided for by the regulations, and in particular those mentioned in Article 6 of Regulation (EU) No. 537/2014. The audit committee takes the necessary measures to implement paragraph 3 of Article 4 of this Regulation;
- pre-approval of the provision of services of the statutory auditors in compliance with the applicable regulations; and
- the regular report to the board of directors on the performance of its duties. The audit committee also reports on the results of the certification of the financial statements, how this mission has contributed to the integrity of financial reporting and the role it has played in this process. It informs the board of directors without delay of any difficulty encountered.

In 2020, the audit committee met five times, with an average participation rate of 100% of committee members.

Nomination and Compensation Committee. Mr. Xavier Guille des Buttes, Dr. Catherine Larue, Mr. Eric Baclet and Mr. Jean-François Mouney currently serve on our nomination and compensation committee. Mr. Guille des Buttes is the chairperson of our nomination and compensation committee.

Our board of directors has specifically assigned the following duties to the nomination and compensation committee:

- ensure the professionalism and objectivity of the appointment procedure for senior executives and corporate officers and senior management of the company. In particular, it is in charge of making any proposal regarding the size and the desirable balance of the composition of the board of directors in view of the structure and evolution of the shareholding of our company, as well as the requirements for good corporate governance, including the proportion of independent directors at our board of directors. Its mission is to research and assess potential candidates as well as the opportunity to renew mandates; and reviews the future succession of our company's chairman and chief executive officer;
- assess the status of each of its board members relative to other relations they might have with our company, which may compromise his or her free judgment or trigger potential conflicts of interest with us; the nomination and compensation committee must also organize a procedure to select future independent members of the Board of Directors; and
- make proposals to the board of directors concerning the elements of compensation or benefits granted to senior executives, corporate officers and senior management, including directors' attendance fees and salaries, allowances or remuneration of any kind that such persons may receive under an employment contract or company contract with our company, the indemnities and benefits due upon termination of their employment, function or subsequent to this, the allocation of warrants or stock options or the free shares, or any form of long-term incentive in the capital of the company. In this respect, the nomination and compensation committee assesses the scale of the compensation offered by the company in comparison with those practiced on the market and gives its recommendations to the board of directors on the remuneration levels and the breakdown between the various elements of the compensation, as well as the changes in compensation that may be proposed by the company to its senior management and corporate officers.

In 2020, the Nomination and Compensation Committee met six times, with an average participation rate of 100% of committee members.

Strategy and Alliances Committee. Mr. Jean-François Mouney, Mr. Xavier Guille des Buttes, Mr. Frédéric Desdouits, Ms. Katherine Kalin and Mr. Jean-François Tiné (since his appointment to the Board of Directors on February 26, 2021) currently serve on our strategy and alliances committee. Mr. Jean-François Mouney is chairman of our strategy and alliances committee.

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

- analyze business and corporate development opportunities, including strategic opportunities for acquisition or licensing of product rights or mergers and acquisitions with other companies;
- evaluate potential target products and companies;
- review the feasibility of any potential transactions.

In 2020, the alliances committee met five times, with an average participation rate of 100% of committee members.

D. Employees

As of December 31, 2020, we had 130 employees. Of these employees, 82 were engaged in research and development and services related to research and development activities, 43 were engaged in administration and management, which includes finance, investor relations, information systems, human resources and legal, and 5 were engaged in marketing and commercial activities.

Of these 130 employees, 117 were employed by Genfit S.A. and 13 were employed by our U.S. subsidiary, Genfit Corp. Employees employed by Genfit Corp. were mainly based in our Cambridge, Massachusetts office.

Following the results of the RESOLVE-IT trial, at the end of 2020, we initiated a reorganization and reduction in force plan (*plan de sauvegarde de l'emploi* or "PSE") in France, subject to the information and consultation procedure with the Economic and Social Committee of the Company, and reached an agreement with the representative union, which was approved by the French labor board or DIRECCTE in November 2020.

This reorganization aimed to reduce the number of employees to reach a headcount of about 130 employees as of December 31, 2020, with most departures taking place on December 28, 2020.

Pursuant to French law, employees employed by Genfit S.A. are subject to the pharmaceutical industry collective bargaining agreement. We consider our relationship with our employees to be good.

E. Share Ownership

For information regarding the share ownership of our directors and senior management, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

Item 7.Major Shareholders and Related Party Transactions.

A. Major Shareholders

The following table sets forth, as of April 1, 2021, information regarding beneficial ownership of our ordinary shares by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our ordinary shares;
- each member of our senior management;
- each of our directors; and
- all of our senior management and directors as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including free shares that vest by June 1, 2021, the date that is 60 days after April 1, 2021, and stock options and warrants that are currently exercisable or exercisable by June 1, 2021. Shares subject to options and warrants currently exercisable or exercisable by June 1, 2021 are deemed to be outstanding for computing the percentage ownership of the person holding these options or warrants and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person. Shares subject to free shares and stock options are not included, as no free shares nor stock options are currently vested because the requisite performance conditions have not been met.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares shown that they beneficially own, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

Our calculation of the percentage of beneficial ownership is based on 45,750,250 of our ordinary shares outstanding as of April 13, 2021.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Genfit S.A., Parc Eurasanté, 885, avenue Eugène Avinée, 59120 Loos, France.

Name of Beneficial Owner	Number of Ordinary Shares	Percentage
Significant Shareholders:		
Biotech Avenir SAS(1)	1,888,6181	4.13%
Directors and Senior Management:		
Jean-François Mouney(2)	1,944,453	4.25%
Pascal Prigent(3)	17,403	*
Dean Hum, Ph.D(4)	33,303	*
Nathalie Huitorel(5)	33,600	*
Carol Addy	0	-
Jean-Christophe Marcoux(6)	14,822	*
Suneil Hosmane(7)	4,354	-
Laurent Lannoo(8)	23,637	*
Thomas Baetz	0	-
Pascal Caisey	0	-
Philippe Motté	0	-
Stefanie Magner(9)	12,758	*
Xavier Guille Des Buttes(10)	6,842	*

Name of Beneficial Owner	Number of Ordinary Shares	Percentage
Catherine Larue, Ph.D(11)	5,000	*
Anne-Hélène Monsellato(12)	5,000	*
Frédéric Desdouits(13)	5,111	*
Florence Séjourné	0	-
Philippe Moons(14)	5,310	*
Katherine Kalin	5,000	*
Eric Baclet	1,200	*
Jean-François Tiné	0	-
All directors and senior management as a group (21 persons)(15)	2,117,793	4,6%

* Represents beneficial ownership of less than 1%

(1) Biotech Avenir SAS is our holding company. Mr. Mouney, the Chairman of our board of directors and our Chief Executive Officer, is also the Chief Executive Officer and Chairman of the Management Committee of Biotech Avenir and holds 17.1% of its share capital. Florence Séjourné, who represents Biotech Avenir on our board of directors, is also a member of the Management Committee of Biotech Avenir and holds 9.9% of its share capital. Dean Hum holds 6.2% of its share capital and Laurent Lannoo, who is a member of the Management Committee of Biotech Avenir, holds less than 0.01% of its share capital.

(2) Consists of 1,913,213 ordinary shares, of which 1,888,618 shares are held directly by Biotech Avenir, 31,240 stock options that are exercisable within 60 days of April 1, 2021.

(3) Consists of 10,740 ordinary shares and 6,699 stock options that are exercisable within 60 days of April 1, 2021.

(4) Consists of 6,124 ordinary shares and 27,179 stock options that are exercisable within 60 days of April 1, 2021.

(5) Consists of 9,126 ordinary shares and 24,474 stock options that are exercisable within 60 days of April 1, 2021.

(6) Consists of 2,200ordinary shares and 12,622 stock options that are exercisable within 60 days of April 1, 2021.

(7) Consists of 4,354 stock options that are exercisable within 60 days of April 1, 2021.

(8) Consists of 9,036 ordinary shares and 14,601 stock options that are exercisable within 60 days of April 1, 2021.

(9) Consists of 1,540 ordinary shares and 11,218 stock options that are exercisable within 60 days of April 1, 2021.

(10) Consists of 1,842 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of April 1, 2021.

(11) Consists of 5,000 BSA share warrants that are exercisable within 60 days of April 1, 2021.

(12) Consists of 5,000 BSA share warrants that are exercisable within 60 days of April 1, 2021.

(13) Consists of 111 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of April 1, 2021.

(14) Consists of 310 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of April 1, 2021.

(15) Includes 1,888,618 shares held directly by Biotech Avenir.

Significant Changes in Percentage Ownership

There were no significant changes in the percentage ownership held by our principal shareholders during the year ended December 31, 2020.

Voting Rights

A double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years. Any of our principal shareholders who have held our ordinary shares in registered form for at least two years have this double voting right.

Shareholders in the United States

As of December 31, 2020, to the best of our knowledge, 1,380,910 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held by 18 shareholders of record in the United States, including The Bank of New York Mellon, the depositary of our ADR program. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Since January 1, 2020, we have engaged in the following transactions with our directors, senior management and holders of more than 5% of our outstanding voting securities and their affiliates, which we refer to as our related parties.

Directors

We have entered into agreements with our directors to provide contractual indemnification, with certain exceptions, for damages and expenses including, among other things, attorneys' fees, judgments and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. See Item 6 - *Limitations on Liability and Indemnification Matters* for more information.

Biotech Avenir

Biotech Avenir SAS, our holding company, holds 4.13% of our share capital and 7.78% of our voting rights, as of April 13, 2021. Mr. Mouney, the Chairman of our board of directors and, until September 2019, our Chief Executive Officer, is also Chairman of the Management Committee of Biotech Avenir and holds 17.1% of its share capital. Florence Séjourné, who represents Biotech Avenir on our board of directors, is also member of the Management Committee of Biotech Avenir and holds 9.9% of its share capital. The registered office of Biotech Avenir is located at the same address as our principal executive offices, without charge to Biotech Avenir.

The NASH Epidemiology Institute (formerly, The NASH Education Program)

The NASH Education Program endowment fund was created in November 2016 at the initiative of our company to develop and finance disease awareness activities targeting medical professionals and the general public. In 2019, the education programs and disease awareness activities developed by The NASH Education Program were transferred to us. The endowment fund was subsequently renamed The NASH Epidemiology Institute.

The endowment fund's board of directors voted to dissolve the fund on December 31, 2020, and in that context, before the final bank fees related to its dissolution, the endowment fund has a positive balance of €17,000. These funds will be transferred to the Fondation de France or any other association in the field healthcare and which is a registered as a charity.

The registered office of The NASH Epidemiology Institute was located at the same address as our principal executive offices, without charge to The NASH Epidemiology Institute.

Shareholders' Agreement

A Shareholders' Agreement binds all shareholders who held equity in our company prior to the private placement we carried out before the admission of our ordinary shares, on December 19, 2006, to trading on the Alternext stock exchange managed by Euronext Paris. In particular, this Shareholders' Agreement grants a right of first refusal to Biotech Avenir or to any shareholder it designates, provided said shareholder is a signatory of the Shareholders' Agreement, in the event that a shareholder who is a party to the Shareholders' Agreement plans an off-market sale of its shares, insofar as the projected sale, plus any other sales carried out in a given year, represents at least 2% of our total share capital.

The parties to the Shareholders' Agreement that hold our shares include the Université de Lille, Fondation partenariale de l'Université de Lille, Finorpa SCR, Biotech Avenir SAS and two of our directors Messrs. Mouney and Guille de Buttes.

This Shareholders' Agreement became effective on December 19, 2006, and remained effective for an initial 10-year period, after which the Shareholders' Agreement was, and may continue to be, automatically renewed for successive one-year periods.

The Shareholders' Agreement was amended on January 30, 2018 as part of the restructuring of the University of Lille, whereby on January 1, 2018, the three universities of Lille (the universities of Lille I, Lille II and Lille III) merged into a single university (the Université de Lille). In this context, the Université de Lille II Droit et Santé (now Université de Lille) made a donation of 200,000 ordinary shares at the end of 2017 to the foundation, Fondation partenariale de l'Université de Lille, which is now one of our shareholders and a party to the Shareholders' Agreement.

Agreement with PCAS Group

Mr. Frédéric Desdouits, member of the Genfit Supervisory Board, then Board of Directors, since June 2014 , was appointed CEO of PCAS Group in March 2019. Elafibranor's active principal ingredient has been made by a PCAS Group production unit since 2013, and as of March 2019, when Mr. Desdouits became PCAS Group's CEO, PCAS Group became a related party as defined by IAS 24.9. In January 2020, we and PCAS Group entered into a memorandum of understanding for PCAS Group to carry out certain additional tasks in relation to elafibranor, including setting up a second manufacturing source for the active ingredient used in the composition of elafibranor. In March 2020, Mr. Desdouits resigned from his position as CEO of PCAS Group, following which PCAS Group is no longer a related party. The cost to carry out technology transfers between the current manufacturing unit and the second source, for an amount of €0.25 million was to be borne by PCAS, except in case of termination of the RESOLVE-IT clinical trial. Due to the decision to terminate the RESOLVE-IT clinical trial in 2020, these costs were included in the closing costs of the study that were recognized in 2020.

Related Person Transaction Policy

We comply with French law regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is defined as (1) any transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are, were or will be participants in and the amount involved exceeds $120,000, or (2) any agreement or similar transaction under French law which falls within the scope of Article L. 225-38 of the French Commercial Code. A related person is any director, member of senior management or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our board of directors for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, member of senior management and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

In addition, under our Code of Business Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our board of directors must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our board of directors determines in the good faith exercise of its discretion.

With the exception of the agreement with PCAS, all of the transactions described above were entered into prior to the adoption of the written policy, but all were approved by our board of directors to the extent required by, and in compliance with, French law.

C. Interests of Experts and Counsel

Not applicable.

Item 8.Financial Information.

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

Our consolidated financial statements are appended at the end of this annual report, starting at page F-1, and are incorporated by reference herein.

Dividend Distribution Policy

We have never declared or paid any dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business, given our state of development.

Subject to the requirements of French law and our bylaws, dividends may only be distributed from our distributable profits, plus any amounts held in our available reserves which are reserves other than legal and statutory and revaluation surplus. See "Item 10.B—Memorandum and Articles of Association" for further details on the limitations on our ability to declare and pay dividends. Dividend distributions, if any in the future, will be made in euros and converted into U.S. dollars with respect to the ADSs, as provided in the deposit agreement.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations, including those described in Note 24 of our consolidated financial statements for the year ended December 31, 2020 appended to this annual report.

On May 14, 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, captioned Schwartz v. Genfit S.A. et al., 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. The complaint alleged 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. The complaint sought unspecified compensatory damages. In October 2020, the plaintiff voluntarily withdrew its action filed in state court in the Commonwealth of Massachusetts.

However, 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 the claims before state court in the States of New York and we and the other defendants intend to vigorously defend this action. The financial impact of the claim cannot be quantified at this stage.

Other than the legal proceeding described above and the proceeding related to the research tax credit described in Note 24 to our consolidated financial statements included in this annual report, we are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. .

B. Significant Changes

Not applicable

Item 9.The Offer and Listing.

A. Offer and Listing Details

Our ADS have been listed on the Nasdaq Global Select Market under the symbol “GNFT” since March 27, 2019. Prior to that date, there was no public trading market for ADSs. Our ordinary shares have been trading on Euronext Paris under the symbol “GNFT” since 2006. Prior to that date, there was no public trading market for our ordinary shares. Our convertible bonds (OCEANE) have been traded on Euronext Access in Paris under the symbol “GNFAA” since October 16, 2017.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol “GNFT” since March 27, 2019 and our ordinary shares have been trading on Euronext Paris under the symbol “GNFT” since 2006. Our convertible bonds (OCEANE) are traded on Euronext Access in Paris under GNFAA since October 16, 2017.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth in the final prospectus dated March 27, 2019 as part of our Registration Statement on Form F-1 (File No. 333-229907), declared effective by the SEC on March 26, 2019, under the headings "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares," "Description of Share Capital—Differences in Corporate Law" and "Limitations Affecting Shareholders of a French Company" is incorporated herein by reference.

C. Material Contracts

Collaboration and License Agreement with Terns Pharmaceuticals, Inc.

On June 24, 2019, we entered into a collaboration and license agreement with Terns Pharmaceuticals, Inc., or Terns, a global biopharmaceutical company based in the United States and China with a focus on developing novel and combination therapies to treat liver disease. Under the agreement, Terns will have the rights to develop and commercialize elafibranor, our proprietary compound, in mainland China, Hong Kong, Macau and Taiwan, which we refer to as Greater China, for the treatment of NASH and PBC.

Under the terms of the licensing agreement, we received an upfront payment from Terns of $35 million and will be eligible to receive up to $193 million in potential clinical, regulatory and commercial milestone payments. Terns obtains the exclusive rights to develop, register and market elafibranor in Greater China for both NASH and PBC. Upon commercial launch of elafibranor for the treatment of NASH in Greater China, we will be entitled to receive mid-teen percentage royalties from Terns based on sales in the territory.

As part of the deal, we and Terns will also undertake joint research and development projects in liver disease, including the development of elafibranor in combination with Terns' proprietary compounds.

The summary provided above does not purport to be complete and is qualified in its entirety by reference to the complete agreement, which is attached as an exhibit to this annual report.

For additional information on our material contracts, please see Note 4.4.2 to the consolidated financial statements for the year ended December 31, 2019 included in our 2019 Annual Report on Form 20-F, as well as "Item 4. Information on the Company," "Item 6. Directors, Senior Management and Employees," and "Item 7.B. Related Party Transactions" of this annual report.

D. Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

E. Taxation

The following describes material U.S. federal income tax and French tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. holder (as defined below). This summary addresses these tax considerations only for U.S. holders that will hold such ADSs as capital assets (generally, property held for investment). This summary does not address all U.S. federal income tax and French tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a "hedging," "integrated," "wash sale" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- certain former citizens or long term residents of the United States;
- persons that received ADSs as compensation for the performance of services;
- persons acquiring ADSs in connection with a trade or business conducted outside of the United States, including a permanent establishment or a fixed base in France;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ADSs and shares or, in the case of the discussion of French tax consequences, 5% or more of the voting stock or our share capital; and
- holders that have a "functional currency" other than the U.S. dollar.

Holders of ADSs who fall within one of the categories above are advised to consult their usual tax advisor regarding the specific tax consequences which may apply to their particular situation.

For the purposes of this description, a "U.S. holder" is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust, or if such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds ADSs, the tax consequences relating to an investment in the ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the specific tax considerations of acquiring, owning and disposing of the ADSs in its particular circumstances.

The discussion in this section is based in part upon the representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms.

Persons considering an investment in the ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of the ADSs, including the applicability of U.S. federal, state and local tax laws, French tax laws and other non-U.S. tax laws.

Material French Tax Considerations

The following describes the material French income tax consequences to U.S. holders of purchasing, owning and disposing of our ADSs.

This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of our ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

The description of the French income tax and real estate wealth tax consequences set forth below is based on the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, or the Treaty, which came into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax guidelines issued by the French tax authorities in force as of the date of this annual report.

This discussion applies only to investors that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty.

U.S. holders are urged to consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of securities in light of their particular circumstances, especially with regard to the "Limitations on Benefits" provision contained in the Treaty.

Please also note that the following discussion does not address the French tax consequences applicable to securities (including ADSs) held in trusts[2]. If ADSs are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of securities (including ADSs).

Estate and Gift Taxes

In general, a transfer of securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978 (as amended from time to time), unless (1) the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or (2) the securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Financial Transactions Tax and Registration Duties

Pursuant to Article 235 ter ZD of the French tax code (Code général des impôts, the "FTC"), purchases of shares or ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the French Financial Market Authority (AMF) are subject to a 0.3% French tax on financial transactions provided that, broadly, the issuer's market capitalization exceeds 1 billion euros as of December 1 of the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the taxation year within the meaning of Article 235 ter ZD of the FTC is published by the French tax authorities on an annual basis in their official guidelines. Pursuant to the official guidelines BOI-ANNX-000467 issued on December 30, 2020, we are currently not included in such list.

1 In 2011, France introduced a comprehensive set of tax rules applicable to French assets that are held by or in foreign trusts (e.g. subject to certain conditions, (i) inclusion of trust real estate assets in the settlor's net assets for the purpose of applying the French real estate wealth tax (impôt sur la fortune immobilière), (ii) application of French gift and death duties to French assets held in trust, (iii) specific tax on capital on the French real estate assets of foreign trusts not already subject to the French real estate wealth tax (impôt sur la fortune immobilière), and French tax reporting and disclosure obligations.

Moreover, Nasdaq Global Select Market, on which ADSs are listed, is not currently acknowledged by the AMF but this may change in the future.

As a consequence, neither the ADSs nor the ordinary shares are currently within the scope of the French tax on financial transactions.

Purchases of our securities may be subject to such tax in the future provided that our market capitalization exceeds 1 billion euros as of December 1 of the taxation year and that the Nasdaq Global Select Market is acknowledged by the AMF.

In the case where Article 235 *ter* ZD of the FTC is not applicable, transfers of shares issued by a French company which are listed on a regulated or organized market within the meaning of the French Monetary and Financial Code are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written statement ("*acte*") executed either in France or outside France. As ordinary shares of our company are listed on Euronext Paris, which is an organized market within the meaning of the French Monetary and Financial Code, their transfer should be subject to uncapped registration duties at the rate of 0.1% in case of the existence of a written statement ("*acte")* and provided that Article 235 *ter* ZD of the FTC is not applicable. Although there is no case law or official guidelines published by the French tax authorities on this point, transfer of ADSs should remain outside of the scope of the aforementioned 0.1% registration duties.

Tax on Sale or Other Disposals

As a matter of principle, under French tax law, a U.S. holder should not be subject to any French tax on any capital gain from the sale, exchange, repurchase or redemption by us of ordinary shares or ADSs, provided such U.S. holder is not a French tax resident for French tax purposes and has not held more than 25% of our dividend rights, known as *"droits aux bénéfices sociaux,"* at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives (as an exception, a U.S holder domiciled, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC, except for those mentioned in paragraph 2 bis-2° of the same Article, should be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds, subject to safe-harbor provisions and the more favorable provisions of the Treaty.

Under application of the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty and entitled to Treaty benefit will not be subject to French tax on any such capital gain unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. U.S. holders who own ordinary shares or ADSs through U.S. partnerships that are not resident for Treaty purposes are advised to consult their own tax advisors regarding their French tax treatment and their eligibility for Treaty benefits in light of their own particular circumstances. A U.S. holder that is not a U.S. resident for Treaty purposes or is not entitled to Treaty benefit (and in both cases is not domiciled, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC, except for those mentioned in paragraph 2-bis-2°) and has held more than 25% of our dividend rights, known as *"droits aux bénéfices sociaux,"* at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives will be subject to a levy in France at the rate (1) of 12.8% for individuals and (2) 26.5% for fiscal years beginning on or after January 1st, 2021 and 25% for fiscal years beginning on or after January 1st, 2022, for legal persons. Special rules apply to U.S. holders who are residents of more than one country.

Taxation of Dividends

Dividends paid by a French corporation to non-residents of France are generally subject to French withholding tax at a rate of (i) 26.5% for fiscal years beginning on or after January 1st, 2021 and 25% for fiscal years beginning on or after January 1st, 2022, for payments benefiting legal persons which are not French tax residents, and (ii) 12.8% for payments benefiting individuals who are not French tax residents. Dividends paid by a French corporation in certain non-cooperative States or territories, as defined in Article 238-0 A of the FTC (except for those mentioned in paragraph 2-bis-2°), will generally be subject to French withholding tax at a rate of 75%, save for the safe-harbor provisions. However, eligible U.S. holders which are legal entities and entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to this 26.5% (to be decreased to 25% in 2022) or 75% withholding tax rate, but may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is generally reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuer; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any.

For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complex, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisors regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that:

- such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000) in accordance with French guidelines (BOI-INT-DG-20-20-20-20 dated September 12, 2012; or

- the depositary or other financial institution managing the securities account in the U.S. of such holder provides the French paying agent with a document listing certain information about the U.S. holder and its ordinary shares or ADSs and a certificate whereby the financial institution managing the U.S. holder's securities account in the United States takes full responsibility for the accuracy of the information provided in the document.

Otherwise, dividends paid to a U.S. holder, if such U.S. holder is a legal person, will be subject to French withholding tax at the rate of 26.5% (to be decreased to 25% in 2022), or 75% if paid in certain non-cooperative States or territories (as defined in Article 238-0 A of the FTC - except for those mentioned in paragraph 2 bis-2°), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides through the French paying agent, the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid.

Certain qualifying pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary. The depositary will arrange for the filing with the French tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depositary in sufficient time so that they may be filed with the French tax authorities before the distribution in order to immediately obtain a reduced withholding tax rate. Otherwise, the depositary must withhold tax at the full rate of 26.5% (to be decreased to 25% in 2022) or 75% as applicable. In that case, the U.S. holders may claim a refund from the French tax authorities of the excess withholding tax.

In any case, individual taxpayers who are not fiscally domiciled in France should not have to comply with these procedures if the French withholding tax applying to them is lower than 15%.

Wealth Tax

As from January 1, 2018, the French wealth tax *(impôt de solidarité sur la fortun*e) is repealed and replaced by the French real estate wealth tax *(impôt sur la fortune immobilière)*. The scope of such new tax is narrowed to real estate assets (and certain assets deemed to be real estate assets) or rights, held directly or indirectly through one or more legal entities and whose net taxable assets amount to at least €1,300,000.

Broadly, subject to provisions of double tax treaties and to certain exceptions, individuals who are not residents of France for tax purposes within the meaning of Article 4 B of the FTC, are subject to real estate wealth tax *(impôt sur la fortune immobilière)* in France in respect of the portion of the value of their shares of our company representing French real estate assets (Article 965, 2° of the FTC). Some exceptions are provided by the FTC. For instance, any participations representing less than 10% of the share capital of an operational company and shares representing real estate for the professional use of the company considered shall not fall within the scope of the French real estate wealth tax *(impôt sur la fortune immobilière)*.

Under the Treaty (the provisions of which should be applicable to this new real estate wealth tax (*impôt sur la fortune immobilière*) in France), the French real estate wealth tax (*impôt sur la fortune immobilière*) will however generally not apply to shares that are held by U.S. Holders who (1) own, alone or with related persons, directly or indirectly, shares in our company which give rise to less than 25% of the rights in the company's earnings, and (2) do not own their shares in connection with a permanent establishment or a fixed base through which the U.S. Holder carries on business or performs personal services in France.

U.S. Holders are advised to consult their usual tax advisor regarding the specific tax consequences which may apply to their particular situation with respect to such French real estate wealth tax *(impôt sur la fortune immobilière)*.

Material U.S. Federal Income Tax Considerations

This section discusses the material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. holder. This description does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the acquisition, ownership and disposition of the ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a position concerning the tax consequences of the acquisition, ownership and disposition of the ADSs or that such a position would not be sustained by a court. We have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax considerations in the purchase, ownership or disposition of our ADSs. Accordingly, holders should consult their own tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of the ADSs in their particular circumstances.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreements will be complied with in accordance with their terms.

In general, and taking into account the earlier assumptions, for U.S. federal income and French tax purposes, a U.S. holder holding ADSs will be treated as the owner of the shares represented by the ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to French tax.

Distributions. Subject to the discussion under "—Passive Foreign Investment Company Considerations," below, the gross amount of any distribution (including any amounts withheld in respect of foreign tax) actually or constructively received by a U.S. holder with respect to ADSs will generally be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will generally be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder's adjusted tax basis in the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis

will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we may not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) and qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. Our ADSs are currently listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance in this regard. The Company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital, signed on August 31, 1994, as amended and currently in force, or the U.S.-France Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-France Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under "—Passive Foreign Investment Company Considerations," below, such dividends will generally be "qualified dividend income" in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any French withholding tax as either a deduction from gross income or a credit against its U.S. federal income tax liability. The foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. holder's U.S. federal income tax liability that such U.S. holder's taxable income bears to such U.S. holder's worldwide taxable income. In applying this limitation, a U.S. holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." This limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ADSs that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for French income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. In addition, the creditability of foreign taxes could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if, as a result of such actions, the holders of ADSs are not properly treated as beneficial owners of the underlying ordinary shares. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the U.S. dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the Depositary receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

Sale, Exchange or Other Taxable Disposition of the ADSs. A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ADSs in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder's adjusted tax basis in those ADSs, determined in U.S. dollars. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in the ADSs generally will be equal to the cost of such ADSs. Capital gain from the sale, exchange or other taxable disposition of ADSs by a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ADSs exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source gain or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

Medicare Tax. Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ADSs. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in the ADSs.

Passive Foreign Investment Company Considerations. If we are classified as a PFIC in any taxable year, a U.S. holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

We will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of our subsidiaries, either: (1) at least 75% of the gross income is "passive income" or (2) at least 50% of the average quarterly value of our total gross assets (which would generally be measured by fair market value of our assets, and for which purpose the total value of our assets may be determined in part by the market value of the ADSs and our ordinary shares, which are subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income."

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of the ADSs. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. If we are classified as a PFIC in any taxable year during which a U.S. holder owns our ordinary shares or ADSs, such U.S. holder will be subject to special tax rules discussed below and could suffer adverse tax consequences.

The market value of our assets may be determined in large part by reference to the market price of the ADSs and our ordinary shares, which is likely to continue to fluctuate. Therefore, fluctuations in the market price of our ordinary shares or ADSs may result in our being a PFIC for any taxable year. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from our offerings. 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 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.

If we are classified as a PFIC in any year with respect to which a U.S. holder owns 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 tests described above unless we cease to be a PFIC and the U.S. holder has made a "deemed sale" election under the PFIC rules or is eligible to make and makes a mark-to-market election (as described below), with respect to all taxable years during such U.S. holder's holding period in which we are a PFIC. If the "deemed sale" election is made, a U.S. holder will be deemed to have sold the ordinary shares or ADSs the U.S. holder holds at their fair market value as of the date of such deemed sale and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if such election becomes available.

If we are a PFIC, and you are a U.S. holder that does not make one of the elections described above (and below in further detail), a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for the ADSs) and (b) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to qualified dividends discussed above under "Distributions."

Certain elections may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs. If a U.S. holder makes a mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in the ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and the ADSs are "regularly traded" on a "qualified exchange." The ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). The Nasdaq Global Select Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to a U.S. holder.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." As a result, even if a U.S. holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Notwithstanding our belief that we were classified as a PFIC for the taxable year ended December 31, 2020, we do not currently intend to provide the information necessary for U.S. holders to make qualified electing fund elections for such taxable year or any other taxable year for which we are if we were treated as a PFIC. U.S. holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. holders in respect of any of our subsidiaries that also may be determined to be PFICs. U.S. holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a U.S. holder owns ADSs during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. holder's federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. U.S. holders and (and prospective U.S. holders) are urged to consult their own tax advisers with respect to the acquisition, ownership and disposition of the ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of the ADSs.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of ADSs that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting. Certain individual U.S. holders are required to report information relating to an interest in the ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL FRENCH AND U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs OR ORDINARY SHARES AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSs OR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.genfit.com*. We intend to post our annual report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as GENFIT S.A., that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. Subsidiary Information

Not required.

Item 11.Quantitative and Qualitative Disclosures About Market Risk.

Foreign Currency Exchange Risk

We use the euro as our functional currency and the majority of our operations are denominated in euros. However, a significant portion of our operating expenses is denominated in U.S. dollars, as well as a significant portion of our cash and cash equivalent and as result, we may be exposed to foreign currency risk. For the year ended December 31, 2020, expenses in U.S. dollars totaled $47.3 million based on the exchange rate in effect at December 31, 2020. As a result, an adverse 10% change in the exchange rate for the U.S. dollar against the euro would have resulted in a foreign exchange rate loss of approximately €4.3 million for the year. For the year ended December 31, 2020, we realized a foreign exchange rate loss of €13.5 million, although any such historical gains or losses do not predict the future impact of exchange rate risk.

In the future, and in particular with respect to our clinical trials, we will continue to have a significant number of transactions denominated in currencies other than the euro or indirectly exposed to currency risk, which will continue to have exposure to this risk.

During 2020, we did not use any specific hedging arrangements in light of the decision to keep a significant part of our cash and cash equivalents in U.S dollars.

See also Note 5.1 “Foreign Exchange Risk” to the consolidated financial statements for the year ended December 31, 2020.

Interest Rate Risk

We are exposed to interest rate risk related to our cash and cash equivalents. We had cash and cash equivalents of €171 million as of December 31, 2020, which consisted of bank accounts and short-term deposits. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income in comparison to the average balance have not been significant.

We had net outstanding debt of €169.6 million as of December 31, 2020 in the form of convertible loans, which loans accrue interest at a fixed rate of 3.5% and for which the nominal amount is €180 million. In January 2021, we finalized the renegotiation of our convertible loan to extend their maturity by 3 years to 2025 and increase the conversion ratio from 1 share per bond to 5.5 shares per bond. GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. Following conversion of OCEANEs into shares up until April 13, 2021, which led to the creation of 6,886,871 new shares, the residual nominal convertible debt, initially reduced to a nominal amount of €94.3 million through the partial buyback transaction, was further reduced by a nominal amount of €37.1 million, with approximately €57.2 million nominal amount outstanding as of April 13, 2021. For more information, see Note 2.2 to the consolidated financial statements for the year ended December 31, 2020.

We also had outstanding at December 31, 2020 a total of €3.2 million in conditional advances from BPI France, €10.1 million of obligations under leases and €1.5 million of loans from commercial banks. The advances from BPI France are generally non-interest bearing or carry interest at fixed rates, and the bank loans all carry fixed interest rates. In the ordinary course of business, we may enter into contractual arrangements to reduce our exposure to interest rate risks. We do not believe that a 10% change in interest rates would have a significant impact on our consolidated financial statements.

Credit Risk

We believe that the credit risk related to our cash and cash equivalents is not significant in light of the quality of the financial institutions at which such funds are held.

Liquidity Risk

Although we were profitable in our early years of development, as a result of profits from our co-research alliances with certain pharmaceutical companies, we have not been profitable in the past 14 years and we have never generated profits from product sales. We do not expect to be profitable in the foreseeable future. We have incurred operating losses and negative cash flows from operations since inception. We incurred net losses of €79.5 million, €65.1 million and €101.2 million during the years ended December 31, 2018, 2019 and 2020, respectively, and had an accumulated deficit of €158.9 million, €238.3 million and €303.6 million as of December 31, 2018, 2019 and 2020, respectively. Net cash used in operating activities was €56.1 million, €47.7 million and €96.4 million for the years ended December 31, 2018, 2019 and 2020, respectively.

We have primarily funded these losses through equity financings, and by obtaining public assistance in support of innovation and reimbursements of research tax credit. We have devoted substantially all of our resources to our research and development efforts relating to our drug candidates and diagnostic program, in which we are developing a new IVD test to identify patients with nonalcoholic steatohepatitis, or NASH, who may be appropriate candidates for drug therapy, including conducting clinical trials of our drug candidates, 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 IVD test. We do not yet have any products approved for sale and have not generated any revenues from product sales.

As of December 31, 2020, we had €171.0 million in cash and cash equivalents, compared to €276.7 million in cash and cash equivalents as of December 31, 2019 and €207.2 million in cash and cash equivalents as of December 31, 2018. As of December 31, 2020, net cash was €14.6 million (calculated as cash and cash equivalents, minus the book value of the convertible bonds (OCEANE) and current and non-current financial liabilities, compared to € 93.1 million and €37.6 million at December 31, 2019 and 2018 respectively (see the table below). Although it is difficult to predict future liquidity requirements, and taking into consideration the renegotiation of the convertible debt in January 2021, we believe that our existing cash and cash equivalents as of December 31, 2020 will be sufficient to fund our operations for at least the next 12 months.

DETAIL OF CALCULATION OF NET CASH	As of		
(in € thousands)	2018/12/31	2019/12/31	2020/12/31
Cash and cash equivalents	207,240	276,748	171,029
Current convertible loans	(1,312)	(1,312)	(1,313)
Other current loans and borrowings	(1,848)	(3,226)	(3,035)
Non-current convertible loans	(159,176)	(164,142)	(169,470)
Other non-current loans and borrowings	(7,255)	(14,939)	(11,873)
Net cash	**37,647**	**93,129**	**(14,662)**

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 12.Description of Securities Other than Equity Securities.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, or ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with BNP Paribas Securities Services, as custodian for the depositary in France. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The depositary's office at which the ADSs are administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

Fees and Charges

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

Persons depositing or withdrawing ordinary shares or ADS holders must pay:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property • Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	• Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs	• Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares
Expenses of the depositary	• Cable and facsimile transmissions (when expressly provided in the deposit agreement) • Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders are responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADSs or allow an ADS holder to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to the ADS holder or sell deposited securities represented by the ADS holder's American Depositary Shares to pay any taxes owed and such ADS holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes. An ADS holder's obligation to pay taxes and indemnify us and the depository against any tax claims will survive the transfer or surrender of his or her ADSs, the withdrawal of the deposited ordinary shares as well as the termination of the deposit agreement.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

In October 2017, we issued convertible bonds for gross proceeds of €180.0 million. The convertible bonds carry a fixed interest rate of 3.5%, with an effective interest rate of 7.2%, payable semi-annually in arrears in April and October.

On November 23, 2020, we presented to all OCEANE bondholders a two-prong renegotiation offer:

•A partial buyback of the outstanding OCEANEs for a maximum amount of 3,048,780 OCEANEs at €16.40 per bond; and

•An amendment of the terms of the remaining OCEANEs to extend their maturity (by 3 years) and increase the conversion ratio (to 5.5 shares per bond).

At the Shareholders' and Bondholders' Meetings on January 25, 2021, the shareholders and bondholders approved this renegotiation offer.

Following the shareholders' and bondholders' decisions, GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. The settlement operations occurred on January 29, 2021. The repurchased OCEANEs were then cancelled by GENFIT.

Following conversion of OCEANEs into shares up until April 13, 2021, which led to the creation of 6,886,871 new shares, the residual nominal convertible debt, initially reduced to a nominal amount of €94.3 million through the partial buyback transaction, was further reduced by a nominal amount of €37.1 million, with approximately €57.2 million nominal amount outstanding as of April 13, 2021.

For more information please see Notes 2.3 "Renegotiation of the convertible bond debt (OCEANEs)" and 12.1 "Breakdown of convertible loan" in the Notes to the consolidated financial statements for the year ended December 31, 2020.

Item 15. Disclosure Controls and Procedures.

A. Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer (*principal executive officer*) and chief financial officer (*principal financial officer*), as appropriate, to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2020, have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

B. Management's Annual Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2020 based on the framework in "Internal Control - Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management has concluded that, as December 31, 2020, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

C. Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

D. Changes in Internal Control Over Financial Reporting

Other than the implementation and formalization of controls to comply with the COSO 2013 framework for internal controls over financial reporting, which was initiated in 2019, there has been no change in our internal control over financial reporting during the year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert.

Our board of directors has determined that Ms. Anne-Hélène Monsellato is an "audit committee financial expert" as defined by SEC rules and regulations and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Ms. Monsellato is independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.

Item 16B. Code of Business Conduct and Ethics.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, senior management and directors. The Code of Conduct is available on our website at *www.genfit.com*.

Item 16C. Principal Accountant Fees and Services.

Ernst & Young et Autres, or E&Y, served as our independent registered public accounting firm for 2019 and 2020. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	Year Ended December 31,	
(in € thousands)	**2019**	**2020**
Audit Fees	1,388	462
Audit-Related Fees	35	30
Tax Fees	—	—
Other Fees	—	—
Total	**1,423**	**492**

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that E&Y provides, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

"Tax Fees" are the aggregate fees billed for professional services rendered by E&Y for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by E&Y.

There were no "Tax Fees" or "Other Fees" billed or paid during 2019 or 2020.

Audit and Non-Audit Services Pre-Approval Policy

The audit committee has responsibility for appointing, setting compensation of and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the audit committee has adopted a policy governing the pre-approval of all audit and permitted non-audit services performed by our independent registered public accounting firm to ensure that the provision of such services does not impair the independent registered public accounting firm's independence from us and our management. Unless a type of service to be provided by our independent registered public accounting firm has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Pursuant to its pre-approval policy, the audit committee may delegate its authority to pre-approve services to the chairperson of the audit committee. The decisions of the chairperson to grant pre-approvals must be presented to the full audit committee at its next scheduled meeting. The audit committee may not delegate its responsibilities to pre-approve services to the management.

Item 16D.Exemptions from the Listing Standards for Audit Committees.

Not applicable.

Item 16E.Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

Item 16F.Change in Registrant's Certifying Accountant.

Not applicable.

Item 16G.Corporate Governance.

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

The following is a summary of the significant ways in which our corporate governance practices differ from those followed by U.S. companies listed on Nasdaq:

- ***Audit Committee***. As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.
- ***Quorum Requirements***. Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least 33$^{1}/_{3}$% of the outstanding shares of the company's voting stock. Consistent with

French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

Item 16H. Mine Safety Disclosure.

Not applicable.

PART III

Item 17. Financial Statements.

See pages F-1 through F-67 of this annual report.

Item 18. Financial Statements.

Not applicable.

Item 19.Exhibits.

Exhibit	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
1.2*	Articles of Association of GENFIT S.A. (English translation)				
2.2	Deposit Agreement	F-6	333-230265	4.2	03/14/19
2.3	Form of American Depositary Receipt	F-6	333-230265	4.3	03/14/19
2.4*	Description of Securities				
4.1†	Summary of 2016 BSAAR Plan	F-1	333-229907	10.2	02/27/19
4.2†	Summary of 2017 BSA Plan	F-1	333-229907	10.1	02/27/19
4.3†	Summary of 2019 BSA Plan	20-F	001-38844	4.3	05/27/2020
4.4†	Summary of 2016, 2017 and 2018 Free Shares (AGA) Plans	F-1	333-229907	10.4	02/27/19
4.5†	Summary of 2019 Free Shares (AGA) Plan	20-F	001-38844	4.5	05/27/2020
4.6†	Summary of 2016, 2017 and 2018 Share Option Plans	F-1	333-229907	10.3	02/27/19
4.7†	Summary of 2019 Share Option Plans	20-F	001-38844	4.7	05/27/2020
4.8*	Summary of 2020 Share Option Plans				
4.9	Summary of Lease Agreement (English translation)	F-1	333-229907	10.5	02/27/19
4.10#	Collaboration and License Agreement between the registrant and Terns Pharmaceuticals, Inc., dated June 24, 2019	20-F	001-38844	4.9	05/27/2020
8.1	Subsidiaries of GENFIT S.A.	F-1	333-229907	21.1	02/27/19
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
13.2**	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				

101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed herewith.
** Furnished herewith.
† Indicates a management contract or any compensatory plan, contract or arrangement.
Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

GENFIT S.A.

By: /s/ Pascal Prigent
Pascal Prigent
Chief Executive Officer

Date: April 23, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Genfit S.A.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Genfit S.A. (“the Group”) as of December 31, 2018, 2019 and 2020, the related consolidated statements of operations, other comprehensive loss, cash flows and changes in equity for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Group at December 31, 2018, 2019 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board.

Adoption of New Accounting Standard

As discussed in Note 4.7 to the consolidated financial statements, the Group changed its method of accounting for leases under IFRS 16 as of January 1, 2019.

Basis for Opinion

These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on the Group’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Group in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Group is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ ERNST & YOUNG et Autres
We have served as the Group’s auditors since 1999
Paris, France
April 23, 2021

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(amounts in thousands of euros)

* The Group applied IFRS 16 “Leases” from January 1, 2019 using the modified retrospective method, and therefore, the comparative information for 2018 has not been restated. The impact of this application is presented in note 4.7 Application of the new IFRS 16 standard.

ASSETS (in € thousands)	Notes	As of 2018/12/31 (*)	2019/12/31	2020/12/31
Current assets				
Cash and cash equivalents	6.	207,240	276,748	171,029
Current trade and others receivables	9.	8,794	12,033	11,919
Other current assets	11.	2,078	1,968	1,765
Inventories	6.9.	4	4	4
Total - Current assets		218,116	290,753	184,717
Non-current assets				
Intangible assets	7.	796	920	791
Property, plant and equipment	8.	7,764	16,453	11,648
Other non-current financial assets	10.	1,313	1,727	1,458
Deferred tax assets	22.	—	—	—
Total - Non-current assets		11,362	19,099	13,897
Total - Assets		**229,478**	**309,853**	**198,614**

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	Notes	As of 2018/12/31	2019/12/31	2020/12/31
Current liabilities				
Current convertible loans	12.	1,312	1,312	1,313
Other current loans and borrowings	12.	1,848	3,226	3,035
Current trade and other payables	14.	35,974	36,917	25,564
Current deferred income and revenue	6.12.	1	139	124
Current provisions	15.	112	2,061	1,031
Total - Current liabilities		39,248	43,657	31,067
Non-current liabilities		—	—	—
Non-current convertible loans	12.	159,176	164,142	169,470
Other non-current loans and borrowings	12.	7,255	14,939	11,873
Non-current trade and other payables	14.	(0)	450	451
Non-current employee benefits	16.	1,085	1,408	1,148
Deferred tax liabilities	22.	1,773	1,193	767
Total - Non-current liabilities		169,291	182,132	183,709
Shareholders' equity		—	—	—
Share capital	17.	7,796	9,715	9,722
Share premium		251,554	377,821	379,057
Retained earnings (accumulated deficit)	—	(158,897)	(238,340)	(303,629)
Currency translation adjustment	6.17.	6	14	(92)
Net profit (loss)	-	(79,521)	(65,144)	(101,221)
Total shareholders' equity - Group share		20,939	84,065	(16,162)
Non-controlling interests	-	—	—	—
Total - Shareholders' equity		20,939	84,065	(16,162)
Total - Shareholders' equity & liabilities		**229,478**	**309,853**	**198,614**

CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands of euros, except per share data)

(in € thousands, except earnings per share data)	Notes	Year ended 2018/12/31 (*)	2019/12/31	2020/12/31
Revenues and other income				
Revenue	2.2.	69	30,839	765
Other income	18.	7,425	10,122	6,993
Revenues and other income		7,494	40,961	7,758
Operating expenses and other operating income (expenses)				
Research and development expenses	19.	(67,024)	(66,170)	(59,097)
General and administrative expenses	19.	(9,076)	(17,265)	(14,270)
Marketing and market access expenses	19.	(717)	(13,708)	(11,216)
Reorganization and restructuring expenses	19.	—	—	(5,308)
Other operating income (expenses)	19.	(162)	(1,649)	(764)
Operating income (loss)		(69,484)	(57,832)	(82,897)
Financial income	21.	728	5,221	6,544
Financial expenses	21.	(11,118)	(13,110)	(25,296)
Financial profit (loss)		(10,391)	(7,889)	(18,752)
Net profit (loss) before tax		(79,875)	(65,721)	(101,649)
Income tax benefit (expense)	22.	354	576	428
Net profit (loss)		**(79,521)**	**(65,144)**	**(101,221)**
Attributable to owners of the Company		(79,521)	(65,144)	(101,221)
Attributable to non-controlling interests		—	—	—
Basic and diluted earnings (loss) per share				
Basic and diluted earnings (loss) per share (€/share)	23.	(2.55)	(1.76)	(2.60)

* The Group applied IFRS16 ”Leases” from January 1, 2019 using the modified retrospective method and therefore, the comparative information for 2018 has not been restated . The impact of this application is presented in note 4.7

CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE LOSS

(amounts in thousands of euros)

(in € thousands)	Notes	Year ended 2018/12/31 (*)	2019/12/31	2020/12/31
Net profit (loss)		**(79,521)**	**(65,144)**	**(101,221)**
Actuarial gains and losses net of tax	16.	(31)	(168)	196
Other comprehensive income (loss) that will never be reclassified to profit or loss		(31)	(168)	196
Exchange differences on translation of foreign operations		14	8	(106)
Other comprehensive income (loss) that are or may be reclassified to profit or loss		14	8	(106)
Total other comprehensive income (loss)		**(79,537)**	**(65,304)**	**(101,131)**
Attributable to owners of the Company		(79,537)	(65,304)	(101,131)
Attributable to non-controlling interests		—	—	—

* The Group applied IFRS16 ”leases” from January 1, 2019 using the modified retrospective method, and therefore, the comparative information for 2018 has not been restated. The impact of the application is presented in note 4.7

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands of euros)

(in € thousands)	Year ended 2018/12/31 (*)	Year ended 2019/12/31	Year ended 2020/12/31
Cash flows from operating activities			
+ Net profit (loss)	(79,521)	(65,144)	(101,221)
+ Non-controlling interests	—	—	—
Reconciliation of net loss to net cash used in operating activities			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets	1,819	3,263	3,559
+ Impairment and provision for litigation	(208)	357	3,015
+ Expenses related to share-based compensation	787	1,657	1,236
- Gain on disposal of property, plant and equipment	(2)	(19)	80
+ Net finance expenses (revenue)	10,971	11,437	10,335
+ Income tax expense (benefit)	(354)	(576)	(428)
+ Other non-cash items including Research Tax Credit litigation	0	1,702	(1,818)
Operating cash flows before change in working capital	(66,507)	(47,324)	(85,242)
Change in:			
Decrease (increase) in trade receivables and other assets	(724)	(1,640)	318
(Decrease) increase in trade payables and other liabilities	11,056	1,284	(11,447)
Change in working capital	10,332	(356)	(11,129)
Income tax paid	93	—	—
Net cash flows used in operating activities	**(56,081)**	**(47,680)**	**(96,371)**
Cash flows from investment activities			
- Acquisition of property, plant and equipment	(2,938)	(2,030)	(900)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	3	2,517	—
- Acquisition of financial instruments	(1,050)	(160)	(66)
Net cash flows provided by (used in) investment activities	**(3,986)**	**327**	**(966)**
Cash flows from financing activities			
+ Proceeds from issue of share capital (net)	—	126,486	7
+ Proceeds from subscription / exercise of share warrants	37	43	—
+ Proceeds from new loans and borrowings net of issue costs	1,800	—	—
- Repayments of loans and borrowings	(2,000)	(6)	207
- Payments of lease debts	—	(1,877)	(2,150)
- Financial interests paid (including finance lease)	(6,351)	(7,785)	(7,762)
+ Financial interests received	—	—	1,442
Net cash flows provided by (used in) financing activities	**(6,514)**	**116,860**	**(8,256)**
Increase (decrease) in cash and cash equivalents	**(66,580)**	**69,508**	**(105,593)**
Cash and cash equivalents at the beginning of the period	273,820	207,240	276,748
Effects of exchange rate changes on cash	—	—	(126)
Cash and cash equivalents at the end of the period	**207,240**	**276,748**	**171,029**

* The Group applied IFRS16 “leases” from January 1,2019 using the modified retrospective method, and therefore, the comparative information for 2018 has not been restated. The impact of the application is presented in note 4.7

Impairment and provision for litigation : please see note 8 “property, plant and equipment” and note 15 “provisions”.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Amounts in thousands of euros, except for number of shares)

(in € thousands)	Share capital		Share premium	Treasury shares	Retained earnings (accumulated deficit)	Currency translation adjustment	Net profit (loss)	Total shareholders' equity Group share	Non-controlling interests	Total shareholders' equity
	Number of shares	Share capital								
As of January 1, 2018	**31,166,437**	**7,792**	**251,932**	**(127)**	**(102,404)**	**(8)**	**(55,728)**	**101,457**	**—**	**101,457**
Net profit (loss)							(79,521)	(79,521)		(79,521)
Other comprehensive income (loss)					(31)	14		(17)		(17)
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**(31)**	**14**	**(79,521)**	**(79,537)**	**—**	**(79,537)**
Allocation of prior period profit (loss)					(55,728)		55,728	—		—
Capital increase	17,484	4	(1,201)		(4)			(1,201)		(1,201)
Equity component of OCEANE net of deferred taxes			—					—		—
Share-based compensation			787					787		787
Treasury shares				(603)				(603)		(603)
Other movements			37					37		37
As of December 31, 2018	**31,183,921**	**7,796**	**251,554**	**(730)**	**(158,167)**	**6**	**(79,521)**	**20,939**	**—**	**20,939**
Net profit (loss)							(65,144)	(65,144)		(65,144)
Other comprehensive income (loss)					(168)	8		(160)		(160)
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**(168)**	**8**	**(65,144)**	**(65,304)**	**—**	**(65,304)**
Allocation of prior period profit (loss)					(79,521)		79,521	—		—
Capital increase	7,674,696	1,919	124,567		(7)			126,479		126,479
Equity component of OCEANE net of deferred taxes			—					—		—
Share-based compensation			1,657					1,657		1,657
Treasury shares				252				252		252
Other movements			43					43		43
As of December 31, 2019	**38,858,617**	**9,715**	**377,821**	**(478)**	**(237,862)**	**14**	**(65,144)**	**84,065**	**—**	**84,065**
Net profit (loss)							(101,221)	(101,221)		(101,221)
Other comprehensive income (loss)					196	(106)		90		90
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**196**	**(106)**	**(101,221)**	**(101,131)**	**—**	**(101,131)**
Allocation of prior period profit (loss)					(65,144)		65,144	—		—
Capital increase	29,762	7	—		(7)			—		—
Equity component of OCEANE net of deferred taxes			—					—		—
Share-based compensation			1,236					1,236		1,236
Treasury shares				(333)				(333)		(333)
Other movements			—					—		—
As of December 31, 2020	**38,888,379**	**9,722**	**379,057**	**(811)**	**(302,818)**	**(92)**	**(101,221)**	**(16,162)**	**—**	**(16,162)**

* As a reminder, the expenses incurred in 2018 and 2019 in relation to the Initial Public Offering are deducted from the share issue premium.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands of euros, except for numbers of shares and per share amounts)

1. THE COMPANY

Founded in 1999 under the laws of France, GENFIT S.A. (the "Company") is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative drugs and diagnostic tools in therapeutic areas of high unmet need due in particular to the lack of effective treatments or diagnostic solutions and/or the increase in patients worldwide.

The Company focuses its research and development (R&D) efforts on the potential marketing of therapeutic and diagnostic solutions to combat certain metabolic, inflammatory, autoimmune and fibrotic diseases affecting in particular the liver (such as Primary Biliary Cholangitis or PBC) and more generally gastroenterological diseases. The head office address is : 885 Avenue Eugène Avinée – 59120 Loos FRANCE

The consolidated financial statements of the Company include the financial statements of GENFIT S.A. and those of its wholly-owned subsidiaries: GENFIT CORP (U.S. subsidiary) and GENFIT PHARMACEUTICALS SAS (French subsidiary) (together referred to in these notes to the consolidated financial statements as "GENFIT" or the "Group" or “we “ or “us”).

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD

2.1 Termination of RESOLVE IT and the development program of elafibranor in NASH

In May 2020, the Company announced the results from the interim analysis of the RESOLVE-IT Phase 3 trial in adult patients with NASH. Elafibranor did not meet the predefined primary efficacy endpoint of NASH resolution without worsening of fibrosis, nor the secondary endpoints in the ITT population of 1,070 patients.

For the primary efficacy endpoint, the response rate in the 717 patients enrolled on the study drug was 19.2% for patients who received elafibranor 120mg compared to 14.7% for patients in the placebo arm, which was not statistically significant (N.S.). On the fibrosis key secondary endpoint, 24.5% of patients who received elafibranor 120mg achieved fibrosis improvement of at least one stage compared to 22.4% in the placebo arm (N.S.).

While the topline results do not support an application for accelerated approval of elafibranor by the FDA under Subpart H or conditional approval by the European Medicines Agency (“EMA”), the Company announced, also in May 2020, its intention to review in detail the full dataset and conduct additional analyses in order to understand why the placebo response rate was higher than what was expected before making a decision regarding continuation of the RESOLVE-IT trial.

On July 22, 2020, following the detailed review of the full RESOLVE-IT interim efficacy dataset, the Company determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the United States and Europe. The Company made an informed decision to prematurely terminate the study due to lack of efficacy but not due to safety concerns and announced that it would engage with the RESOLVE-IT investigators to expedite the trial termination process.

Following this decision, some of the studies that had been put on hold since the inception of the COVID-19 pandemic have not resumed. These decisions are unrelated to the COVID-19 pandemic nor to any concern with the safety of the Company’s drug candidate.

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD (Continued)

More specifically, the Phase 1 trials of the development program of elafibranor in NASH have been terminated early as sufficient data was available for the research goals, the only exception being the bioequivalence section of the bioequivalence and food interaction study, which has continued.

The Phase 2 trials of this program have also been terminated early, including the PK/PD trial in pediatric NASH and the hepatic lipid composition trial.

As such, the termination process of the RESOLVE-IT study, and more broadly, the termination of the development program of elafibranor in NASH, as analyzed under IAS37 and detailed hereafter, have had very significant impacts on the results of the 2020 period and will continue to impact those of the 2021 period (contracts). Besides, the termination of this development program has led the company to define a new strategy in September 2020 and to implement a series of financial measures, most significant of which are reduction in force plan, rationalization of building occupancy and renegotiation of the Company's convertible bonds, which are discussed below.

Impact on subcontracting costs

The termination of the development program of elafibranor in NASH and the closing of the RESOLVE-IT study in particular involve external costs notably due to regulatory activities, expenses related to final patient visits, site closures, clinical data recording, finalizing the Clinical Study Report, updating the Trial Master File, and invoking a supply contract termination clause, etc.

Overall, the amount of contracting costs recognized in 2020 for the termination is €9.7 million, with a further €8 to 10 million estimated to be recognized in 2021.

The Company has completed an analysis of these costs to be incurred in 2021 (see estimate above) under IAS 37 and reached the following conclusion:

- If the RESOLVE-IT study had not been initiated, Genfit would have needed to complete similar work (preparation of a drug safety file for elafibranor) to the work that will be completed in 2021 as part of the closing of the RESOLVE-IT study and bear the related costs for the needs of elafibranor in the PBC project (ELATIVE).
- Therefore, and after detailed review, these costs can be tied to elafibranor in the PBC project, which, insofar as Genfit intends to complete it, may not be designated as onerous contract under IAS 37, and therefore were not provisioned in the 2020 accounts.

In keeping with this analysis, administrative fees and fees for the destruction of drug tablets were provisioned for €378 (see Note 15 "Provisions") as they cannot be linked to the elafibranor program in PBC.

Impact on scientific equipment leased and owned

The Group has analyzed the impact of the closing of RESOLVE-IT and its decision to reorganize its activities on its scientific equipment. An inventory of the equipment that may be sold, kept as a spare, or disposed of, was completed.

Leased equipment
As the Group received the agreement of the lessor to purchase this equipment as well as an offer for its sale, an impairment loss of €503 has been recognized in 2020 in order to account for the estimated loss in comparison to the net book value of the rights of use of the asset.

Owned equipment

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD (Continued)

As the Group received an offer for the sale of some of this equipment, an impairment loss of €363 has been recognized in 2020 in order to account for the estimated loss in comparison to the net book value.

For the impact on the fixed assets, which included analyzing which equipment will continue to be used and which equipment will be disposed of or sold, we have identified an impairment loss of € 866 Please see Note.8 “Property, Plant and Equipment”.

Premises

Part of the premises that we rent is no longer in use (offices in Paris and some laboratories at our headquarters in Loos); As part of the review under IAS 36, and since neither use nor sublease was under consideration in the near future, an impairment loss of the right of use €1,275 has been recognized (see Note 8 “Property, Plant and Equipment”). This amount includes an impairment loss for fixtures, fittings and improvements of €93.

Event after the reporting period related to leased premises: on March 29, 2021, we signed a negotiated agreement for early termination of our commercial lease for part of the office space we lease in Paris. This agreement took effect on March 31, 2021, and in 2021, the lease liability will be adjusted.

Reorganization and reduction in force

At June 30, 2020 the Group had 203 employees on our sites based in Lille and Paris (France) and Cambridge (Massachusetts, USA). Following the disappointing results of the RESOLVE-IT trial, the Company has initiated a reorganization and reduction in force plan (*plan de sauvegarde de l’emploi* or “PSE”) in France, subject to the information and consultation procedure with the Economic and Social Committee of the Company, and reached an agreement with the representative Union, which was approved by the DIRECCTE in November 2020.

In total for the Group, this reorganization results in reducing the number of employees to a headcount of 130 employees as of December 31, 2020, with most departures taking place on December 28, 2020.

The costs related to this PSE are estimated at €1,850 and were the object of provisions (for support measures such as return-to-work bonuses, trainings, business start-up assistance and other such costs) and accruals (for notice periods, severance pay, and compensation for voluntary departure) in the 2020 accounts. They will be disbursed starting in January 2021 (see Notes 19.1 “Employee Expenses” and 15 “Provisions”).

2.2 Renegotiation of the convertible bond debt (OCEANEs)

OCEANEs buyback and amendments of terms

On November 23, 2020, GENFIT presented to all OCEANE bondholders its renegotiation offer involving two interdependent facets:

- A partial buyback of the outstanding OCEANEs for a maximum amount of 3,048,780 OCEANEs at €16.40 per bond; and
- An amendment of the terms of the remaining OCEANEs allowing to extend their maturity (by 3 years) and increase the conversion ratio (to 5.5 common shares per bond).

The objectives of this renegotiation were:

- Liquidity preservation for GENFIT’s operational functionality;
- Reduction of the nominal amount of financial debt to be redeemed;

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD (Continued)

- Deferment of the remaining debt maturity date in line with the next milestones in GENFIT's priority programs (Phase 3 development program of elafibranor in PBC and development of an IVD test in NASH based on NIS4 technology for diagnosis).

Within the context of this offer, GENFIT announced on December 7, 2020 that it had signed a bond repurchase agreements with OCEANEs holders to buyback a total of 2,895,260 OCEANEs (representing 47.6% of the outstanding OCEANEs and €85.7 million in nominal amount), for a total repurchase price of €47.48 million. The settlement of the OCEANEs partial buyback remained entirely contingent on the approval of the new terms of the OCEANEs by GENFIT shareholders and bondholders at meetings held in January 2021.

At December 31, 2020, GENFIT continues to categorize the debt component of the OCEANE under "Non-current loans and borrowings" corresponding to the contingent buyback commitment since GENFIT is under no obligation to payout the OCEANE within twelve months after the closing date.

The fees related to this renegotiation (financial advising, counsel fees, meeting costs, etc) are estimated at €2,400 of which €745 were incurred in 2020 and recognized in 2020. The other fees incurred in January 2021 will be recognized in the 2021 period.

Events after the reporting period, not affecting the financial statements closed at December 31, 2020

For the purposes of this part of the Note 2.2, amounts are provided in millions, or thousands of euros, as indicated, except for numbers of shares, per shares amounts and share capital.

Both the Shareholders' and Bondholders' Meetings took place on January 25, 2021, and approved the bond renegotiation offer described above.

Following the shareholders' and bondholders' decisions, GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. The settlement operations occurred on January 29, 2021. The repurchased OCEANEs were then cancelled by GENFIT.

For the non-cancelled, renegotiated OCEANEs (i.e. 3,185,821 remaining OCEANEs), the maturity was extended to October 16, 2025 and the conversion ratio changed from 1 OCEANE for 1 share to 1 OCEANE for 5.5 shares. The nominal amount and the payout value of the remaining OCEANEs remains unchanged at €29.60 per bond.
This renegotiation operation of the OCEANE will be recognized in the 2021 consolidated accounts, as will be the derecognition of the full initial OCEANE as of January 25, 2021 against a payment of €47.48 million and the issuance at its fair value of 3,185,821 new amended OCEANEs.

As the conversion option for the new OCEANEs (2025 maturity) fits the definition of an equity instrument under IAS 32 (*Financial Instruments: Presentation*), the components of this new OCEANE (debt vs. equity) will be recognized separately on January 25, 2021, in accordance with the accounting rules and methods presented in Note 4.15 "Loans and Borrowings". The fair value of a new amended OCEANE and its debt component have been estimated at January 25, 2021 respectively at €27.80 and €24.12. The difference between these two values results in the value of the conversion option that will be recognized in equity, i.e. €3.68 per OCEANE.

On the basis of fair values (of the OCEANE and its debt component) as explained above, a reduction of the amortized cost of the financial debt (OCEANE) of €94.8 million is expected at January 25, 2021 (removal of the initial debt of €171.6 million and recognition of the new debt of €76.8 million) in return for:

- An increase in equity of €11.7 million before deferred taxes (corresponding to the recognition of the value of the conversion option of the amended OCEANE);

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD (Continued)

- The payment of €47.5 million for the OCEANEs partial buyback; and
- The recognition of financial gain (buyback bonus) of €35.6 million before tax.

Following the implementation of the partial buyback operation and the approval of the amendment of the terms of the OCEANEs, 552,238 of the new OCEANEs were subject to a request for share conversion at the end of January 2021. On February 4, 2021, given these conversion requests, a capital increase of €759,327.25 has been recognized, corresponding to the creation of 3,037,309 new shares. This conversion of 552,238 new OCEANEs will result in a reduction in financial debt for the Group of €13.32 million.

Following the implementation of the partial buyback operation and the approval of the amendment of the terms of the OCEANEs, 483,330 of the new OCEANEs were subject to a request for share conversion at the end of February 2021. On March 12, 2021, given these conversion requests, a capital increase of €664,578.75 has been recognized, corresponding to the creation of 2,658,312 new shares. This conversion of 483,330 new OCEANEs will result in a reduction in financial debt for the Group of €11.66 million.

Following the implementation of the partial buyback operation and the approval of the amendment of the terms of the OCEANEs, 216,591 of the new OCEANEs were subject to a request for share conversion at the end of March 2021. On April 13, 2021, given these conversion requests, a capital increase of €297,812.50 has been recognized, corresponding to the creation of 1,191,250 new shares. This conversion of 216,591 new OCEANEs will result in a reduction in financial debt for the Group of €5.22 million.

2.3 Signature of a second license agreement with Labcorp in September 2020

In September 2020, the Company has announced a new exclusive license agreement with Labcorp to allow them to develop and commercialize an LDT (Laboratory Diagnostic Test) powered by NIS4™ technology for use in routine clinical diagnostic testing in the United States and Canada.

The main provisions of the contract include a transfer of technology and a right to use of its intellectual property.
Within the scope of the contract, the Company has received or may receive:

- An initial payment at the first anniversary date of the contract;
- Payments depending on the achievement of certain milestones; and
- Royalties on the sales.

2.4 COVID-19

Major events in the period

A new coronavirus strain, COVID-19, was identified in Wuhan, China in December 2019. Since then, the COVID-19 coronavirus has spread to several countries, including countries where the Company is headquartered, countries in which the Company has clinical trials in progress, countries where it plans to conduct clinical trials and countries in which major subcontractors for carrying out its clinical trials and the production units of the active ingredient suppliers and therapeutic units of elafibranor, its most advanced drug candidate, are located.

2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE PERIOD (Continued)

The most significant impact of this unprecedented spread of COVID-19 has affected the Phase 3 clinical trial in PBC (ELATIVE™) and the deployment of the NIS4™ technology in NASH diagnostics:

- Delay in launching Phase 3 in PBC, with the first patient recruitment in late 2020 instead of early 2020;
- Likely impact on the recruitment speed for this Phase 3 trial, since a reinforced protocol has been established in order to protect patients and healthcare professionals;
- Likely impact on the deployment speed of NIS4™ technology by our partner Labcorp/Covance, in the field of clinical research due to the potential delays in the relevant clinical trials.

Even though the COVID-19 pandemic has evolved rapidly, the plans of the Company were adjusted accordingly and the Company did not experience supply disruptions for its current or upcoming clinical trials.

All support activities related to the continuation of current studies or the inception of the planned new studies have been maintained in order to minimize potential delays when the COVID-19 pandemic crisis subsides.

2.5 Phase 3 trial evaluating elafibranor in PBC

In September 2020, the Company announced the completion of the first patient first visit in the ELATIVE Phase 3 trial in patients with PBC. Appropriate measures have been implemented, including virtual appointments, biological evaluations performed by local laboratories and delivery of the drug candidate to the patients' home, to ensure the safety of participants in the study. As of the date of the approval of the financials statements , enrolment is continuing, and new clinical research centers have been opened. We estimate that the recruitment period will span over 18 months instead of the 12 months that were expected before the COVID-19 pandemic.

3. BASIS OF PRESENTATION

The Consolidated Financial Statements of GENFIT have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"), and in accordance with IFRS as adopted by the European Union at December 31, 2020. The comparative information presented reflect the year ended December 31, 2019 and the year ended December 31, 2020.

The consolidated financial statements have been prepared using the historical cost measurement basis except for certain assets and liabilities that are measured at fair value in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality and aggregation

These consolidated financial statements for the year ended December 31, 2020 were prepared under the responsibility of the Board of Directors that approved such statements on April 1, 2021.

The term IFRS includes International Financial Reporting Standards ("IFRS"), International Accounting Standards (the "IAS"), as well as the Interpretations issued by the Standards Interpretation Committee (the "SIC"), and the International Financial Reporting Interpretations Committee ("IFRIC").

The principal accounting methods used to prepare the Consolidated Financial Statements are described below.

All financial information (unless indicated otherwise) is presented in thousands of euros (€).

3. BASIS OF PRESENTATION (Continued)

3.1. Changes in accounting policies and new standards or amendments

The Group adopted IFRS 16 Leases on January 1, 2019.

With the exception of those mentioned below, the accounting policies applicable for the present consolidated annual financial statements are the same as those applied to the last consolidated annual financial statements.

The following new standards are applicable from January 1, 2020, but do not have any material effect on the Group's financial statements for the year ended December 31, 2020.

- Updating a Reference to the Conceptual Framework (Amendments to IFRS 3),,
- Amendment to IFRS 3: Definition of a Business,
- Amendment to IAS 1 and IAS 8: Definition of the term "material",
- Amendment to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark reform– Phase 1

It should also be noted that the amendment to IFRS 16 related to rent concessions is not applicable, as no rent concession nor free rent has been requested by GENFIT for its lease agreements.

It must be noted that, following the release of the final decision by IFRS IC on December 16, 2019 related to the duration of lease agreements and its relation with the depreciation period for fixtures, fittings and improvements, the Group conducted an impact analysis regarding the implementation of this decision. This analysis mainly focused on the identification of possibly affected agreements, the collection of relevant information, notably regarding existing fixtures, fittings and improvements, and the determination of estimates to define the applicable duration, then the lease duration.

The IFRS IC decision was therefore applied, the analysis that was conducted concluding that there was no impact, and, as such, no significant consequences on the Group's accounts.

3.2. Standards, interpretations and amendments issued but not yet effective

The Group has not identified any standards or amendments issued and in force and anticipated as of January 1, 2020 that may have a significant impact on the Group's consolidated financial statements, notably:

- Amendments to IAS 37 *Onerous contracts – Cost of fulfilling a contract* will become effective in 2022,
- Amendment to IAS 1 *Classification of Liabilities as Current or Non-current* will become effective in 2023,
- Amendment to IAS 1 *Disclosure of Accounting Policies* will become effective in 2023,
- Amendment to IAS 8 *Definition of Accounting Estimates* will become effective in 2023,
- Annual improvements,
- Amendments to IFRS 4 *Extension of the Temporary Exemption from Applying* IFRS 9 is effective in 2021
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 related to *Interest Rate Benchmark Reform (phase 2)* are effective in 2021

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

4.1. Use of estimates and judgments

In preparing these consolidated financial statements, management makes judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, incomes and expenses. Actual amounts may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

The estimates and underlying assumptions mainly relate to research tax credits (see Note 4.19.2, "Research tax credit", employee benefits (see Note 4.18, "Employee benefits"), leases (see Note 4.6 “Property, plant and equipment” and Note 4.7 “Leases”), share-based payments (see Note 20, "Share-based compensation"), accruals related to clinical trials (see Note 19, "Operating expenses", Note 2.1 “Termination of RESOLVE IT and the development program of elafibranor in NASH”) and convertible loans (see Note 12.1 "Breakdown of convertible loan").

When assessing going concern, the Group’s Board of Directors considers mainly the following factors:

The liquidity available at the statement of financial position date, the cash spend projections for next 12-month period as from the date of the financial statements are issued and the availability of other funding.

4.2. Consolidation

The Group controls an entity when it is exposed to variable returns from its involvement with the entity, and it has the ability to affect those returns through its power over the entity.

The Group controls all the entities included in the scope of consolidation.

4.3. Foreign currency

4.3.1. Foreign currency transactions

Transactions in foreign currencies are translated into the respective functional currencies of the entities of the Group at the exchange rates applicable at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the reporting date.

The resulting exchange gains or losses are recognized in the statements of operations.

4.3.2. Translation of foreign subsidiary financial statements

The assets and liabilities of foreign operations having a functional currency different from the euro are translated into euros at the closing exchange rate. The income and expenses of foreign operations are translated into euros at the exchange rates effective at the transaction dates or using the average exchange rate for the reporting period unless this method cannot be applied due to significant exchange rate fluctuations.

Gains and losses arising from foreign operations are recognized in the statement of other comprehensive loss. When a foreign operation is partly or fully divested, the associated share of gains and losses recognized in the currency translation reserve is transferred to the statements of operations.

The Group’s presentation currency is the euro, which is also the functional currency of GENFIT S.A. The functional currency of GENFIT CORP is the U.S. dollar. The applicable exchange rates used to translate the financial statements of this entity for each of the periods are as follows:

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

	As of		
Ratio : 1 US dollars (USD) = x euros (EUR)	**2018/12/31**	**2019/12/31**	**2020/12/31**
Exchange rate at period end	0.87336	0.89015	0.81493
Average exchange rate for the period	0.84758	0.89341	0.87755

4.4 Revenues from ongoing activities under client agreements

The Group's accounting policies associated with revenue are as follows:

4.4.1. IFRS 15

Under IFRS 15, revenue is recognized when the Company fulfills a performance obligation by providing separate goods or services to a customer, i.e., when the customer obtains control of those goods or services. An asset is transferred when the customer obtains control of that asset or service.

Under this standard, each contract must be analyzed, on a case-by-case basis, in order to verify whether it contains performance obligations towards third parties, and, if applicable, to identify their nature in order to determine the appropriate accounting of amounts that the Company has received or is entitled to receive from third parties, for example:

- The transfer of control over the intellectual property, via a license granted by the Company, as it exists at the time of the sale, the date of which will determine that of the revenue recognition;
- If the license is considered as a right of access to the intellectual property of the Company over the life of the license, the revenue would be recognized over this lifetime;
- The supply of products whose revenues would be recognized at the time of transfer of control of the delivered products,
- Potential revenue from milestones, or from royalties or royalties based on sales, would not be recognized until the achievement of the milestone or completion of the sale.

The Group signed an agreement with Terns Pharmaceuticals on June 24, 2019. The Group's accounting policies associated with this agreement are as follows:

4.4.2 Application to the Terns Pharmaceuticals license agreement

The Company identified three performance obligations under the license agreement with Terns:

- An exclusive license, with the right to sub-license, to develop, manufacture, distribute and promote elafibranor in NASH and PBC in Greater China;
- A transfer to Terns Pharmaceuticals of the Company's Licensed Know-How and data regarding elafibranor and related support until the Marketing Authorization Application by Terns Pharmaceuticals; and
- Supply by the Company to Terns Pharmaceuticals of drug product to carry out its clinical trials in Greater China. The supply of drug product following the market authorization would be subject to a separate agreement if applicable.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Under the terms of the licensing agreement, the Company has received or could potentially receive:

- A $35 million non-refundable Upfront Payment payable within 10 business days from June 24, 2019 upon the transfer of the existing Company's Licensed Know-How. This Upfront Payment was received on July 3, 2019;
- Development Milestone Payments upon the achievement of the development milestones for the licensed product;
- Commercial Milestone Payments upon the achievement of commercial milestones depending on reaching certain aggregate thresholds;
- Mid-teen percentage Royalties based on sales by Terns Pharmaceuticals in Greater China; and
- Compensation for the supply of drug product for the clinical trials on a cost-plus basis.

The potential Development and Commercial Milestone payments may represent up to $193 million.

Under IFRS 15, the allocation and recognition of revenue was determined as follows based on the fair value of each of the performance obligations:

- The $35 million upfront payment was allocated to the license and the transfer of the existing know-how and related support to Terns Pharmaceuticals based on an estimate of the latter measured as the maximum estimated value to be incurred by the Company's employees and management for the support given to Terns Pharmaceuticals. On this basis, $34.9 million was recognized as revenue in 2019 and $0.1 million was deferred to future periods. No such revenue was recognized in 2020.
- Development and Commercial Milestones Payments whose payment depends on the achievement of certain scientific, regulatory or commercial objectives, as provided in the contract, are variable compensation that will be recognized as revenue when the milestones are met. No amounts were recognized in 2019 and 2020.
- Royalties on commercial sales by Terns Pharmaceuticals will be recognized as revenue pursuant to information given to the Company by Terns Pharmaceuticals, under the terms and timeframes set out in the agreement. No amounts were recognized in 2019 and 2020.
- Revenue on Supply for drug product will be recognized based on the delivery of drug product to Terns Pharmaceuticals. No amounts were recognized in 2019 and revenue in 2020 is immaterial.

As part of this agreement, Genfit and Terns Pharmaceuticals will also undertake joint research and development projects in liver disease, including the development of elafibranor in combination with Terns Pharmaceuticals' proprietary compounds. This collaboration agreement is only potential at the date of signing the license agreement and does not yet constitute a reciprocal commitment at December 31, 2020. It therefore has no accounting impact at this time.

This contract contains several delivery obligations. As a result, the Company has ensured, as required by IFRS 15, that the revenue allocation of the transaction corresponds to the fair value of each obligation.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

4.5. Intangible assets

Intangible assets mainly consist of software and operating licenses acquired by the Group. They are recognized at cost less accumulated amortization and impairment. Amortization expense is recorded on a straight-line basis over the estimated useful lives of the intangible assets. The estimated useful lives of both software and license agreements are between 1 and 8 years.

4.6. Property, plant and equipment

Property, plant and equipment are initially recognized at cost. Cost includes expenditures that are directly attributable to the acquisition of the asset. Routine maintenance costs are expensed as incurred.

Subsequently, depreciation expense is recognized on a straight-line basis over the estimated useful lives of the assets. If components of property, plant and equipment have different useful lives, they are accounted for separately. Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted, if appropriate.

Estimated useful lives are as follows:

Building on non-freehold land	10 years
Fittings and fixtures	Between 9 and 25 years
Scientific equipment	Between 2 and 12 years
Computer equipment	Between 2 and 5 years
Furniture	Between 4 and 10 years
Vehicles	Between 4 and 6 years

Any gain or loss on disposal of an item of property, plant and equipment is determined by comparing the proceeds from disposal with the carrying amount of the item. The net amount is recognized in the consolidated statements of operations under the line item "Other operating income (expenses)."

4.7. Leases

IFRS 16 introduces for the lessee a single model of accounting on the balance sheet for leases. The lessee recognizes a "right of use" asset which represents its right to use the underlying asset, and a lease liability for its obligation to pay the rent.

The Group recognizes a "right of use" asset and a lease liability at the start of the lease term. The "right of use" asset is initially measured at cost and then at cost less any amortization and accumulated impairment losses. The amount can be adjusted based on certain revaluations of the lease liability.

The lease liability is initially measured at the discounted value of the rents owed and not yet paid at the start date of the contract. The discount rate used is the implicit interest rate of the contract or, if it cannot be easily determined, the Company’s incremental borrowing rate. The Group generally uses the latter as the discount rate.

The lease liability is then adjusted by the interest expense minus the amounts of rent paid. It is revalued in the event of a change in future rents following a change in the index or rate, a new estimate of the amount to be paid under a residual value guarantee or, where applicable, a revaluation of the exercise of an option to purchase or to extend, or the non-exercise of an option to terminate (which then becomes reasonably certain).

The Group has exercised its judgment in determining the term of the lease agreements that provide for extension options. The fact that the Group has determined that it is reasonably certain to exercise such options has an impact on the lease term used

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

and has a significant impact on the amount of lease debt and the "right of use" asset in the accounts. The amount of short term or low value leases which are not included in the IFRS 16 model is not material .

4.8. Impairment of tangible assets, intangible assets and goodwill

The Company does not have any goodwill.

If indicators of impairment are identified, amortizable intangible assets and depreciable tangible assets are subject to an impairment test under the provisions of IAS 36, *Impairment of Assets*.

The Group has considered that the discontinued use of some equipment following the termination of RESOLVE-IT as well as the decision to no longer use part of the leased premises were indicative of an impairment loss requiring the completion of an impairment test of property, plant and equipment or of the rights of use recognized in the statement of financial position for this equipment and lease agreements.

The recovery value of an asset is the higher value between the value in use and the fair value less costs of divestment. The value in use is evaluated in relation to the future forecasted cash flows, discounted at current interest rates, before tax, which reflects the current market appreciation of the time value of money and the risks specific to the asset. In the present case, the recovery value of the tested assets corresponds to their fair value less costs of divestments.

The impacts related to the impairment of tangible assets and rights of use related to equipment and premises that are no longer in use due to the discontinuation of the RESOLVE-IT study are recognized in the consolidated statement of operations under “Reorganization and restructuring costs”.

4.9. Financial instruments

IFRS 9 “Financial Instruments” takes into account the following three aspects of booking financial instruments:

- Classification and measurement;
- Impairment and;
- Hedge accounting.

Loans and borrowings are initially measured at fair value and subsequently recorded at amortized cost.

4.10. Inventories

The Company recognizes inventories of laboratory consumables in connection with its former co-research agreements.

These inventories are measured at the lower of cost and net realizable value. Cost is determined using the weighted average cost method.

4.11. Trade and other receivables

Trade and other receivables are recognized at fair value, which is the nominal value of invoices unless payment terms require a material adjustment for the time value discounting effect at market interest rates. Trade receivables are subsequently measured at amortized cost. Impairment losses on trade accounts receivable are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables .

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Receivables are classified as current assets, except for those with a maturity exceeding 12 months after the reporting date.

4.12. Other financial assets

Loans and receivables are financial assets with fixed or determinable payments that are not listed on an active market and are valued using the amortized cost method.

A gain or loss arising from a change in the fair value of a financial asset is recognized in other comprehensive income (loss) except for impairment losses and foreign exchange gains and losses, until the financial asset is derecognized. At that time the cumulative gain or loss previously recognized in other comprehensive income (loss) is reclassified from equity to profit or loss as a reclassification adjustment.

4.13. Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, bank accounts and term deposits, together with short-term deposits and highly liquid investments. They are readily convertible to a known amount of cash and thus present a negligible risk of a change in value. They also include Undertakings for Collective Investments in Transferable Securities (UCITs) whose characteristics allow them to be classified as cash and cash equivalents.

Initially recognized at their purchase cost at the transaction date, investments are subsequently measured at fair value. Changes in fair value are recognized in net financial income (expenses).

4.14. Equity

Share capital comprises ordinary shares and ordinary shares with double voting rights classified in equity. Costs directly attributable to the issue of ordinary shares or share options are recognized as a reduction in the share premium.

The liquidity agreement consists of a share buyback program contracted to an investment service provider. Purchases and sales of the Company's shares carried out under the contract are recognized directly in shareholders’ equity under treasury shares. See note 10 “Other financial income”.

4.15. Loans and borrowings

Financial liabilities are initially recognized at fair value, net of directly attributable transaction costs, and are subsequently measured at amortized cost using the effective interest rate method.

The Group derecognizes financial liabilities when the contractual obligations are discharged, cancelled or expire.

The bonds convertible or exchangeable into new or existing shares (OCEANE—see Section 12.1, "Breakdown of convertible loan") are recognized as follows: in accordance with IAS 32, *Financial Instruments—Presentation* , if a financial instrument has different components and the characteristics indicate that some should be classified as liabilities and others as equity, the issuer must recognize the different components separately.

The liability component is measured, at the date of issuance, at its fair value on the basis of future contractual cash flows discounted at market rates (taking into consideration the issuer's credit risk) of a debt having similar characteristics but without the conversion option.

The value of the conversion option is measured by the difference between the bond's issue price and the fair value of the liability component. After deduction of the pro rata portion of expenses related to the transaction, this amount is recognized in the line item "Share premium" under shareholders' equity and is subject to a calculation of deferred tax according to IAS 12.28.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The liability component (after deduction of the pro rata portion of the transaction expenses attributed to the liability and the conversion option) is measured at amortized cost. A non-monetary interest expense, recorded in net loss is calculated using an effective interest rate to progressively bring the debt component up to the amount which will be repaid (or converted) at maturity. A deferred tax liability is calculated on the basis of this amount. The shareholders' equity component is not remeasured. See Note 2.2 “Renegotiation of the convertible bond debt (OCEANEs)” for the accounting to be applied in 2021 following the renegotiation.

4.16. Trade and other payables

Trade and other payables are initially recognized at the fair value of the amount due. This value is usually the nominal value, due to the relatively short period of time between the recognition of the instrument and its repayment.

4.17. Provisions

In accordance with IAS 37, *Provisions Contingent Liabilities and Contingent Assets*, provisions are recognized when the Group has a present obligation (legal, regulatory, contractual or constructive) as a result of a past event, for which it is probable that an outflow of resources will be required to settle the obligation, and of which the amount can be estimated reliably.

The amount recognized as a provision is the best estimate at the reporting date of the expenditure required to settle the present obligation.

Provisions are discounted when the time value effect is material.

A provision for reorganization is recognized when the Group has approved a formal and detailed plan for its reorganization and has either started to implement it or publicly disclosed it.

A provision for onerous contract is estimated at the actual value of the lowest expected cost of either the cancellation or the execution of the contract, the latter being established on the basis of the additional costs required to fulfill the obligations stipulated by the contract. Before a provision is established, the Group recognizes any impairment loss that occurred on the assets dedicated to this contract (see Note 2.1 “Termination of RESOLVE IT and the development program of elafibranor in NASH”).

4.18. Employee benefits

The Group's pension schemes and other post-employment benefits consist of defined benefit plans and defined contribution plans.

4.18.1. Defined benefit plans

Defined benefit plans relate to French retirement benefit plans under which the Group is committed to guaranteeing a specific amount or level of contractually defined benefits. The obligation arising from these plans is measured on an actuarial basis using the projected unit credit method. The method consists of measuring the obligation based on a projected end-of-career salary and vested rights at the measurement date, according to the provisions of the collective bargaining agreement, corporate agreements and applicable law.

Actuarial assumptions are used to determine the benefit obligations. The amount of future payments is determined on the basis of demographic and financial assumptions such as mortality, staff turnover, pay increases and age at retirement, and then discounted to their present value. The discount rate used is the yield at the reporting date on AA credit-rated bonds with maturity dates that approximate the expected payments for the Group's obligations.

Re-measurements of the net defined benefit liability which comprise actuarial gains and losses are recognized in the statements of other comprehensive loss.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Group determines the net interest expense on the net defined benefit liability for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period to the then-net defined benefit liability, taking into account any changes in the net defined benefit liability during the period as a result of contributions and benefit payments.

4.18.2. Defined contribution plans

Under defined contribution plans, the management of plans is performed by an external organization, to which the Group pays regular contributions. Payments made by the Group in respect of these plans are recognized as an expense for the period in the statements of operations.

4.18.3. Short-term employee benefits

A liability is recognized for the amount expected to be paid under short-term cash bonus or profit-sharing plans if the Group has a present legal or constructive obligation to pay the amount as a result of past service provided by the employee, and the obligation can be estimated reliably.

4.19. Other income

4.19.1. Government grants

The Group received until 2016 various forms of government grants. This government aid is provided for and managed by French state-owned entities, and specifically "BPI France" (" *Banque Publique d'Investissement* "), formerly named "OSEO Innovation".

Subsidies received are non-refundable. Conditional advances received are interest-free or are subject to low interest rates depending on contractual provisions.

Conditional advances related to research programs

Conditional advances that are interest-free or subject to low interest rates are intended to finance research program’s needs.

In accordance with IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance* , the advantage resulting from interest-free or low interest rates as compared to a market interest rate is considered and accounted for as a government grant. A financial liability is recognized for proceeds received from the advance less the grant, and interest expense is subsequently recorded under the effective interest rate method using a market interest rate.

The grant portion of conditional advances is treated as a grant related to income.

For advances granted by BPI France, repayment is required in the event of commercial success. In addition, if the Group decides to stop the research program, the conditional advance may be required to be repaid. If a program is unsuccessful, a pre-determined amount may be repayable. The remaining amount, if any, is then considered as a grant and written off in the line item "Other income" in the statements of operations.

4.19.2. Research tax credit

The Research Tax Credit (" *Crédit d'Impôt Recherche* ", or "CIR") is granted to entities by the French tax authorities in order to encourage them to conduct technical and scientific research. Entities that demonstrate that their research expenditures meet the required CIR criteria receive a tax credit that may be used for the payment of their income tax due for the fiscal year in which the expenditures were incurred, as well as in the next three years. If taxes due are not sufficient to cover the full amount of tax credit at the end of the three-year period, the difference is paid in cash to the entity by the tax authorities. If a company meets certain criteria in terms of sales, headcount or assets to be considered a small/mid-size company, immediate payment of the Research Tax Credit can be requested. The Group meets such criteria.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Group applies for CIR for research expenditures incurred in each fiscal year and recognizes the amount claimed in the line item "Other income" in the statements of operations in the same fiscal year. In the notes to the financial statements, the amount claimed is recognized under the heading "Research tax credit" (see Note 9, "Trade and other receivables" and Note 18, "Revenue and other income").

4.20. Research and development expenses

Research expenses are recorded in the financial statements as expenses (see Note 19, "Operating expense").

In accordance with IAS 38, *Intangible Assets* , development expenses are recognized as intangible assets only if all the following criteria are met:

- Technical feasibility necessary for the completion of the development project;
- Intention on the Group's part to complete the project and to utilize it;
- Capacity to utilize the intangible asset;
- Proof of the probability of future economic benefits associated with the asset;
- Availability of the technical, financial, and other resources for completing the project; and
- Reliable evaluation of the expenses attributed to the intangible asset during its development.

As of the date of these financial statements none of these criteria have been met.

4.21. Classification of operating expenses

Research and development expenses include:

- employee-related costs;
- costs related to external employees seconded to the Company (such as clinical development, biometrics and IT…);
- lab supplies and facility costs;
- fees paid to scientific advisers and contracted research and development activities conducted by third parties;
- intellectual property fees corresponding to the filing of the Group's patents and,
- provision and reversals of provisions in relation to the Research Tax Credit dispute.

Contracted research and development activities conducted by third parties include services subcontracted to research partners for technical and/or regulatory reasons. In particular, this includes the production of active ingredients and therapeutic units, all or a part of clinical trials and pre-clinical trials that are necessary to the development of GENFIT's drug candidates and biomarker candidates.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

General and administrative expenses include:

- employee-related costs for executive, business development, intellectual property, finance, legal and human resources and communications functions;
- facility-related costs;
- marketing, legal, audit and accounting fees;
- press relations and communications firm fees;
- the cost of external employees seconded to the Company (such as security, reception, and accounting..);
- other service costs (recruitment, etc.);
- intellectual property fees corresponding to the maintenance of the Group's patents.

Marketing and market access expenses include:

- employee-related costs for marketing and business development functions;
- marketing, and market access firm fees;

Extraordinary reorganization and restructuring expenses include:

- the accruals and provisions recognized within the scope of the reduction in force plan;
- the extraordinary amortization, loss of value and impairment of fixed assets recognized within the scope of the reorganization of GENFIT;
- the impairment of the right of use of the leased equipment and premises,
- the portion of the OCEANE renegotiation expenses recognized in 2020;
- the provision recognized for some of the costs of the closing process for the RESOLVE-IT study, which, after detailed analysis, do not have any future economic advantage for the PBC program.

4.22. Share-based compensation

The fair value of equity-settled share-based compensation granted to employees, officers, board members and consultants as determined on the grant date is recognized as a compensation expense with a corresponding increase in equity, over the vesting period. The amount recognized as an expense is adjusted to reflect the actual number of awards for which the related service and non-market performance conditions are expected to be met.

The fair values of equity-settled share-based compensation granted to employees are measured using the Black-Scholes model with respect to the share warrants (BSA) and redeemable share warrants (BSAAR) and using the Monte Carlo model for the stock options (SO) and free shares (AGA). Measurement inputs include share price on the measurement date, the exercise price of the instrument, expected volatility, expected maturity of the instruments, expected dividends, and the risk-free interest rate (based on government bonds). With respect to the redeemable share warrants, service and non-market performance conditions attached to the transactions are not taken into consideration in determining fair value but are taken into consideration related to recognition of expense. Regarding the stock options and free shares, market conditions are taken into account in the determination of the fair value of the plans award. For share-based compensation awards with non-vesting conditions, the grant date fair value of

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the share-based compensation is measured to reflect such conditions and there is no adjustment for differences between expected and actual outcomes.

GENFIT may also grant equity-settled share-based compensation in exchange for services to consultants who are not considered employees. In such cases, the value of the services is measured when they are rendered by the consultants and the share-based compensation exchanged for the services is measured at an equal amount. If the value of the services cannot be measured reliably, then such value is measured with reference to the fair value of the equity instruments granted.

Share-based compensation granted to consultants consists of share warrants, some of which may be redeemed at GENFIT's discretion.

Share-based compensation granted to employees consists of redeemable share warrants, stock options and free shares.

4.23. Income tax

Income tax expense (or benefit) comprises current tax expense (or benefit) and deferred tax expense (or benefit), as applicable.

Deferred taxes are recognized for all the temporary differences arising from the difference between the tax basis and the accounting basis of assets and liabilities.

Deferred tax assets are recognized for unused tax losses, unused tax credits and temporary deductible differences to the extent that:

- it is probable that future taxable profit will be available against which they can be used; or
- if there are deferred tax liabilities for the same entity in the same tax jurisdiction on which they can be applied.

4.24. Earnings (loss) per share

Basic earnings (loss) per share are calculated by dividing profit or loss attributable to the Company's ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per share are calculated by adjusting profit attributable to ordinary shareholders and the average number of ordinary shares outstanding weighted for the effects of all potentially dilutive instruments (share warrants, redeemable share warrants, free shares, stock options and bonds convertible into new and/or existing shares).

4.25. Operating segments

The Board of Directors and Chief Executive Officer are the chief operating decision makers.

The Board of Directors and the Chief Executive Officer oversee the operations and manage the business as one segment with a single activity; namely, the research and development of innovative medicines and diagnostic solutions, the marketing of which depends on the success of the clinical development phase.

5. FINANCIAL RISKS MANAGEMENT

The Group may be exposed to the following risks arising from financial instruments: foreign exchange risk, interest rate risk, liquidity risk and credit risk.

5.1. Foreign exchange risk

The nature and exposure of the Group to currency risk has evolved. It had been anticipated that a growing portion of its operations would be denominated in US dollars, and the Group decided not to convert into euros the US dollar denominated cash it raised in its March 2019 IPO. The Company expected to use cash held in US dollars to meet expenses denominated in this currency over the next few years.

Because of the decision to initiate the termination of the RESOLVE-IT trial (see note 2“Major Events in the Period and Events after the Reporting Period”), the Group has started to implement a cost savings plan in the second half of 2020 and will manage a smaller number of transactions denominated in foreign currencies or indirectly exposed to currency risk.

The increase in the overall exposure of the Company to this risk will depend, in particular, on:

- the currencies in which the Group receives its revenues;
- the currencies chosen when agreements are entered into, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on drug or biomarker candidates;
- the ability, for its co-contracting parties to indirectly transfer foreign exchange risk to the Company;
- the Group’s foreign exchange risk policy; and
- the fluctuation of foreign currencies against the euro.

During 2020, the Company did not use any specific hedging arrangements in light of the Company’s decision to leave a significant part of its cash and cash equivalents in US dollars.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

The following table shows the sensitivity of the Group's cash and cash equivalent and expenses in U.S. dollars to a variation of 10% of the U.S. dollar against the euro in 2018, 2019 and 2020:

Sensitivity of the Group's cash and cash equivalents to a variation of +/- 10% of the US dollar against the euro (in € thousands or in US dollar thousands, as applicable)	**As of**		
	2018/12/31	**2019/12/31**	**2020/12/31**
Cash and cash equivalents denominated in US dollars	1,188	153,438	111,221
Equivalent in euros, on the basis of the exchange rate described below	1,038	136,582	90,637
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	1,153	151,758	100,708
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	944	124,166	82,398

Sensitivity of the Group's expenses to a variation of +/- 10% of the US dollar against the euro (in € thousands or in US dollar thousands, as applicable)	**Year ended**		
	2018/12/31	**2019/12/31**	**2020/12/31**
Expenses denominated in US dollars	9,613	40,355	47,277
Equivalent in euros, on the basis of the exchange rate described below	8,396	35,922	38,528
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	9,328	39,914	42,808
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	7,632	32,657	35,025

2020/12/31 : Equivalent in euros, on the basis of a 1 euro = 1,2271 US dollar ratio
2019/12/31 : Equivalent in euros, on the basis of a 1 euro = 1,12341 US dollar ratio
2018/12/31 : Equivalent in euros, on the basis of a 1 euro = 1,145 US dollar ratio

Cash, cash equivalents and financial assets (in € thousands or in US dollar thousands, as applicable)	**As of**		
	2018/12/31	**2019/12/31**	**2020/12/31**
At origin, denominated in EUR			
Cash and cash equivalents	206,199	139,863	80,391
Current and non current financial assets	1,303	1,614	1,391
Total	**207,502**	**141,477**	**81,782**
At origin, denominated in USD			
Cash and cash equivalents	1,041	136,884	90,637
Current and non current financial assets	10	113	67
Total	**1,051**	**136,997**	**90,704**
Total, in EUR			
Cash and cash equivalents	207,240	276,748	171,029
Current and non current financial assets	1,313	1,727	1,458
Total	**208,553**	**278,474**	**172,486**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

5. FINANCIAL RISKS MANAGEMENT (Continued)

5.2. Interest rate risk

As of December 31, 2020, the Group was only liable for governmental advances or conditional advances with no interest or interest at a fixed rate, generally below market rate, and for fixed-rate bank loans (the only variable-rate loan was repaid in 2017).

As of December 31, 2018, 2019 and 2020, the Group's financial liabilities totaled €169,593, €183,619, and €185,691 respectively (net of the equity component of the convertible loan and debt issue costs). Current borrowings are at a fixed rate. The Group's exposure to interest rate risk through its financial assets is also insignificant due to low market rates and since these assets are mainly euro-denominated Undertakings for the Collective Investment of Transferable Securities (UCITs), medium-term negotiable notes or term deposits with progressive rates denominated in euros or US dollars..

5.3. Liquidity risk

The Group's loans and borrowings mainly consist of bonds convertible or exchangeable into new or existing shares (OCEANE), initially repayable for an nominal amount of €180 million on October 16, 2022 (see Note 12.1 “Breakdown of convertible loan”), government advances for research projects and bank loans. For conditional advances, reimbursement of the principal is subject to the commercial success of the related research project (see Note 12.2.1 “Refundable and conditional advances”).

The Company has conducted a specific review of its liquidity risk and considers that it is able to meet its future maturities. On December 31, 2018, 2019 and 2020, the Group had €208,553, €278,474, and €172,486 respectively in cash and cash equivalents and other financial assets. The Company does not believe it is exposed to short-term liquidity risk. The Company believes that the Group's cash and cash equivalents and current financial instruments are sufficient to ensure its financing, in light of its current projects and obligations and of the renegotiation, effective in 2021, of its obligations pertaining to the OCEANE debt, including the extension of the maturity date, for at least the next twelve months.

If the Group's funds are insufficient to cover any additional financing needs, the Group would require additional financing. The conditions and arrangements for any such new financing would depend, among other factors, on economic and market conditions that are beyond the Group's control.

5.4. Credit risk

Credit risk is the risk of financial loss if a customer or counterparty to a financial asset defaults on their contractual commitments. The Group is exposed to credit risk due to trade receivables and other financial assets.

The Group's policy is to manage this risk by transacting with third parties with good credit standards.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

6. CASH AND CASH EQUIVALENTS

The main components of cash equivalents were:

- UCITS and interest-bearing current accounts, available immediately;
- Term accounts, available within the contractual maturities or by the way of early exit with no penalty; and
- Negotiable medium-term notes, available with a quarterly maturity or by the way of early exit with no penalty.

These investments, summarized in the tables below, are short-term, highly liquid and subject to insignificant risk of changes in value.

Cash and cash equivalents	**As of**		
(in € thousands)	**2018/12/31**	**2019/12/31**	**2020/12/31**
Short-term deposits	201,522	263,147	166,034
Cash on hand and bank accounts	5,718	13,601	4,995
TOTAL	**207,240**	**276,748**	**171,029**

Short-term deposits	**As of**		
(in € thousands)	**2018/12/31**	**2019/12/31**	**2020/12/31**
UCITS	29,189	3,096	2,060
TERM ACCOUNTS	124,316	215,018	143,827
INTEREST-BEARING CURRENT ACCOUNT	48,017	45,033	20,147
TOTAL	**201,522**	**263,147**	**166,034**

(amounts in thousands of euros, except for numbers of shares and per share amount)

7. INTANGIBLE ASSETS

Intangible assets consist mainly of office and administrative software as well as scientific software purchased by the Group.

The following tables show the variations in intangible assets for the years ended December 31, 2018, 2019 and 2020:

Intangible assets—Variations (in € thousands)	As of 1/1/2018	Increase	Decrease	Translation adjustments	Reclassification	As of 2018/12/31
Gross						
Software	1,900	216	(67)	—	—	2,049
Patents	21	—	—	—	—	21
Other intangibles	—	313	—	—	—	313
TOTAL - Gross	**1,921**	**529**	**(67)**	**—**	**—**	**2,384**
Accumulated depreciation and impairment						
Software	(1,264)	(370)	67	—	—	(1,567)
Patents	(21)	—	—	—	—	(21)
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	**(1,285)**	**(370)**	**67**	**—**	**—**	**(1,588)**
TOTAL - Net	**636**	**159**	**—**	**—**	**—**	**796**

Intangible assets—Variations (in € thousands)	As of 1/1/2019	Increase	Decrease	Translation adjustments	Reclassification	As of 2019/12/31
Gross						
Software	2,049	340	(29)	—	378	2,739
Patents	21	70	—	—	—	91
Other intangibles	313	65	—	—	(378)	—
TOTAL—Gross	**2,384**	**475**	**(29)**	**—**	**—**	**2,830**
Accumulated depreciation and impairment						
Software	(1,567)	(350)	29	—	—	(1,888)
Patents	(21)	—	—	—	—	(21)
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	**(1,588)**	**(350)**	**29**	**—**	**—**	**(1,910)**
TOTAL - Net	**796**	**125**	**—**	**—**	**—**	**920**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

Intangible assets - Variations (in € thousands)	As of 1/1/2020	Increase	Decrease	Translation adjustments	Reclassification	As of 2020/12/31
Gross						
Software	2,739	231	(691)	—	(48)	2,231
Patents	91	—	—	—	—	91
Other intangibles	—	(24)	(25)	—	48	—
TOTAL - Gross	**2,830**	**207**	**(715)**	**—**	**—**	**2,322**
Accumulated depreciation and impairment						
Software	(1,888)	(309)	688	—	—	(1,510)
Patents	(21)	—	—	—	—	(21)
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	**(1,910)**	**(309)**	**688**	**—**	**—**	**(1,531)**
TOTAL - Net	**920**	**(102)**	**(27)**	**—**	**—**	**791**

(amounts in thousands of euros, except for numbers of shares and per share amounts)

8. PROPERTY, PLANT AND EQUIPMENT

The following tables show the variations in tangible assets for the years ended December 31, 2018, 2019 and 2020:

Property, plant and equipment - Variations (in € thousands)	As of 1/1/2018	Increase	Decrease	Translation adjustments	Reclassification	As of 2018/12/31
Gross						
Buildings on non-freehold land	11	—	—	—	1,447	1,458
Scientific equipment	9,576	1,484	(235)	—	54	10,879
Fittings	1,126	443	(43)	—	5	1,531
Vehicles	99	—	—	—	—	99
Computer equipment	1,954	200	(5)	—	(702)	1,446
Furniture	357	8	(4)	—	—	361
In progress	(0)	805	—	—	(804)	0
TOTAL - Gross	**13,123**	**2,940**	**(288)**	**—**	**—**	**15,774**
Accumulated depreciation and impairment						
Buildings on non-freehold land	(0)	(1)	—	—	—	(1)
Scientific equipment	(5,063)	(1,142)	218	—	—	(5,988)
Fittings	(722)	(91)	43	—	—	(769)
Vehicles	(24)	(21)	—	—	—	(45)
Computer equipment	(703)	(216)	4	—	—	(915)
Furniture	(285)	(11)	4	—	—	(292)
In progress	—	—	—	—	—	—
TOTAL - Depreciation and impairment	**(6,798)**	**(1,481)**	**270**	**—**	**—**	**(8,010)**
TOTAL - Net	**6,324**	**1,459**	**(18)**	**—**	**—**	**7,764**

Property, plant and equipment - Variations (in € thousands)	As of 1/1/2019	Increase	Decrease	Translation adjustments	Reclassification	As of 2019/12/31
Gross						
Buildings on non-freehold land	1,458	12,218	—	—	(1,447)	12,229
Scientific equipment	10,879	556	(120)	—	(54)	11,260
Fittings	1,531	66	—	—	(5)	1,592
Vehicles	99	—	—	—	—	99
Computer equipment	1,446	227	(15)	—	11	1,669
Furniture	361	31	(3)	—	—	389
In progress	0	241	(1,737)	—	1,496	—
TOTAL - Gross	**15,774**	**13,339**	**(1,875)**	**—**	**—**	**27,238**
Accumulated depreciation and impairment						
Buildings on non-freehold land	(1)	(1,215)	—	—	—	(1,216)
Scientific equipment	(5,988)	(1,303)	119	—	—	(7,172)
Fittings	(769)	(105)	—	—	—	(875)
Vehicles	(45)	(21)	—	—	—	(66)
Computer equipment	(915)	(252)	12	—	—	(1,155)
Furniture	(292)	(13)	3	—	—	(303)
In progress	—	—	—	—	—	—
TOTAL - Depreciation and impairment	**(8,010)**	**(2,909)**	**133**	**—**	**—**	**(10,785)**
TOTAL - Net	**7,764**	**10,429**	**(1,741)**	**—**	**—**	**16,453**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amount)

Property, plant and equipment - Variations (in € thousands)	As of 1/1/2020	Increase	Decrease	Translation adjustments	Reclassification	As of 2020/12/31
Gross						
Buildings on non-freehold land	12,229	—	—	—	(62)	12,167
Scientific equipment	11,260	450	(2,630)	—	—	9,080
Fittings	1,592	233	(113)	—	(10)	1,703
Vehicles	99	—	—	—	—	99
Computer equipment	1,669	69	(194)	—	(11)	1,534
Furniture	389	8	(68)	—	—	329
In progress	—	15	(17)	—	2	—
TOTAL - Gross	**27,238**	**775**	**(3,022)**	**—**	**(80)**	**24,911**
Accumulated depreciation						
Buildings on non-freehold land	(1,216)	(1,398)	10	—	—	(2,603)
Scientific equipment	(7,172)	(1,368)	2,588	0	—	(5,952)
Fittings	(875)	(218)	107	4	—	(982)
Vehicles	(66)	(20)	—	—	—	(85)
Computer equipment	(1,155)	(260)	193	4	—	(1,217)
Furniture	(303)	(15)	68	(1)	—	(251)
In progress	—	—	—	—	—	—
TOTAL - Depreciation	**(10,785)**	**(3,279)**	**2,967**	**7**	**—**	**(11,090)**
Impairment						
Buildings on non-freehold land	—	(1,182)	—	—	—	(1,182)
Scientific equipment	—	(866)	—	—	—	(866)
Fittings	—	(93)	—	—	—	(93)
Vehicles	—	—	—	—	—	—
Computer equipment	—	(27)	—	—	—	(27)
Furniture	—	(3)	—	—	—	(3)
In progress	—	—	—	—	—	—
TOTAL - Impairment	**—**	**(2,172)**	**—**	**—**	**—**	**(2,172)**
TOTAL - Net	**16,453**	**(4,676)**	**(56)**	**7**	**(80)**	**11,648**

Assets related to contracts that were classified as finance leases under IAS 17 are scientific equipment. These contracts are accounted for in the same manner under IFRS 16. Their net carrying value as of December 31, 2018, 2019 and 2020 amounted to €1,889, €1,413 and €873 respectively.

Impairment test of assets under IAS 36

Some equipment belonging to the Group and others under a leasing agreement will no longer be used following the reorganization of the group's activities and the termination of the RESOLVE-IT trial.

This indication of loss of value led the Group to conduct an impairment test over owned and leased equipment.

These impairment tests account for the value at which this equipment should be divested (on the basis of the agreement of the lessors for the early purchase of the equipment) and a purchase offer that should be fulfilled in the near term) in order to determine the recovery value.

The tests resulted in the recognition of an impairment of €990 (of which €363 related to owned equipment, €503 of leased equipment, €96 related to premises and €30 related to furniture and IT equipment).

8. PROPERTY, PLANT AND EQUIPMENT (Continued)

Parts of the leased premises (a portion of the office space in Paris and of the former laboratories at headquarters) will no longer be used. The vacant space is segmented and separate from the premises that will continue to be occupied. An impairment test of the rights of use of this space has also been performed.

At this stage, the recovery value has been estimated to be null considering that subleasing is prohibited for the office space in Paris and that the COVID-19 related health situation creates significant uncertainty on the potential to sublease the space in Loos. Subleasing is therefore not under consideration for the foreseeable future.

The test of the rights of use pertaining to these premises resulted in the recognition of an impairment of €1,182.

In accordance with IFRS 16, the Group has chosen not to present the right of use separately from other assets and has added them to the fixed assets of the same nature as the underlying leased assets.

Therefore, the rights of use and related amortization as of December 31, 2020 included in the table affect:

- The item “Buildings on non-freehold land”, for respectively €11,911 and €2,558,
- The item “Scientific equipment” for respectively €2,906 and €2,033.

Fixtures and fittings were also depreciated (see above).

Reminders

On January 1,2019, upon adoption of IFRS 16, the right of use asset and liability related to the existing headquarters were recognized for an amount of €7.8 million. In May 2019, the right of use asset and lease liability related to a new building were recognized for an amount of €2.2 million.

GENFIT CORP signed a new lease agreement as of July 1, 2019.

The right of use asset and depreciation as of December 31, 2019 in the table above are related to :

- The line item “Building on non freehold land”, of €11,974 and €1,196, respectively;
- The line item "Scientific equipment", at €4,346 and €2,933, respectively.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

8. PROPERTY, PLANT AND EQUIPMENT (Continued)

9. TRADE AND OTHER RECEIVABLES

Trade and other receivables consisted of the following:

Trade and other receivables - Total (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade receivables, net	25	207	793
Research tax credit	8,785	9,585	7,911
Social security costs receivables	10	5	24
VAT receivables	1,103	1,814	2,766
Grants receivables	(0)	3	3
Other receivables	361	420	422
TOTAL	**10,284**	**12,033**	**11,919**

Trade and other receivables - Current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade receivables, net	25	207	793
Research tax credit	7,295	9,585	7,911
Social security costs receivables	10	5	24
VAT receivables	1,103	1,814	2,766
Grants receivables	(1)	3	3
Other receivables	361	420	422
TOTAL	**8,794**	**12,033**	**11,919**

Trade and other receivables - Non-current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade receivables, net	—	—	—
Research tax credit	1,489	—	—
Social security costs receivables	—	—	—
VAT receivables	—	—	—
Grants receivables	—	—	—
Other receivables	—	0	—
TOTAL	**1,489**	**0**	**—**

Trade receivables : see note 18 " other income"

Research tax credit

The research tax credit due for 2018 was received on November 18, 2019.

The research tax credit due for 2019 was received in June 2020.

The research tax credit receivable for the year 2020 amounts to €7,911.

VAT receivables

The increase in VAT receivables is notably due to an audit on the basis of documents, by the French revenue services, of the VAT refund requests since August 2020, which increases the time for a refund from the French revenue services.

Other receivables

The line item "other receivables" primarily consists of credit notes from suppliers for €406, €408, and €235 respectively as of December 31, 2020, December 31, 2019 and December 31, 2018.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

10. OTHER FINANCIAL ASSETS

Other financial assets consisted of the following:

Financial assets - Total (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Loans	259	307	352
Deposits and guarantees	284	396	418
Liquidity contract	770	1,023	688
TOTAL	**1,313**	**1,727**	**1,458**

Financial assets - Current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Loans	—	—	—
Deposits and guarantees	—	—	—
Liquidity contract	—	—	—
TOTAL	**—**	**—**	**—**

Financial assets - Non current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Loans	259	307	352
Deposits and guarantees	284	396	418
Liquidity contract	770	1,023	688
TOTAL	**1,313**	**1,727**	**1,458**

The liquidity contract consists of a share buyback program contracted to an investment service provider in order to facilitate the listing of the Group's shares.

As of December 31, 2020, the liquidity account had a cash balance of €688.
As of December 31, 2020, CMC-CIC Market Solutions holds on behalf of Genfit 88,929 shares, recorded as a deduction from equity.

As of December 31, 2019, the liquidity account had a cash balance of €1,023.

As of December 31, 2019, CMC-CIC Market Solutions holds on behalf of Genfit 18,132 shares, recorded as a deduction from equity.

As of December 31, 2018, the liquidity account had a cash balance of € 770.

As of December 31, 2018, CMC-CIC Market Solutions holds on behalf of Genfit 27,911 shares, recorded as a deduction from equity. During that period, Genfit made an additional contribution of €1.0 million to the liquidity agreement with CM-CIC Market Solutions.

11. OTHER ASSETS

Other assets of €1,765 at December 31, 2020, €1,968 at December 31, 2019, €2,078 at December 31, 2018 and respectively, consisted of prepaid expenses related to current operating expenses.

12. LOANS AND BORROWINGS

12.1. Breakdown of convertible loan

On October 16, 2017, the Company issued 6,081,081 OCEANEs at par with a nominal unit value of €29.60 per bond for an aggregate nominal amount of €180 million. The exchange or conversion premium is 30% of the reference share price of €22.77. Annual nominal interest rate is a fixed 3.5% payable semi-annually in arrears. The effective interest rate is 7.2%. The OCEANEs are due October 16, 2022. Redemption prior to maturity is at the option of the Company from November 6, 2020 if the arithmetic volume-weighted average price of the Company's share price and the then-prevailing conversion ratio (over a 20-day trading period) exceeds 150% of the nominal value of the OCEANEs.

As of December 31, 2018, 2019 and 2020, the Group recorded a liability of €160,489, €165,454 and €170,782 respectively, related to the OCEANEs net of the equity portion and debt issue costs. Of this amount €1,312, €1,312 and €1,312 respectively, was classified as current and €159,176, €164,142 and €169,470 respectively, was classified as non-current.

As indicated in Note 2.2 “Renegotiation of the convertible bond debt (OCEANEs), these convertible bonds were renegotiated subsequent to December 31,2020.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (Continued)

12.2. Breakdown of other loans and borrowings

Other loans and borrowings consisted of the following:

Other loans and borrowings - Total (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Refundable and conditional advances	3,229	3,229	3,229
Bank loans	3,964	2,645	1,540
Obligations under leases	1,900	12,281	10,131
Accrued interests	3	1	1
Other financial loans and borrowings	7	7	7
TOTAL	**9,104**	**18,165**	**14,908**

Other loans and borrowings - Current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Refundable and conditional advances	—	—	—
Bank loans	1,319	1,105	942
Obligations under leases	520	2,112	2,085
Accrued interests	3	1	1
Other financial loans and borrowings	7	7	7
TOTAL	**1,848**	**3,226**	**3,035**

Other loans and borrowings - Non current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Refundable and conditional advances	3,229	3,229	3,229
Bank loans	2,645	1,540	598
Obligations under leases	1,381	10,169	8,046
Accrued interests	—	—	—
Other financial loans and borrowings	—	—	—
TOTAL	**7,255**	**14,939**	**11,873**

12.2.1. Refundable and conditional advances

The following table summarizes advances outstanding at December 31, 2020, 2019 and 2018.

Refundable and conditional advances - general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2020/12/31
BPI FRANCE - IT-DIAB	12/23/2008	3,229	3,229	—	—	3,229
Development of a global strategy for the prevention and management of type 2 diabetes						
TOTAL						**3,229**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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12. LOANS AND BORROWINGS (Continued)

Refundable and conditional advances—general overview (in thousands of euros)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2019/12/31
BPI FRANCE—IT-DIAB	12/23/2008	3,229	3,229	—	—	3,229
Development of a global strategy for the prevention and management of type 2 diabetes						
TOTAL						**3,229**

Refundable and conditional advances—general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2018/12/31
BPI FRANCE—IT-DIAB	12/23/2008	3,229	3,229	—	—	3,229
Development of a global strategy for the prevention and management of type 2 diabetes						
TOTAL						**3,407**

BPI FRANCE IT-DIAB

On December 23, 2008, the Group received an advance from BPI France (the BPI France IT-DIAB) as part of a framework innovation aid agreement involving several scientific partners and for which the Group was the lead partner. The contribution expected at each stage by each of the partners in respect of work carried out and results achieved is defined in the framework agreement. With respect to the Group, the aid consisted of a €3,229 conditional advance and a €3,947 non-repayable government grant.

The conditional advance is not refundable except in the event of success. The program ended on December 31, 2014. In the event of success, defined as the commercial spin-offs of the IT-Diab program which involves products for the treatment or diagnosis of type 2 diabetes, in that case, the financial returns generated will be used initially to repay the €3,229 conditional advance and the agreement stipulates that the conditional advance will be regarded as repaid in full when the total payments made in this regards by the recipient, discounted at the rate of 5.19%, equal the total amount, discounted at the same rate, of the aid paid. Any further amounts will be classified as additional payments, up to a maximum amount of €14,800.

As provided in the project assistance contract, we sent a letter to BPI in December 2019 in order to notify it of our LabCorp and Terns contracts while indicating that elafibranor was now aimed at treating hepatic diseases and no longer type 2 diabetes as provided for in the aid agreement. We proposed to BPI to establish a statement of abandonment of the IT DIAB project on which the above advance is based. Following this letter, the parties met in March 2020 for the

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (Continued)

presentation of our arguments, and in June 2020 following the publication of the results of the RESOLVE-IT study, and a new letter was sent in November 2020. In this context, we are awaiting a proposal from BPI on new financial terms related to this situation and a draft amendment to the repayable advance agreement.

12.2.2. Bank loans

The Group did not take any new bank loan in 2020.

Bank loans are primarily used to finance research and laboratory equipment. Bank loans consisted of the following as of December 31, 2018:

				Available		Outstanding
Bank loans (in € thousands)	**Loan date**	**Facility size**	**Interest rate**	**As of 2018/12/31**	**Installments**	**As of 2018/12/31**
CDN 5	November 2018	500	0.46%	—	48 monthly	490
CIC 5	July 2017	1,000	0.69%	—	60 monthly	753
CDN 4	June 2017	600	0.36%	—	48 monthly	376
BNP 4	April 2017	800	0.87%	—	60 monthly	695
CIC 4	December 2016	265	0.69%	—	60 monthly	164
BNP 3	October 2016	1,050	0.80%	—	20 quarterly	735
NEUFLIZE 2	June 2016	500	1.10%	—	12 quarterly	84
BNP 2	June 2016	500	0.80%	—	20 quarterly	277
CDN 3	April 2016	500	0.72%	—	60 monthly	236
CIC 3	March 2015	500	0.85%	—	16 quarterly	32
BNP	December 2014	500	2.00%	—	20 quarterly	103
Other		—		—		19
TOTAL		6,715				**3,964**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (Continued)

Bank loans consisted of the following as of December 31, 2019:

Bank loans (in € thousands)	Loan date	Facility size	Interest rate	Available As of 2019/12/31	Installments	Outstanding As of 2019/12/31
CDN 5	November 2018	500	0.00%	—	48 monthly	365
CIC 5	July 2017	1000	0.00%	0	60 monthly	554
CDN 4	June 2017	600	0.00%	0	48 monthly	226
BNP 4	April 2017	800	0.00%	0	60 monthly	537
CIC 4	December 2016	265	0.00%	—	60 monthly	111
BNP 3	October 2016	1050	0.00%	0	20 quarterly	525
NEUFLIZE 2	June 2016	500	0.00%	0	12 quarterly	0
BNP 2	June 2016	500	0.00%	0	20 quarterly	177
CDN 3	April 2016	500	0.00%	—	60 monthly	135
CIC 3	March 2015	500	0.00%	0	16 quarterly	0
BNP	December 2014	500	0.00%	0	20 quarterly	0
Other		0		0		14
TOTAL		6,715				**2,645**

Bank loans consisted of the following as of December 31, 2020:

Bank loans (in € thousands)	Loan date	Facility size	Interest rate	Available As of 2020/12/31	Installments	Outstanding As of 2020/12/31
CDN 5	November 2018	500	0.00%	—	48 monthly	241
CIC 5	July 2017	1000	0.00%	0	60 monthly	354
CDN 4	June 2017	600	0.00%	0	48 monthly	75
BNP 4	April 2017	800	0.00%	0	60 monthly	377
CIC 4	December 2016	265	0.00%	—	60 monthly	58
BNP 3	October 2016	1050	0.00%	0	20 quarterly	315
NEUFLIZE 2	June 2016	500	0.00%	0	12 quarterly	0
BNP 2	June 2016	500	0.00%	0	20 quarterly	76
CDN 3	April 2016	500	0.00%	—	60 monthly	34
CIC 3	March 2015	500	0.00%	0	16 quarterly	0
BNP	December 2014	500	0.00%	0	20 quarterly	0
Other		0		0		9
TOTAL		6,715		—		**1,540**

12. LOANS AND BORROWINGS (Continued)

12.4. Maturities of financial liabilities

Maturity of financial liabilities (in € thousands)	As of 2020/12/31	Less than 1 year	Less than 2 years	Less than 3 years	Less than 4 years	Less than 5 years	More than 5 years
BPI FRANCE - IT-DIAB	3,229	—	—	—	—	—	3,229
TOTAL - Refundable and conditional advances	**3,229**	**—**	**—**	**—**	**—**	**—**	**3,229**
Convertible loans	170,782	1,313	169,470	—	—	—	—
Bank loans	1,540	942	544	54	—	—	—
Leases	10,131	2,085	1,564	1,150	1,109	1,039	3,184
Accrued interests	1	1	—	—	—	—	—
Other financial loans and borrowings	7	7	—	—	—	—	—
TOTAL - Other loans and borrowings	**182,461**	**4,348**	**171,577**	**1,205**	**1,109**	1,039	**3,184**
TOTAL	**185,691**	**4,348**	**171,577**	**1,205**	**1,109**	**1,039**	**6,413**

Under the initial terms, the convertible bond results in the payment of yearly interest of €6,300 and a reimbursement at par in October 2022. The nominal amount of the convertible loan of €180 million is due in less than 2 years. Regarding the renegotiation of this bond debt, please see Note 2.2 “Renegotiation of the convertible bond debt (OCEANEs)”.

Regarding the IT-DIAB advance, please see Note 12.2.1 “Refundable and conditional advances”.

13. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables provide the financial assets and liabilities carrying values by category and fair values as of December 31, 2020, December 31, 2019 and December 31, 2018:

	As of December 31, 2018						
	Carrying value				Fair value		
(in thousands of euros)	As per statement of financial position	Assets at fair value through profit & loss	Loans & receivables	Debt at amortized cost	Level 1	Level 2	Level 3
Assets							
Financial investments							
Loans	259		259			259	
Deposits and guarantees	284		284			284	
Trade receivables	25		25			25	
Cash and cash equivalents	207,240	207,240			207,240		
TOTAL—Assets	**207,808**	**207,240**	**568**		**207,240**	**568**	
Liabilities							
Conditional advances	3,229			3,229			3,229
Convertible loans	160,489			160,489		160,489	
Bank loans	3,964			3,964		3,964	
Obligations under finance leases	1,900			1,900		1,900	
Accrued interests	3			3		3	
Other financial loans and borrowings	7			7		7	
Trade payables	32,649			32,649		32,649	
Other payables	71			71		71	
TOTAL—Liabilities	**202,313**			**202,313**		**199,084**	**3,229**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

13. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

	As of December 31, 2019						
	Carrying value				Fair value		
(in thousands of euros)	As per statement of financial position	Assets at fair value through profit & loss	Loans & receivables	Debt at amortized cost	Level 1	Level 2	Level 3
Assets							
Financial investments							
Loans	307		307			307	
Deposits and guarantees	396		396			396	
Trade receivables	207		207			207	
Cash and cash equivalents	276,748	276,748			276,748		
TOTAL - Assets	**277,658**	**276,748**	**911**		**276,748**	**911**	
Liabilities							
Conditional advances	3,229			3,229			3,229
Convertible loans	165,454			165,454		165,454	
Bank loans	2,645			2,645		2,645	
Obligations under finance leases	12,281			12,281		12,281	
Accrued interests	1			1		1	
Other financial loans and borrowings	7			7		7	
Trade payables	32,753			32,753		32,753	
Other payables	527			527		527	
TOTAL - Liabilities	**216,898**			**216,898**		**213,669**	**3,229**

	As of December 31, 2020						
	Carrying value				Fair value		
(in thousands of euros)	As per statement of financial position	Assets at fair value through profit & loss	Loans & receivables	Debt at amortized cost	Level 1	Level 2	Level 3
Assets							
Financial investments							
Loans	352		352			352	
Deposits and guarantees	418		418			418	
Trade receivables	793		793			793	
Cash and cash equivalents	171,029	171,029			171,029		
TOTAL - Assets	**172,592**	**171,029**	**1,563**		**171,029**	**1,563**	
Liabilities							
Conditional advances	3,229			3,229			3,229
Convertible loans	170,782			170,782		170,782	
Bank loans	1,540			1,540		1,540	
Obligations under finance leases	10,131			10,131		10,131	
Other financial loans and borrowings	7			7		7	
Trade payables	20,337			20,337		20,337	
Other payables	569			569		569	
TOTAL - Liabilities	**206,596**			**206,596**		**203,367**	**3,229**

(amounts in thousands of euros, except for numbers of shares and per share amounts)

14. TRADE AND OTHER PAYABLES

Trade and other payables consisted of the following:

Trade and other payables - Total (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade payables (*)	32,649	32,753	20,337
Social security costs payables	2,967	3,598	4,477
VAT payables	1	2	314
Taxes payables	286	487	319
Other payables	71	527	569
TOTAL	**35,974**	**37,368**	**26,015**

Trade and other payables - Current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade payables	32,649	32,753	20,337
Social security costs payables	2,967	3,598	4,477
VAT payables	1	2	314
Taxes payables	286	487	319
Other payables	71	76	118
TOTAL	**35,974**	**36,917**	**25,564**

Trade and other payables - Non current (in € thousands)	As of 2018/12/31	2019/12/31	2020/12/31
Trade payables	—	—	—
Social security costs payables	—	—	—
VAT payables	—	—	—
Taxes payables	—	—	—
Other payables	(0)	450	451
TOTAL	**(0)**	**450**	**451**
(*) Of which : Accrued expenses	19,395	18,682	13,809

A very significant part of the accrued expenses reflects the estimation of the expected invoicing by the clinical trial sites via the Clinical Research Organization in charge of the RESOLVE-IT study ($9.6 million and €2.3 million, i.e. a total of €10.1 million based on the exchange rate at December 31, 2020). The timeframe in which those invoices will be received by the Company is unknown and may be spread out over a long period after the services have been performed.
In 2019, the CRO (Clinical Research Organization) commissioned as part of the RESOLVE IT trial updated its investigators costs estimation model by referring certain assumptions on the basis of historical data. These changes constitute a change in accounting estimate within the meaning of IAS 8 and have led in 2019 to a reduction in the amount recognized for invoices not received related to this specific costs in an amount of €6,994 compared to the previous model.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

15. PROVISIONS

At December 31, 2020, 2019 and 2018, this line item amounted to €1,031, €2,061, and €112, respectively.

The provisions recorded as of December 31, 2020 are mainly related to:

- The closing those costs of RESOLVE-IT for (€378)that, following a detailed review, do not have any economic benefit under IAS 37 ;
- The estimated support costs related to the reduction in force plan implemented in late 2020, such as return-to-work bonuses for €178, trainings for €264, business start-up assistance for €30 and various other benefits for €51 (i.e. a total of €523).

The accruals as of December 31, 2019 related to the research tax credit dispute (€1,892) have been reversed during the year as the dispute has been resolved following the payment of the 2014 research tax credit balance following the receipt of the assessment notice in July 2020.

16. EMPLOYEE BENEFITS

In France, pension funds are generally financed by employer and employee contributions and are accounted for as a defined contribution plan with the employer contributions recognized as expense as incurred. The Group has no actuarial liabilities in connection with these plans. Expenses recorded for the years ended December 31, 2020, 2019 and 2018 amounted to €923, €927, and €765 respectively.

French law also requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement, which are accounted for as a defined benefit plan. Benefits do not vest prior to retirement. The liability is calculated as the present value of estimated future benefits to be paid, applying the projected unit credit method whereby each period of service is seen as giving rise to an additional unit of benefit entitlement, each unit being measured separately to build up the final liability. At December 31, 2020, 2019 and 2018 pension provisions recorded were €1,148, €1,408, and €1,085 respectively.

As part of the measurement of the retirement indemnity to employees, the following assumptions were used for all categories of employees in 2018, 2019 and 2020:

Population	Permanent staff
Retirement age	65
Terms of retirement	Initiated by the employee
Life expectancy	On the basis of the INSEE table
Probability of continued presence in the company at retirement age	On the basis of the DARES table

(1) INSEE is the French National Institute of Statistics; DARES is the French Bureau of Studies and Statistics

Rate	**As of**		
(in € thousands)	**2018/12/31**	**2019/12/31**	**2020/12/31**
Salary growth rate - in 2021	5.80%	5.80%	3.00%
Salary growth rate - beyond	3.00%	3.00%	3.00%
Discount rate	1.53%	0.75%	0.50%

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

16. EMPLOYEE BENEFITS (Continued)

The discount rates are based on the market yield at December 31, 2018, 2019 and 2020 on high-quality corporate bonds.

The following table presents the changes in the present value of the defined benefit obligation:

Changes in the present value of the defined benefit obligation (in € thousands)	As of 2020/12/31
Defined benefit obligation as of January 1, 2018	**936**
Current service cost	104
Interest cost on benefit obligation	14
Past service costs / amendment or settlement of plan	—
Actuarial losses on obligation	31
Past service costs	—
Defined benefit obligation as of December 31, 2018	**1,085**
Current service cost	138
Interest cost on benefit obligation	17
Past service costs / amendment or settlement of plan	—
Actuarial losses on obligation	168
Past service costs	—
Defined benefit obligation as of December 31, 2019	**1,408**
Current service cost	181
Interest cost on benefit obligation	11
Past service costs / amendment or settlement of plan	(255)
Actuarial losses / (gains) on obligation	(196)
Past service costs	—
Defined benefit obligation as of December 31, 2020	**1,148**

The reduction of €255 is explained by €450 of settlement of the employee's rights less €196 of actuarial losses .

Sensitivity of the Group's retirement and post-employment benefits to a variation of the discount rate :

Sensitivity of the Group's retirement and post-employment benefits to a variation of the discount rate (in € thousands)	Retirement and post-employment benefits	
	Changes in assumptions / discount rate	Impact / present value of the undertaking
	0.25%	(42)
	-0.25%	45

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17. EQUITY

Ordinary shares are classified under shareholders' equity. Any shareholder, regardless of nationality, whose shares are fully paid-in and registered for at least two years, is entitled to double voting rights under the conditions prescribed by law (Article 32 of the Company's bylaws)

At December 31, 2020, 2,332,647 shares have been held for more than two years and entitle their holders to double voting rights (6% of the issued share capital).

As of December 31, 2020, the share capital amounts to €9,714,654.25 represented by 38,888,379 fully authorized, subscribed and paid-up shares with a nominal value of €0.25 per share. This number does not include instruments granting access to share capital which have been issued by the Company and granted to certain directors, employees and consultants of the Group including stock options, free shares (AGA) that have not fully vested and share warrants (BSA) or the shares underlying our OCEANE convertible bonds.

The remaining unused authorizations to issue additional share-based compensation or other share-based instruments (stock options, free shares and share warrants) represent a total of 407,900 shares.

Changes in share capital in 2020

The Chief Executive Officer, acting on a decision and delegation from the Board of Directors on November 27, 2019, determined on January 26, 2021, with retroactive effect to December 31, 2020, that some of the performance and attendance conditions of the AGA D 2017-2 and AGA D 2018 and all of the AGA S 2017-2 and AGA S 2018 free shares had been satisfied as of December 31, 2020. 29,762 free shares were thus definitively vested and the same number of new shares were created. The share capital was increased accordingly.

At December 31, 2020, the total number of shares comprising the share capital, taking into account the above, was 38,888,379 shares

Changes in share capital in 2019

The Chairman and CEO, acting on a decision and delegation from the Board of Directors on March 13, 2019, decided on March 26, 2019, in accordance with the 17th and 18th resolutions of the Shareholders Meeting of June 15, 2018, to proceed with a capital increase by offering ordinary shares in the form of American Depositary Shares in the United States and a private placement of ordinary shares in Europe and other countries outside the United States. This transaction led to the issuance of 7,647,500 new shares representing a subscription of a gross amount of €137.6 million. Settlement-delivery took place on March 29, 2019 and the share capital has been increased accordingly. See note 2.1 “Initial Public Offering on the Nasdaq Global Select Market”.

In addition, the Chief Executive Officer, acting on a decision and delegation from the Board of Directors on November 27, 2019, determined on December 16, 2019, with retroactive effect to December 15, 2019, that some of the performance and attendance conditions of the AGA D 2016-1 and AGA D 2016-2 and all of the AGA S 2016-2 free shares had been satisfied as of December 15, 2019. 7,796 free shares were thus definitively vested and the same number of new shares were created. The share capital was increased accordingly.

Finally, the Chief Executive Officer, acting on a decision and delegation from the Board of Directors on November 21, 2017, determined on January 2, 2020, with retroactive effect to December 31, 2019, that some of the performance and attendance conditions of the AGA D 2017-1 and all of the AGA S 2017-1 free shares has been satisfied. As a result, 19,400 free shares definitively vested and the same number of new shares were created and the share capital was increased accordingly.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

17. EQUITY (Continued)

At December 31, 2019, the total number of shares comprising the share capital, taking into account the above, was 38,858,617 shares.

Changes in share capital in 2018

On December 27, 2018, the Board of Directors of the Company determined that some of the performance conditions for the AGA D 2016-1 and all of the performance conditions for the AGA S 2016-1 were met, and therefore 17,484 ordinary shares were definitively acquired by their beneficiaries, and the share capital was increased by the nominal amount.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

18. OTHER INCOME

The industrial income recognized in 2020 for €765 pertains to a one-time transaction and relates to the income recognized within the scope of the license agreement with Labcorp (see Note 2.3).

Other income consisted of the following:

Other income	Year ended		
(in € thousands)	2018/12/31	2019/12/31	2020/12/31
CIR tax credit	7,295	8,125	6,020
Other operating income (including CICE tax credit)	130	1,992	968
Government grants and subsidies	—	5	5
TOTAL	**7,425**	**10,122**	**6,993**

The research tax credit (CIR) amount of €6,020 comprises:

- The 2020 Research Tax Credit for the amount of €7,911,
- the accrual corresponding to the resolution of the dispute on the 2010, 2011, 2012 and 2014 Research Tax Credit balanced with the reversal of the operating provision recognized in 2019 (€1,892).(see note 19).

During 2020, the Group recognized in “Other operating income” €951 for exchange gains on trade receivables (€1,985 were recognized for exchange gains on trade receivables in 2019 and €38 were recognized as financial income in 2018).

19. OPERATING EXPENSE

Year Ended December 31, 2018

		Of which:					
Operating expenses and other operating income (expenses) (in € thousands)	Year ended 2018/12/31	Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(67,024)	(1,724)	(47,659)	(9,431)	(6,502)	(1,707)	—
General and administrative expenses	(9,076)	(126)	(2)	(3,778)	(5,451)	283	—
Marketing and market access expenses	(717)	(4)	—	(416)	(287)	(11)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
TOTAL	**(76,979)**	**(1,855)**	**(47,662)**	**(13,625)**	**(12,403)**	**(1,435)**	**2**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

Operating expenses and other operating income (expenses) (in € thousands)	Year ended 2019/12/31	Of which: Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(66,170)	(2,017)	(41,509)	(11,740)	(6,188)	(4,716)	—
General and administrative expenses	(17,265)	(177)	(59)	(7,598)	(8,972)	(458)	—
Marketing and market access expenses	(13,708)	(8)	(0)	(1,645)	(11,979)	(76)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(1,649)	—	—	—	(1,668)	—	19
TOTAL	**(98,793)**	**(2,202)**	**(41,568)**	**(20,984)**	**(28,807)**	**(5,251)**	**19**

The depreciation, amortization and impairment charges totaled €4.7million, consists of a provision of €1.8 million with respect to the research tax credit litigation and due to additional depreciation due to the adoption of IFRS 16. The reversal of this provision of €1.8 million with respect to the research tax credit litigation was booked in 2020 (see above) .

Operating expenses and other operating income (expenses) (in € thousands)	Year ended 2020/12/31	Of which: Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(59,097)	(1,876)	(39,216)	(11,554)	(5,465)	(985)	—
General and administrative expenses	(14,270)	(202)	(92)	(6,936)	(6,545)	(495)	—
Marketing and market access expenses	(11,216)	(7)	(2)	(1,298)	(9,818)	(90)	—
Reorganization and restructuring expenses	(5,308)	—	—	8	(2,141)	(3,175)	—
Other operating income (expenses)	(764)	—	—	—	(684)	—	(80)
TOTAL	**(90,655)**	**(2,085)**	**(39,310)**	**(19,779)**	**(24,655)**	**(4,746)**	**(80)**

19. OPERATING EXPENSE (Continued)

Research and development expenses at each reporting date take into account estimates for ongoing activities subcontracted as part of the clinical trials and not yet invoiced, on the basis of detailed information provided by subcontractors and reviewed by the Group's internal departments. The accuracy of these estimates for some types of expenses improves with the progression of the trials and the review of their determination methods.

The decrease in "Contracted Operating Expense" in 2020 is related to the suspension or the discontinuation of some studies. See Note 2 "Major events in the period and events after the reporting period".

Employee-related costs decreased due to the progressive reduction in headcount due to voluntary resignations during the second half of 2020 (employees totaled 130 at December 31, 2020 compared to 194 at December 31, 2019) and the reduction applied to bonuses paid in 2020 within the scope of the agreement signed during the reduction in force plan (PSE) and the absence of incentive bonuses, partially compensated by the accrual recognized as employee related cost due to the PSE and the evolution of employee profiles.

The change in "Other Expenses" is attributed notably to the costs pertaining to the renegotiation of the OCEANEs and related costs, the facilities and their maintenance, the intellectual property costs, and most particularly the reduction in expenses pertaining to pre-marketing of elafibranor in NASH and expenses related to the specific insurance policy required for the first year of listing on the Nasdaq in 2019 (only one D&O insurance policy is recurrent) .

The change in "Net amortization, depreciation and provisions" is mainly due to the impairment recorded following the closing of RESOLVE-IT and the costs resulting from the implementation of the PSE.

The other operating income and expense are mainly currency exchange loss due to trades receivables.

The reorganization and restructuration costs of €5,308 in 2020 mainly include:

- accruals and provisions recognized within the scope of the PSE (€1,850);
- extraordinary amortizations, impairment losses and depreciation of fixed assets recognized within the scope of the reorganization of GENFIT (€363);
- the impairment loss of the rights of use of leased premised, fittings and fixtures and leased equipment (€1,275 and €503);
- the OCEANE renegotiation costs recognized in 2020 (€745);
- the provision recognized for some closing costs of the RESOLVE-IT study, which, after detailed analysis, do not have any economic advantage (€378).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

19. OPERATING EXPENSE (Continued)

19.1. Employee expenses

The 2020 employee expenses include the costs pertaining to the reduction in force (PSE), notably the notice periods for €712, severance pay for €459, voluntary departure compensation for €135, totaling €1,327.

Employee expenses and number of employees were as follows:

Employee expenses (in € thousands)	Year ended 2018/12/31	2019/12/31	2020/12/31
Wages and salaries	(9,012)	(14,018)	(13,570)
Social security costs	(3,722)	(5,171)	(5,047)
Changes in pension provision	(104)	(138)	74
Share-based compensation	(787)	(1,657)	(1,236)
TOTAL	**(13,625)**	**(20,984)**	**(19,779)**

Number of employees at year-end - detail	Year ended 2018/12/31	2019/12/31	2020/12/31
Average number of employees	135	175	193
Average age of employees	38 years 11 months	37 years 1 month	38 years 8 months
Number of employees			
Research and development	84	108	66
Services related to research and development	16	19	16
Administration and management	48	60	43
Marketing and commercial	—	7	5
TOTAL	**148**	**194**	**130**
Number of employees			
Senior staff	115	144	105
Staff	30	45	23
Others (apprentices)	3	5	2
TOTAL	**148**	**194**	**130**
Number of employees			
Male	57	78	52
Female	91	116	78
TOTAL	**148**	**194**	**130**

The reduction of the workforce took place at the end of December 2020 which explain the average number of employees in 2020.

20. SHARE-BASED COMPENSATION

Share-based compensation is granted by the Group to employees, executive officers, board members and consultants.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

Share-based compensation granted to employees and executive officers in 2014 through 2020 corresponds to redeemable share warrants (" *Bons de Souscriptions et/ou d'Acquisition d'Actions* " or "BSAAR"), stock options ("SO") and free shares (" *actions gratuites* " or "AGA")

Share-based compensation granted to board members and consultants in 2014, 2015, 2017 and 2019 corresponds to share warrants (" *Bons de Souscriptions d'Actions* " or "BSA").

For the measurement of this share-based compensation, the Group has determined that under IFRS its consultants were not equivalent to employees.

Under these programs, holders of vested instruments are entitled to subscribe to shares of the Company at a pre-determined exercise price. All of the plans are equity settled.

No instruments were exercised during 2020, 2019 and 2018.

New plans were put in place in 2020 under the terms and conditions discussed below.

The expense recognized during 2020 pursuant to IFRS 2 was €1,236 (compared to €1,656 at December 31, 2019 and €787 at December 31, 2018).

In 2019, the Group revised its estimate of the number of equity instruments expected to be vested taking into account the number of lapsed instruments noted after 4 years of successive plans. As a result, Genfit revised the turnover rate assumption, which was estimated at 15%, to a rate of 0%, taking into account recent observations and the actual number of lapsed instruments at each closing.

The table below shows the share-based compensation under each plan according to the change in estimate mentioned above .

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

Share-based compensation - Annual expense	Year ended 2018/12/31	2019/12/31	2020/12/31
AGA S 2016-1	151	—	—
AGA S 2016-2	22	44	—
AGA D 2016-1	127	21	21
AGA D 2016-2	17	39	6
SO 2016-1	83	213	49
SO 2016-2	38	93	13
SO US 2016-1	12	(24)	—
SO US 2016-2	5	(11)	—
AGA S 2017-1	—	209	—
AGA S 2017-2	24	45	13
AGA D 2017-1	17	190	—
AGA D 2017-2	29	56	4
SO 2017-1	28	27	335
SO 2017-2	48	2	110
SO US 2017-1	3	(4)	—
SO US 2017-2	5	(6)	—
BSA-2017-A	63	—	—
BSA-2017-B	66	—	—
AGA S 2018	12	148	62
AGA D 2018	10	135	65
SO 2018	24	285	225
SO US 2018	3	25	24
AGA S 2019	—	41	55
AGA D 2019	—	35	63
SO 2019	—	70	123
SO 2019 - US	—	16	35
BSA 2019	—	7	20
SO US 2019	—	1	14
SO D 2020	—	—	—
SO C 2020	—	—	—
SO US 2020	—	—	—
TOTAL	**787**	**1,656**	**1,236**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

20.1. Share warrants (*bons de souscription d'actions* or BSA)

The key terms and conditions related to each program are detailed in the following tables:

Share-based compensation Share warrants (BSA)	**2019**	**2017**		**2015**		**2014**	
		BSA 2017-A	BSA 2017-B	BSA 2015-A	BSA 2015-B	BSA 2014-A	BSA 2014-B
Date of the Shareholders meeting	06/15/2018	06/16/2017		04/02/2014		04/02/2014	
Date of the Management Board meeting				01/09/2015		07/24/2014	
Date of the decision and delegation of the Board of Directors to the CEO	10/18/2019	11/21/2017					
Date of the CEO decision	10/31/2019	12/06/2017					
Beneficiaries	Consultants	Consultants and officers		Consultants and officers		Consultants and officers	
Total number of BSAAR subscribed	35,070	18,345	18,345	12,860	12,860	46,765	46,765
Total number of BSAAR voided	0	0	0	12,860	12,860	46,765	46,765
Total number of BSAAR remaining	35,070	18,345	18,345	0	0	0	0
Issue Price	€1.23	€2.00		€0.01		€0.01	
Excercise price	€12.32	€19.97		€35.95		€23.50	
Estimated fair value - according to IFRS 2	€0.75	€3.78	€3.81	€25.33 /€26.89	€25.33 /€26.31	€15.61 /€24.84	€15.61 /€24.85
End of exercise period	05/31/2024	06/30/2022	07/15/2022	05/31/2019	11/30/2019	09/30/2018	02/28/2019
Valuation method used	Black & Scholes						
Expected dividends	0%	0%		0%		0%	
Expected volatility	40.0%	36.4%	35.7%	74.9%		74.9%	
Risk-free interest rate	0%	0.0%		0.4%		0.4%	
Expected life	0.7 years	6 years		4 years		4 years	

The services performed by the consultants are mainly:

- to evaluate product development plans and propose, if necessary, changes to strategic or technical approaches;
- to advise the Company's management and the Scientific Board in identifying strategies and selecting drug candidates, based in particular on the scientific results obtained by the Group (new therapeutic targets, new compounds); and
- to assist and advise the Group in its alliance strategies, such as external growth-supporting synergies (acquisition of new competencies and the purchase of operating rights, drug candidates and innovative technologies, etc.).

20.2. Redeemable warrants (*bons de souscription et/ou d'acquisition d'actions remboursables* or BSAAR)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

Share-Based compensation Redeemable share subscription warrants (BSAAR)	**2016** **BSAAR 2016-A and B**	**2014** **BSAAR 2014-A - B and C**
	Employees	Employees and Officers
Date of the Shareholders' meeting	02/24/2015	04/02/2014
Date of the Management Board meeting	07/22/2016	09/16/2014
Date of the decision and delegation of the Board of Directors to the CEO Date of the CEO decision		
Total number of BSAAR subscribed	10,800	62,717
Total number of BSAAR voided	10,800	61,484
Total number of BSAAR exercised	0	1,233
Total of BSAAR remaining	0	0
Issue Price	€23.50	€23.50
Subscription period	From 01/01/2018 to 07/27/2020	voided on 09/2018 - 05/2019 and 07/2019
Estimated fair value - valued by expert opinion	€4.60	From €8.44 to €11.29
Valuation method used	Black & Scholes	Black & Scholes
Expected dividends	0%	0%
Expected volatility	75.4%	75.4%
Risk-free interest rate	0.0%	0.4%
Expected life	4 years	4 years

As of December 31, 2020, all of the non-exercised BSAAR 2016 became void.

20.3. Free shares (*actions gratuites attribuées* or AGA)

The key terms and conditions related to each program are detailed in the following tables:

Share-based compensation Free shares (AGA)	**2 019** AGA D		**2 019** AGA S		**2 018**	**2 017**	**2 016**
	Officers(1)	Employees	Officers(1)	Employees	AGA D and S	AGA D and S 2017-1 and 2017-2	AGA D and S 2016-1 and 2016-2
Date of the Shareholders meeting	06/15/2018				06/15/2018	06/16/2017	06/21/2016
Date of the Management Board meeting							12/15/2016
Date of the decision and delegation of the Board of Directors to the CEO	07/18/2019				11/07/2018	11/22/2017	
Date of the Executive Board Meeting	07/18/2019				11/22/2018	12/06/2017	
Total number of AGA subscribed	3,000	16,070	0	17,556	35,800	41,196	30,709

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20.SHARE-BASED COMPENSATION (Continued)

Total number of AGA voided	0	450	0	702	1,872	9,846	5,429
Total number of AGA definitively vested	0	0	0	0	0	19,403	25,280
Total number of AGA remaining	3,000	15,620	0	16,854	33,928	11,947	0
Acquisition period	From 07/18/2019 to 09/16/2022				From 07/18/2019 to 09/16/2022	From 12/06/2017 to 12/31/2020	From 12/15/2016 to 12/15/2019
Valuation method used	Monte Carlo						
Price of the share at the time of allocation	€17.06				€20.02	€21.95	€20.78
Expected dividends	0%				0%	0%	0%
Expected volatility	40.2%				38.0%	53.7%	63.0%
Risk-free interest rate	0.0%				0.0%	0.0%	0.0%
Turnover rate	0.00%				15.00%	15.00%	15.00%

(1) : Chairman and CEO

The final allocation of free shares is subject to continued employment with the Group and performance conditions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

20.4. Stock options (*options de souscription d'actions* or SO)

The key terms and conditions related to each program are detailed in the following tables:

Share-based compensation	2020			2019			2018		2017		2016	
Stock option SO	SO		SO US	SO 2019	SO US 1	SO US 2	SO 2018	SO US 2018	SO 1 and 2 2017	SO US 2017	SO 1 and 2 2016	SO US 2016
	Officers (1)	Employees	Employees	Employees and Officers	Employees	Employees	Employees and Officers	Employees	Employees and Offices	Employees	Employees and Offices	Employees
Date of the Shareholders meeting	11/27/2019			06/15/2018	11/27/2019		06/15/2018		06/16/2017		06/21/2016	
Date of the Management Board meeting											12/15/2016	
Date of the decision and delegation of the Board of Directors to the CEO	12/11/2020			07/18/2019		11/27/2019	11/07/2018		11/21/2017			
Date of the CEO decision	12/11/2020			07/18/2019		11/27/2019	11/07/2018		12/06/2017			
Total number of SO subscribed	35,000	103,750	56,250	107,880	30,620	13,350	122,000	17,500	96,250	13,000	62,875	10,500
Total number of SO voided	0	0	0	13,350	7,000	4,450	50,322	7,787	35,273	13,000	13,169	10,500
Total number of SO definitively vested	0	0	0	0	0	0	0	0	60,977	0	49,706	0
Total number of SO remaining	35,000	103,750	48,750	94,530	23,620	8,900	71,678	9,713	0	0	0	0
Exercice price	€4.38	€3.50	€4.52	€13.99	€16.90	€14.31	€16.00	€21.65	€17.91	€22.54	€15.79	€21.12
Vesting period	From 12/31/2020 to 12/31/2023			From 07/18/2019 to 09/16/2022 and From 11/27/2019 to 01/16/2023			From 11/07/2018 to 12/31/2021		From 12/06/2017 to 12/31/2020		From 12/15/2016 to 12/15/2019	
Exercice period	From 01/01/2024 to 12/31/2027			From 09/17/2022 to 09/17/2029 and From 01/17/2023 to 01/17/2030			From 01/01/2022 to 12/31/2028		From 01/01/2021 to 12/31/2027		From 12/16/2019 to 12/16/2026	
Fair value	€1.16	€1.46	€1.12 €	€4.59	€3.67	€3.23	€9.32	€6.90	€9.32		€10.30	€8.52
Valuation method used	Black-Scholes											
Price of the share at the time of allocation	€3.99		€3.99	€17.06		€14.50	€22.12		€21.95		€20.79	
Expected dividends	0%		0%	0%		0%	0%		0%		0%	
Expected volatility	49.0%		49.0%			40.0%	44.1%		53.7%		63.0%	
Risk-free interest rate	-0.7%		-0.7%	0.0%		0.0%	0.0%		0.0%		0.0%	
Turnover rate	0.00%		0.00%	0.00%		0.00%	15.00%		15.00%		15.00%	

(1) Chief Executive Officer

Volatility assumptions in the above tables are determined by reference to the Company's historical share price observed on the grant date over a two- and three-year period prior to the grant date, adjusted for extreme variations, if any.

Definitive vesting is subject to continued employment with the Group and performance conditions.

20.5. Performance conditions

The SO and SO US stock option plans as well as certain free share plans (AGA "D") implemented in 2016, 2017, 2018 and 2019 are subject to internal performance conditions related to the progress of the Group's research and development programs, and to external performance conditions related to the evolution of the Company's stock price.

The other free share plans (AGA "S") are subject only to internal performance conditions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

20.5.1. Performance conditions of the 2020 plans

Plans	Evaluation date for performance conditions	Nature of conditions
SO D 2020 SO C 2020 SO US 2020	31/12/2023	50% of the 2020 instruments will be exercisable, if at least one of the three following conditions relating to the development of elafibranor in PBC and the ELATIVE clinical is fulfilled: (i) “Last Patient Visit” in ELATIVE in Q4 2022 or earlier; (ii) ELATIVE results are communicated to the market during or before the first half of 2023; (iii) if a registration application for elafibranor in PBC is filed with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in 2023. 25% of the 2020 instruments will be exercisable if at least if at least one of the two following conditions relating to the NI4 diagnostics technology is fulfilled: (i) a partnership agreement in research and development for the development of an IVD test integrating NIS4 technology with at least on major player in NASH (“big pharma, biotechnologies company, institution, etc.) is entered into by the Company; (ii) NIS4 technology has been used in at least 20 clinical trials.. 25% of the 2020 instruments will be exercisable if at least if at least one of the two following conditions relating to the development of the Company’s pipeline is fulfilled: (i) a new clinical trial for a new indication with elafibranor or NTZ in ongoing or complete; (ii) the Company has developed or acquired the rights of a new molecule. The exercise of 2020 instruments is also conditional to the presence of their beneficiaries at December 31, 2022, unless an exception usually provided for in the terms of conditions of the stock options granting plans applies. The granting of stock options D2020 to the CEO has been conditioned to the granting by the Company, in accordance with article L225-186-1 of the French Commercial Code, of free shares, existing or to be issued, to the benefit of the employees of the Company during the first half of 2021.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

21. FINANCIAL INCOME AND EXPENSES

Financial income and expenses (in € thousands)	Year ended 2018/12/31	2019/12/31	2020/12/31
Financial income			
Interest income	202	2,626	1,442
Foreign exchange gain	101	2,272	4,983
Other financial income	425	324	119
TOTAL - Financial income	**728**	**5,221**	**6,544**
Financial expenses			
Interest expenses	(10,955)	(11,289)	(11,643)
Interest expenses for leases	(21)	(148)	(134)
Foreign exchange losses	(127)	(1,657)	(13,508)
Other financial expenses	(14)	(17)	(11)
TOTAL - Financial expenses	**(11,118)**	**(13,110)**	**(25,296)**
FINANCIAL GAIN (LOSS)	**(10,391)**	**(7,889)**	**(18,752)**

The financial expenses are related to the interest of the OCEANE and they mainly relate to the payment of coupons at the rate of 3.5% and the amortization of the discount of the bond debt at the effective interest rate of 7.2%. to accrete the bond debt up to the amount that will be repaid (or converted) at maturity, recognizing a theoretical annual interest accrual as a result of the accretion on the period of an amount equivalent to the equity component at an effective interest rate.

The interest income recognized are almost exclusively related to investments in US dollars; the income generated has however been significantly reduced in 2020.

The financial result related to currency exchange is a loss of €8,525 in 2020 notably due to the difference in currency exchange recognized on the cash investments in US dollars, as GENFIT has decided to keep some of its cash in US dollars. See Note 6 “Cash and cash equivalents”. These cash investments in US dollars are to be used to pay directly expenses in US dollars (natural currency hedge).

22. INCOME TAX

22.1. Losses available for offsetting against future taxable income

At December 31, 2018, 2019 and 2020, the tax loss carry forwards for the Company amounted to €305,530, €384,471, and €483,356, respectively.

Such carry forwards can be offset against future taxable profit within a limit of €1.0 million per year plus 50% of the profit exceeding this limit. Remaining unused losses will continue to be carried forward indefinitely.

22.2 Deferred tax assets and liabilities

The Group's main sources of deferred tax assets and liabilities as of December 31, 2018 and 2019 related to:

Tax loss carry forwards: €305,530 and €384,471 respectively;

- Temporary differences:
  - related to the OCEANE: a net deferred tax liability for €1,773 and €1,193 as of December 31, 2018 and 2019, respectively and
  - related to post-employment benefits: €1,085 and €352, respectively, or an impact on deferred tax assets of €304 and €352, respectively.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

The Group's main sources of deferred tax assets and liabilities as of December 31, 2020 related to:

- Tax loss carry forwards: €483,356 (compared to €384,471 at December 31, 2019);
- Temporary differences related to:
  - the OCEANE: a deferred tax liability of €2,050 and an asset of €1,282, i.e., a net deferred tax liability of €767; and
  - post-employment benefits: a deferred tax liability of €287 offset by an asset of the same amount;

The Company offsets its deferred tax assets and liabilities (€1,282 and €2,050, respectively), as permitted by IAS 12, resulting in a net deferred tax liability of €767 as of December 31, 2020..

The income tax benefit for the period is mainly due to the decrease in the net deferred tax liability over the period.

Oher than as it relates to deferred tax assets recognized based on the available deferred tax liabilities, no other deferred tax asset has been recognized as it is not probable that taxable profit will be available to offset deductible temporary differences and tax loss carry forwards.

23. EARNINGS (LOSS) PER SHARE

The components of the earnings (loss) per share computation are as follows:

Basic loss per share is equal to diluted loss per share.

	Year ended		
Earnings per share	**2018/12/31**	**2019/12/31**	**2020/12/31**
Profit (loss) for the period (in € thousands)	**(79,521)**	**(65,144)**	**(101,221)**
Weighted average number of ordinary shares for the period	31,167,203	36,987,982	38,858,617
Profit (loss) per share (in €)	**(2.55)**	**(1.76)**	**(2.60)**

24. LITIGATION AND CONTINGENT LIABILITIES

Class Action

In May 2020, following the Group announcement on the interim results of our RESOLVE-IT Phase 3 clinical trial in which elafibranor had not achieved the primary or key secondary endpoints, a purported shareholder class action complaint was filed in state court in the Commonwealth of Massachusetts, naming the Group, the board of directors and certain members of the senior management as defendants, alleging that defendants 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, the Company and the other defendants filed a motion to dismiss and intend to vigorously defend this action.

25. RELATED PARTIES

Biotech Avenir SAS and The NASH Epidemiology Institute™ , an endowment fund set up by the Company, are related parties within the meaning of IAS 24.9.

The registered office of Biotech Avenir SAS and that of The NASH Epidemiology Institute™ are located at the same address as the Company. These domiciliations are provided without charge.

Biotech Avenir

Biotech Avenir SAS is a holding company incorporated in 2001 by the Company's founders. Most of its share capital is currently held by individuals, i.e. the four co-founders of the Company and twelve Company employees.

Jean-François Mouney, the Chairman of the Company, is also the Chairman of Biotech Avenir SAS.

At December 31, 2020, Biotech Avenir SAS held 4.86% of the share capital of the Company.

The Company did not carry out any transactions with Biotech Avenir in 2020, 2019 or 2018, with the exception of the domiciliation without charge.

The NASH Epidemiology Institute™

The NASH Education Program ™ (which became The NASH Epidemiology Institute ™) endowment fund was created in November 2016 at the initiative of the Group to develop and finance disease awareness activities targeting medical professionals and the general public. It has been dissolved on December 31, 2020, and in that context, before the final bank fees related to its dissolution, the endowment fund has a positive balance of €17. These funds will be transferred to the benefit of the Fondation de France or any other association in the field healthcare and registered as a charity.

PCAS Group

Mr. Frédéric Desdouits, member of the Genfit Board of Directors since June 2014 , was appointed CEO of PCAS Group in March 2019. Elafibranor’s principal active ingredient has been made by a PCAS Group production unit since 2013, and as Mr. Frédéric Desdouits became PCAS Group’s CEO, he temporarily became a related party as defined by IAS 24.9 until his resignation from this position in March 2020.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

25. RELATED PARTIES (Continued)

In January 2020, the Company signed a Memorandum of Understanding with PCAS settings out the conditions under which the PCAS Group would set up a second manufacturing source for the active ingredient used in the composition of elafibranor, as part of initiatives to secure the supply chain, and undertake the necessary investments to carry out this goal and to increase the production capacity of the active ingredient in view of a potential future marketing authorization. The cost to carry out technology transfers between the current manufacturing unit and the second source, €255, was to be borne by PCAS, except in case of termination of the RESOLVE-IT program. Due to the termination decision enacted on July 22, 2020, these costs were included in the closing costs of the study that were recognized in 2020. See note 2 “Major events in the period and events after the reporting period”.

26. COMPENSATION OF CORPORATE OFFICERS

On September 2, 2019, the Board of Directors accepted the resignation of the Chairman and Chief Executive Officer of the Company and decided to separate the roles of Chairman of the Board of Directors and Chief Executive Officer of Genfit SA with effect from September 16, 2019.

At the same meeting, the Board of Directors appointed the Chief Executive Officer of the Company and confirmed the former Chairman and Chief Executive Officer in his functions as Chairman of the Board of Directors and member of certain committees of the Company's Board of Directors.

Under these conditions, the following table details the compensation paid to the Chairman and Chief Executive Officer in 2018 and during the period from January 1, 2019 to September 16, 2019, and the compensation paid to the Chief Executive Officer in 2020 and during the period from September 16 to December 31, 2019 (after the change in governance) and the years in which the amounts were recognized in the statement of operations.

Compensation paid to the Chairman during the period from January 1, 2019 to September 16, 2019	**Year ended**		
	2018/12/31	**2019/12/31**	**2020/12/31**
Short-term employee benefits (gross + employer's social contributions, paid)	1,569	1,338	—
Post-employment pension & medical benefits	—	—	—
Share-based payment transactions	104	109	—
Director fees Genfit Corp (net)	30	22	—
TOTAL	**1,703**	**1,469**	**—**

Compensation paid to the Chief Executive Officer for the period beginning on September 16, 2019	**Year ended**		
	2018/12/31	**2019/12/31**	**2020/12/31**
Short-term employee benefits (gross + employer's social contributions, paid)	—	140	534
Post-employment pension & medical benefits	—	—	—
Share-based payment transactions	—	—	41
Director fees Genfit Corp (net)	—	—	—
TOTAL	**—**	**140**	**575**

(1) Within this total, only the portion of the amounts paid in 2019 to the Chairman and Chief Executive Officer pursuant to the 13th resolution of the Annual General Meeting of June 13, 2019, for the part of the Incentive Plan corresponding to that portion of work on the initial public offering of the Company on the Nasdaq Global Select Market carried out in 2018, i.e., ¾ of the amount due, i.e. a gross amount of €562,893. However, the Chairman of the Board of Directors decided to forgo the balance amount of €187,631, which had been recorded in 2019.

26. COMPENSATION OF CORPORATE OFFICERS (Continued)

The Chairman of the Board of Directors, Jean-François Mouney, receives a fixed compensation. He also has use of a company vehicle and the Group's insurance and disability plan. These benefits are totaled in the tablebelow in the "Other remuneration" line. The Chairman of the Board of Directors also receives attendance fees granted for his participation in the work of some of the committees of the Board of Directors.

The Chief Executive Officer's corporate contract contains a clause whereby, in the event of termination, he would receive a non-compete indemnity equal to:

(i) twelve (12) months of fixed compensation, calculated on the basis of the gross amounts due for the past twelve months ended and

(ii) increased, where applicable, by the amount of the annual variable compensation due for the previous year. This compensation is intended to compensate the prohibition made to the Chief Executive Officer, for a period of 12 months following the termination of his functions, for whatever reason, to work in any way whatsoever with certain companies carrying out a directly competitive activity of the Company.

In addition, the Chief Executive Officer, except in the event of gross negligence within the meaning of labor law, shall receive severance pay equal to:

(i) twelve (12) months of fixed compensation, calculated on the basis of the gross amounts due for the twelve past completed months and

(ii) increased, where applicable, by the amount of annual variable compensation due for the previous year. This compensation will be paid one month after his effective termination of activity within the Group. The compensation will not be paid if, on his initiative, the Chief Executive Officer leaves the Company to exercise new functions or changes functions within the Group, or even if he has the possibility of asserting in the short term his retirement rights. It is also specified that any sum paid under the non-competition clause will be deducted from the sums due under the severance pay and vice versa. The total and maximum commitment represented by this indemnity (gross, employer charges and payroll tax) as of December 31, 2020 would amount to €415.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

26. COMPENSATION OF CORPORATE OFFICERS (Continued)

The directors' fees and other compensation due and paid to the non executive directors are as follows:

Attendance fees and other forms of remuneration payable to each of the non executive officer (in euros)	Amounts due* 2018	Amounts paid* 2018	Amounts due* 2019	Amounts paid* 2019	Amounts due* 2020	Amounts paid* 2020
	During the year ended December 31,					
Jean-François MOUNEY (1)						
Attendance fees	—	—	14,791	633	49,937	49,939
Other remuneration (outside compensation as CEO)	—	—	88,874	88,874	286,469	286,469
Total	—	—	103,665	89,507	336,406	336,408
Xavier GUILLE DES BUTTES						
Attendance fees	53,330	41,311	68,016	67,580	85,020	80,660
Other remuneration	—	—	—	—	—	—
Total	53,330	41,311	68,016	67,580	85,020	80,660
Frédéric DESDOUITS						
Attendance fees	21,174	17,113	33,136	30,302	53,360	44,640
Other remuneration	—	—	—	—	—	—
Total	21,174	17,113	33,136	30,302	53,360	44,640
BIOTECH AVENIR						
Represented by Florence Séjourné						
Attendance fees	—	—	—	—	—	—
Other remuneration	—	—	—	—	—	—
Total	—	—	—	—	—	—
Philippe MOONS						
Attendance fees	29,704	22,345	36,188	41,202	45,780	41,420
Other remuneration	—	—	—	—	—	—
Total	29,704	22,345	36,188	41,202	45,780	41,420
Anne-Hélène MONSELLATO						
Attendance fees	37,075	24,307	44,472	53,410	50,140	45,780
Other remuneration	—	—	—	—	—	—
Total	37,075	24,307	44,472	53,410	50,140	45,780
Catherine LARUE						
Attendance fees	21,256	17,985	33,136	28,122	43,600	43,600
Other remuneration	—	—	—	—	—	—
Total	21,256	17,985	33,136	28,122	43,600	43,600
Katherine KALIN						
Attendance fees	—	—	—	—	15,805	4,360
Other remuneration	—	—	—	—	—	—
Total	—	—	—	—	15,805	4,360
Eric BACLET						
Attendance fees	—	—	—	—	20,165	6,540
Other remuneration	—	—	—	—	—	—
Total	—	—	—	—	20,165	6,540
TOTAL	**162,539**	**123,061**	**318,613**	**310,123**	**650,276**	**603,408**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

26. COMPENSATION OF CORPORATE OFFICERS (Continued)

(1) The attendance fees and other remuneration for Jean-François Mouney above correspond to amounts due for the period from September 16, 2019 to December 31, 2019 and the full year 2020.

*

In addition, the Company has provided corporate officers, directors and members of the Executive Committee a “directors and officers” insurance against claims relating to certain actions they may take in the performance of their duties. For the 12 month of the calendar year 2020, the insurance premium for the implementation of this insurance coverage amounted to €1,316 (€3,146 for 2019)

27. COMMITMENTS

Subcontracting agreements

The Group enters into contracts for its business needs with clinical research organizations (CROs) for clinical trials, as well as with Contract Manufacturing Organizations (CMOs) for clinical and commercial supply manufacturing, commercial and pre-commercial activities, research and development activities and other services and products for operating purposes. The Group’s agreements generally provide for termination with specified periods of advance notice.

Such agreements are generally cancelable contracts and not included in the description of the Group’s contractual obligations and commitments.

Deposits and guarantees

The Company has guaranteed its rental payment obligation under the lease agreement for the headquarters in Loos, France in the amount of €600 at December 31, 2020, €542 at December 31, 2019 and €455 at December 31, 2018.

Obligations in respect of the co-ownership of intellectual property rights

To date, the Company has not been required to license any third-party intellectual property to develop drug candidates and biomarker candidates that comprise its portfolio of proprietary programs and products.

The Company ensures, with regard to these programs, that the collaboration or subcontracting agreements that it is required to enter into, systematically stipulate that the results of the research are the Company's property. This is particularly the case for research consortia, in which the Group is associated with university laboratories and other biotechnology companies. It therefore holds all the intellectual property rights over its portfolio of proprietary programs and products.

On the other hand, the agreements signed in the framework of the Company's historical co-research alliances with partners in the pharmaceutical industry provided that the intellectual property rights of the drug candidates developed under these alliances belonged to the partners. These agreements also provided that the Company had intellectual property rights over the innovative technologies discovered on this occasion, even if it had to grant a royalty free and non-exclusive license to the industrial partner for the purpose of developing drug candidates discovered under the co-research programs.

To date, Sanofi remains the only industrial partner likely to still have exploitation rights on a drug candidate developed as part of its historical co-research alliance with the Company and therefore able to use on a royalty-free basis, but not exclusively, technologies developed by the Company under this program. The other historic partners have informed the Company of their decision not to exploit or stop exploiting the results of joint research. Nevertheless, to date, Sanofi has not communicated to the Company its desire to continue the development of this program despite the last research phase shared with the Company's teams having ended in May 2015.

GENFIT SA
Corporation with a Board of Directors and a share capital of €11,443,812.50
Registered office: Parc Eurasanté, 885 Avenue Eugène Avinée, 59120 LOOS
424 341 907 R.C.S. LILLE Métropole

ARTICLES OF ASSOCIATION

As of April 6, 2021

PART I
FORM - NAME - REGISTERED OFFICE - PURPOSE - TERM

ARTICLE 1 - Form

The owners of the shares created below and of those that may be created at a future date have formed a limited liability company (hereafter, the "**Company**") governed by the laws and regulations in force (hereafter, the "**Law**") and by these Articles of Association.

ARTICLE 2 - Name

The Company's name is: "GENFIT".

On all deeds and documents issued by the Company, its corporate name must be preceded or immediately followed by the words "Limited Company with Board of Directors" and a declaration of the company's capital, as well as the place of registration and the Company's registration number in the Trade and Companies Register.

ARTICLE 3 - Registered office

The Company's registered office is at PARC EURASANTÉ, 885 Avenue Eugène Avinée, 59120 LOOS.

It may be transferred to any other place, in accordance with the provisions of the laws and regulations in force.

ARTICLE 4 - Purpose

The company's direct or indirect purpose, both in France and abroad is:

- Research concerning the production and sale, at different stages of development, of biological molecules and all other activities regardless of what they may be, linked to the pharmaceutical industry.

- And more generally, to carry out all commercial, industrial, financial, securities or real estate transactions and operations linked directly or indirectly to its activity or capable of its facilitation.

ARTICLE 5 - Term

The Company, except in the event of its extension or early dissolution, has a term of 99 years starting as from the date of its registration in the trade and companies register.

PART II
CONTRIBUTIONS - COMPANY CAPITAL - FORM OF SHARES - RIGHTS AND OBLIGATIONS ATTACHED TO THE SHARES

ARTICLE 6 - Capital

The Company's capital is fixed at the sum of eleven million four hundred forty three thousand eight hundred twelve euros and fifty cents (€11,443,812.50). It is divided into forty five million seven hundred seventy five thousand two hundred fifty (45,775,250) ordinary shares of twenty-five cents of Euro (€ 0.25) each, fully subscribed and paid up in cash.

ARTICLE 7 - Changes to the capital

I. Capital may be increased, either by issuing new ordinary shares or preference shares, or by increasing the nominal value of the existing shares.

New shares may be paid-up either in cash, or by contributions in kind, or by offsetting them against cash receivables, or by the incorporation of profits, reserves or issue premiums into the capital, or as a consequence of a merger or split, or as a consequence of a right attached to securities giving access to the capital being exercised, and in such circumstances payment of the corresponding sums.

Securities representing new capital are issued, either at their nominal value, or at this amount plus an issue premium.

Only the Extraordinary General Meeting is competent to agree to an increase in capital based on a report from the Board of Directors containing the information required by Law.

Under the terms laid down by Law, the Extraordinary General Meeting may, however, delegate this competence to the Board of Directors. Within the limits of the powers thus granted by the Extraordinary General Meeting, the Board of Directors has the powers required for the purpose of increasing the capital one or more times, to set the terms of the increase, to monitor the increase and to amend the Articles of Association as a consequence.

When the Extraordinary General Meeting decides on an increase in capital, it may delegate the powers required to carry out the transaction to the Board of Directors.

When it is a matter of delegating powers or competence, the Board of Directors is required to prepare a supplementary report for the next Ordinary General Meeting.

If the capital is increased by incorporating profits, reserves or issue premiums, the Extraordinary General Meeting must rule under the terms of a quorum and majority specified for Ordinary General Meetings. In this case, it may decide that rights forming fractional shares are neither negotiable nor transferable and that the corresponding securities must be sold. Money arising from the sale will be allocated to the holders in proportion to their rights.

An increase in the capital achieved by increasing the nominal amount of shares can only be determined with the unanimous consent of the shareholders, except when it results from the incorporation of profits, reserves or issue premiums into the capital.

II. The Extraordinary General Meeting of shareholders, or the Board of Directors where such authority has been delegated, may also, subject, if applicable, to creditors' rights, authorize or agree on a reduction of capital for any reason and in any manner. Under no circumstances may a reduction in capital impinge upon shareholder equality.

A decision to reduce capital to an amount lower than the legal minimum can only be agreed upon under the condition precedent of an increase in capital designed to raise it to an amount at least equal to the legal minimum, unless the Company intends converting into another form of Company. Failing this, any interested party may apply to the courts for the dissolution of the Company; dissolution cannot be pronounced, if on the day the Court rules on the substance, the matter has been rectified.

ARTICLE 8 - Paying up of shares

Shares subscribed for in cash must be paid up by at least a quarter of their nominal value at the time of subscription and, if where relevant, by the whole of the issue premium.

The surplus must be paid up in one or more instalments, when called for by the Board of Directors and within a period of five years from the date the capital increase becomes final.

Calls for funds are brought to subscribers' attention by registered letter with a form for acknowledgement of receipt at least fifteen (15) days before the date fixed for each instalment.

Should a shareholder fail to pay up the sums due and payable for the amount of shares he has subscribed for, at the times fixed by the Board of Directors, these sums will automatically be subject to interest in the Company's favor, at the legal rate defined in article L.313-2 of the French Monetary and Financial Code, as from the expiry of the month following the date they become due and without any need for an application to the courts or formal notice. In addition, shares for which payment is due and has not been made on the expiry of a period of thirty (30) days as from formal notification sent to the defaulting shareholder is without effect, cease to give the right to admission to General Meetings and to vote in these General Meetings and will be deducted for the calculation of the quorum. The right to dividends and the preferential rights to subscribe to capital increases attached to the shares are suspended. These rights are recovered after payment of the sums due in terms of capital and interest. The shareholder can then request payment of dividends that have not lapsed and exercise the preferential subscription right if the time limit fixed for the exercise of this right has not expired.

Capital must be fully paid-up before any new shares can be issued that must be paid up in cash.

ARTICLE 9 - Form of shares – Management of securities accounts

Shares issued must be recorded in individual accounts opened in the name of each shareholder by the Company or, if legislation permits, depending on the shareholder's choice, by any authorized intermediary, and kept under the terms and according to the procedures specified by the Law.

The company is allowed to make use of the provisions specified by the Law, and in particular article L. 228-2 of the French Commercial Code, with regard to the identification of holders of bearer securities. To this end, it may at any time ask the central securities depository that keeps its securities account, against remuneration for which it is responsible, for the information referred to in article L. 228-2 of the French Commercial Code. Thus the Company in particular has the right at any time to ask for the name and date of birth or if it is a matter of a company, the name and year of incorporation, the nationality and address of holders of securities conferring an immediate or subsequent right to vote at its General Meetings, as well as the number of securities held by each of them and, if need be, any restrictions to which the securities may be subject.

The Company, after having followed the procedure laid down in the preceding paragraph and in the light of the list provided by the central securities depository, has the option of requesting, either through this central depository or directly to the people included on this list, and where the Company believes they may be registered on behalf of third-parties, the information concerning the ownership of securities specified in the preceding paragraph. These persons are required, when they are acting as intermediaries, to reveal the identity of the owners of the securities. The information is supplied directly to the authorized financial intermediary keeping the account, who is responsible for communicating it,

depending on the circumstances, to the Company or to the above-mentioned central securities depository.

ARTICLE 10 - Transmission of shares

Securities registered in an account are passed on by transfer from one account to another.

Shares paid up in cash are freely negotiable from the time of the capital increase. Shares paid for by a contribution are freely negotiable from the time of the capital increase, i.e. on the date of the General Meeting or of the meeting of the Board of Directors, acting by delegation, that approves the contributions, in the event of a contribution in kind during the life of the company.

Transfer of ownership results from their registration in the buyer's account, on the date and under the terms defined by Law.

Subject to the provisions laid down by the Law, the shares are freely transferable.

ARTICLE 11 - Exceeding of thresholds

Any individual or company referred to in articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code acquiring directly or indirectly, alone or in concert, a number of shares representing a fraction of the Company's capital or voting rights greater than or equal to two percent (2%) or a multiple of this percentage, must inform the Company of the total number of shares and voting rights and securities giving access to capital or voting rights it owns immediately or subsequently, by registered letter with advice of delivery addressed to the registered office within a period of four (4) stock exchange days as from the date it exceeds the aforesaid investment threshold or thresholds.

The obligation to provide the information specified above also applies under the same terms when such holdings are reduced below each of the thresholds referred to above.

The individual or company required to provide the above information is, in addition obliged to inform the Company of the objectives it intends pursuing during the next twelve (12) months when the thresholds are crossed, either upwards or downwards, of a tenth, fifth or third of the capital or voting rights. This declaration specifies whether the purchaser is acting alone or in concert, if it intends stopping its purchases or sales or continuing them, or whether it intends acquiring or transferring control of the Company, requesting its nomination or that of one or more other persons, or its resignation, as a director of the Board of Directors.

If this declaration is not made under the terms expressed in the three paragraphs above, the shares or voting rights in excess of the fraction that should have been declared are deprived of voting rights in shareholders' General Meetings for all General Meetings that are held up to the expiry of a period of two years following the date such notification is regularized in accordance with article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

The above declarations apply without prejudice to declarations regarding the exceeding of thresholds specified by the Law.

ARTICLE 12 - Rights and obligations attached to the shares

Each share gives the right to a share in the profits and company assets proportional to the share of the capital it represents.

In addition, it gives the right to vote and the right of representation in General Meetings under the legal and statutory terms.

Shareholders are only liable up to the nominal amount of the shares they own; beyond this any call for funds is prohibited.

Ownership of a share automatically comprises acceptance of the Company's Articles of Association and decisions of the General Meeting.

Heirs, creditors, successors in title, or other representatives of a shareholder, may not require the Company's assets and securities to be sealed, nor ask for them to be shared or sold by auction, nor interfere in the actions of its administration. They must, in order to exercise their rights, refer to the company inventories and the decisions of the General Meeting.

Each time several shares are required in order to exercise a particular right, in the event of the exchange, amalgamation or allocation of securities, or as a consequence of an increase or reduction in capital, merger or other company transaction, owners of individual securities or of a number less than that required may only exercise these rights on condition that they make it their personal business to amalgamate and, possibly, purchase or sell the necessary securities.

However, the Company may, in circumstances where it has carried out either an exchange of securities subsequent to a merger, split, capital reduction, amalgamation or division transaction and the compulsory conversion of bearer shares into named securities, or distributions of securities charged to the reserves or linked to a capital reduction, or distributions or allocations of free shares, via a simple decision by the Board of Directors, sell securities that successors in title have not asked to be issued on condition that they carry out the advertising formalities specified by the regulations at least two years in advance.

From the date of this sale, old shares and old rights to distributions or allocations are cancelled as required and their holders may no longer lay claim to the distribution in cash of the net proceeds from the sale of securities not claimed.

ARTICLE 13 - Beneficial ownership / bare ownership

Shares are indivisible in respect of the Company.

Joint owners of shares are required to arrange to be represented in relation to the Company by one of them alone, considered as the sole owner or by a single representative; in the event of disagreement, the single representative may be appointed by the courts at the request of the joint owner making the application.

Unless an agreement to the contrary is notified to the Company, beneficial owners of shares validly represent bare owners in respect of the Company. Voting rights at Ordinary General Meetings belong to the beneficial owner and to the bare owner at Extraordinary General Meetings.

Unless otherwise agreed by the parties, when capital securities are subject to beneficial ownership, the preferential subscription rights attached to them belong to the bare owner.

PART III
ADMINISTRATION AND CONTROL OF THE COMPANY

ARTICLE 14 - Mode of administration

The company is directed by a Board of Directors.

ARTICLE 15 - Composition of the Board of Directors

The Company is governed by a Board of Directors composed of not less than three nor more than fifteen directors, without prejudice of the temporary exemption provided for in the event of merger, in which case the number may be increased to twenty-four.

The Ordinary General Meeting shall appoint the directors or renew their terms of office and may remove them from office at any time.

The directors may be individuals or legal entities. Upon their appointment, the legal entities are required to designate a permanent representative, who shall be subject to the same conditions and obligations and shall incur the same civil and criminal liability as if he were a director in his own name, without prejudice to the joint and several liability of the legal entity that he represents. The permanent representative shall be appointed for a term of office equivalent to the term of office of the legal entity that he represents. This term of office must be renewed upon each renewal of the legal entity's term of office.

When the legal entity removes its representative from office, it must immediately notify said removal from office to the Company, without delay by registered letter, and appoints a new permanent representative under the same terms and conditions; the same applies in the event of the death or resignation of the permanent representative.

The number of directors who are bound by an employment contract with the Company must not exceed one-third of the directors in office.

The number of directors over 75 years of age may not exceed one-third of the directors in office. If this limit is reached, the eldest director shall be deemed to have resigned.

In the event of a vacancy, due to death or resignation, of one or more directors' seats, the Board of Directors may, between two General Meetings, make provisional appointments.

However, if only one or two directors remain in office, the said director or directors, or failing that, the Auditors must immediately call the Ordinary General Meeting to complete the members of the Board of Directors.

Temporary appointments made by the Board of Directors shall be subject to approval by the next Ordinary General Meeting. Failing approval, deliberations made and actions previously carried out by the Board of Directors shall remain valid.

The director appointed to replace another director shall remain in office only for the unexpired period of his predecessor's term of office.

ARTICLE 16 - Term of office of the Directors

The term of office of the directors is five (5) years. This office ends at the end of the General Meeting called to approve the annual financial statements for the year ended and held during the year in which its term of office expires.

Directors are eligible for re-election.

They may be revoked at any time by the Ordinary General Meeting.

ARTICLE 17 - Chairman of the Board of Directors

The Board of Directors elects, from among its members who are individuals, a Chairman. It shall fix his/her term of office as Chairman, which shall not exceed the period of his/her term of office as director.

The age limit for holding the office of Chairman of the Board of Directors is set at 80 years of age. If he/she reaches this age, he/she shall be deemed to have automatically resigned.

The Chairman of the Board of Directors organizes and manages the Board of Directors' work, for which he/she reports thereon to the General Meeting. He/she ensures that the Company's bodies operate properly and, in particular, that the directors are able to fulfil their assignments.

As it may be decided by the Board of Directors and as provided in the article 21-I of these Articles of Association, he/she may hold this office concurrently with that of Chief Executive Officer of the Company.

The Board of Directors may elect a Deputy Chairman which fulfils the functions of the Chairman in his/her absence.

ARTICLE 18 - Meetings and deliberations of the Board of Directors

I. Meetings

The Board of Directors meets as often as the Company's interest requires so, upon summons by the Chairman of the Board of Directors. When no meeting has been held for more than two (2) months, at least one-third of the members of the Board of Directors may request the Chairman to convene a meeting on a specific agenda.

The Chief Executive Officer may also request the Chairman of the Board of Directors to convene a Board of Directors' meeting on a specific agenda.

The Chairman is bound to comply with the requests made by virtue of the two previous paragraphs.

The Chairman of the Board of Directors chair the meetings. If the Chairman is unable to attend to his duties, the Board shall appoint one of the members present to chair the meeting.

The Board may appoint a secretary at each meeting, who is not required to be a Board of Directors' member.

An attendance record is also kept and signed by the directors attending the Board of Directors' meeting.

II. Deliberations

The Board of Directors meets as often as the Company's interest requires it, as convened by its Chairman, either at the head office, or in any other place indicated in the notification to attend. At least a third of the members of the Board of Directors may submit a motivated request to convene the Board of

Directors to its Chairman by registered post. The Chairman must convene a Board of Directors' meeting at a date which may not be later than fifteen (15) days as from receipt of the request. Should the meeting not be convened within this period, the authors of the request may convene a Board of Directors' meeting themselves and set its agenda.

Notifications to attend can be issued by all means, even verbally.

Except when the Board of Directors is convened to carry out the operations referred to in the articles L.232-1 and L.233-16 of the French Commercial Code, the directors are deemed present, for the purpose of calculating the quorum and the majority, when they participate in the Board of Directors' meeting using videoconference or telecommunication means allowing them to be identified and ensuring an effective participation in accordance with applicable laws and regulations.

Any director may be represented in the deliberations of the Board of Directors by another director of the Board of Directors. Each member of the Board of Directors cannot have more than one representation's mandate.

The Board of Directors may validly deliberate only if at least half of its members are presents.

The Board of Directors' decisions are taken by a majority of members present and represented.

In the event of a split-vote, the chairman of the session's vote take precedence.

Evidence of the number of current members of the Board of Directors and their presence or representation shall result *vis-à-vis* third parties, the mere mention in the minutes of the Board of Directors of the names of the members present, represented or absent.

ARTICLE 19 - Minutes

The deliberations of the Board of Directors shall be recorded in minutes with the required details. The minutes are drawn up and signed in accordance with applicable laws and regulations.

These minutes are signed by the director acting as Chairman for the purpose of the meeting and at least one Director.

Copies or extracts of the minutes are validly certified by the Chairman of the Board of Directors or any person duly empowered for such purpose.

After the winding-up of the Company, copies or extract of the minutes are certified by any of the liquidators or by the sole liquidator.

ARTICLE 20 - Powers of the Board of Directors

The Board of Directors determines the orientations of the Company's activity and ensures their implementation. Subject to the powers expressly assigned to the general meetings, and within the limits of the corporate purpose of the Company, it shall deal with all issues pertaining to the proper functioning of the Company and settle by its decisions the Company's business.

In relation to third parties, the Company will be committed even by the actions of the Board of Directors which do not fall within the scope of the Company's purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that they could not be unaware thereof given the circumstances, it being understood that the sole publication of the Articles of Association is not sufficient to establish such proof.

The Board of Directors shall carry out audits and perform the controls and verifications that it deems appropriate. Each director receives all information needed to the fulfilment of its assignment and may obtain disclosure of all documents that he considers relevant.

The Board of Directors may decide on the creation of director's committees responsible for dealing with issues that the Board of Directors submits to them. It shall determine the membership, powers, privileges and operating rules of such committees, which shall carry on their business under its responsibility.

The Board of Directors shall distribute attendance fees among the directors, the total amount of which is voted by the General Meeting.

ARTICLE 21 - General Management

I. Choice between the two forms of General Management

The General Management of the Company is handled, under his responsibility, either by the Chairman of the Board of Directors or by another individual appointed by the Board of Directors and having the title of Chief Executive Officer.

The Board of Directors chooses between the two forms of General Management at the majority of members present or represented. It shall inform the shareholders in accordance with regulatory requirements.

When the Chairman of the Board of Directors assumes the General Management of the Company, the provisions hereinafter relating to the Chief Executive Officer shall apply to him.

II. Chief Executive Officer

The Chief Executive Officer may be chosen among the directors or elsewhere. The Board of Directors fixes his term of office and remuneration.

The age limit for being Chief Executive Officer is fixed to the age of 70. Once he has reached this age, he will be deemed to have automatically resigned.

The Board of Directors may dismiss the Chief Executive Officer at any time. If the dismissal is decided without sufficient justification, it may give rise to damages.

The Chief Executive Officer is invested with the broadest powers to act on behalf of the Company in all circumstances. He exercises these powers within the limits of the Company’s purpose and subject to the powers expressly assigned by the French Law to the general meeting and the Board of Directors.

He represents the Company in relations with third parties. The Company will be committed even by the actions of the Chief Executive Officer which do not fall within the scope of the Company’s purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that it could not be unaware thereof, given the circumstances, it being understood that the sole publication of the Articles of Association is not sufficient to establish such proof.

The provisions of the Articles of Association or the decisions of the Board of Directors that limit the powers of the Chief Executive Officer are not enforceable against third parties.

III. Deputy Chief Executive Officers

Based on proposal of the Chief Executive Officer, the Board of Directors may appoint one or more individuals to assist the Chief Executive Officer, having the title of Deputy Chief Executive Officer, whose remuneration shall be determined by the Board of Directors.

The number of Deputy Chief Executive Officers cannot exceed five.

The Board of Directors may dismiss the Deputy Chief Executive Officers at any time based on the proposal Chief Executive Officer. If the dismissal is decided without sufficient justification, it may give rise to damages.

When the Chief Executive Officer ceases to carry out or is prevented from carrying out his duties, the Deputy Chief Executive Officers shall, unless decided otherwise by the Board of Directors, retain their duties and attributions until the appointment of a new Chief Executive Officer.

With the consent of the Chief Executive Officer, the Board of Directors shall determine the limits and term of the powers granted to the Deputy Chief Executive Officers. They shall have, *vis-à-vis* third parties, the same powers as the Chief Executive Officer.

The age limit applicable to the Chief Executive Officer also applies to the Deputy Chief Executive Officers.

ARTICLE 22 – Plurality of terms of office

An individual may simultaneously hold a maximum of five offices of director or chairman of a board of directors of public companies (*société anonyme*) having their registered office in France.

However, an individual may not hold more than one office as Chief Executive Officer. As an exception, the Chief Executive Officer of a company may hold a second office of the same nature within another company controlled by the first company insofar as the securities of the controlled Company are not listed on a regulated market.

Directors who are not chairmen in other companies may hold an unlimited number of offices in controlled companies of the same kind.

The list of all mandates and functions held in all companies by each of the officers during the financial year is set forth in the management report of the Board of Directors.

ARTICLE 23 - Regulated agreements

I. All agreements entered into between the Company and one of the director of the Company, its Chief Executive Officer, one of its Deputy Chief Executive Officer, an observer as defined in article 24 below or a shareholder that holds over 10% of the voting rights, or further, if a legal person, a controlling Company within the meaning of article L. 233-3 of the French Commercial Code holding over 10% of the voting rights, must be subject to prior authorization from the Board of Directors.

The same is true for agreements in which one of the persons referred to in the preceding paragraph is indirectly involved or for which they deal with the Company indirectly or through an intermediary.

Agreements between the Company and another company are also subject to prior authorization if one of the directors of the Company, its Chief Executive Officer, one of its Deputy Chief Executive Officer or the Company's observer is the owner, a partner with unlimited liability, manager, director, Chief Executive Officer, director of the board of directors or the supervisory board, or, in a general manner is in a position of responsibility within this company.

The foregoing provisions are not applicable to agreements concerning day-to-day operations and entered into under normal conditions.

The directors of the Company, its Chief Executive Officer, its involved Deputy Chief Executive Officers are required to inform the Board of Directors as soon as he/she becomes aware of an agreement subject

to authorization. If he/she is a member of the Board of Directors, he/she shall not take part in the vote on the authorization sought.

The President of the Board of the Directors gives notice to the Auditors of all authorized agreements and submits them to the General Meeting for approval.

II. The Auditors present a special report on these agreements to the General Meeting which rules on these agreements.

The party involved may not take part in the vote and the shares he owns are not taken into account when calculating either a quorum or a majority.

ARTICLE 24 - Observers

The Board of Directors may appoint, at its discretion, one or more observers, whether companies or individuals, shareholders or not.

The term of office of these observers is five years.

Observers may be re-elected indefinitely. Their appointment may be revoked at any time by the Board of Directors.

Observers are convened and participate to all meetings of the Board of Directors, with a consultative vote, according to procedures that are identical to those specified for directors of the Board of Directors, without having their absence affecting the value of the latter's deliberations.

Observers may not be assigned any management, supervisory or monitoring roles, the latter being under the exclusive jurisdiction of the statutory bodies prescribed for limited companies for which they must not be a substitute.

ARTICLE 25 - Obligation of confidentiality and responsibility

I. Directors of the Company, the Chief Executive Officer and, as the case may be, the Deputy Chief Executive Officers and the observers, as well as any person required to attend meetings of these bodies, are required to maintain total discretion in respect of information of a confidential nature that is supplied as such by the Chairman of the Board of Directors and/or the Chief Executive Officer.

II. Directors of the Company, the Chief Executive Officer and, as the case may be, the Deputy Chief Executive Officers, are, according to their respective responsibilities, responsible to the Company or to third-parties for infringements of the legal provisions governing public limited companies, for violations of these Articles of Association, and for misconduct committed in the context of their responsibilities, under the terms and at the risk of the sanctions specified in the legislation in force.

PART IV
AUDITORS

ARTICLE 26 - The Auditors

Audits of the Company are carried out by one or more Auditors, in accordance with the legal requirements.

I. The Ordinary General Meeting appoints, pursuant to legal requirements, one or several Auditors which are entrusted with the mission determined by the Law. These appointments are for six financial years, and ends-up after the General Meeting called to rule on the annual financial statements for the sixth year after such appointments.

The Ordinary General Meeting also appoints, pursuant to legal requirements, one or several Alternate Auditors which may be required to replace the incumbents Auditors, in case of death, resignation, impediment or refusal.

II. The Auditors, are convened by registered post with confirmation of receipt:

- to every General Meeting, at the latest when the shareholders are convened; and
- at the same time than the members of the Board of Directors at the meetings reviewing and approving the yearly or semi-annual financial statements, whether individual or consolidated.

PART V
SHAREHOLDERS MEETINGS

A - Provisions common to the different types of Meetings

ARTICLE 27 - Meetings

The General Meeting, lawfully convened, represents all the shareholders.

Its deliberations undertaken in accordance with the Law and the Articles of Association are binding on all shareholders, even those that are absent, dissident or subject to incapacity.

Depending on the subject of the resolutions proposed, there are three forms of Meetings:

- Ordinary General Meetings,
- Extraordinary General Meetings,
- Special Meetings for holders of shares in a particular category.

ARTICLE 28 - Notifications to attend

Meetings are convened by the Board of Directors. They may also be convened by the Auditor or Auditors or by a court representative under the terms and procedures specified by the Law.

During a period of liquidation, Meetings are convened by the liquidator or liquidators.

Meetings are held at the registered offices or in any other place indicated in the notification to attend the meeting.

No later than thirty-five (35) days before the date of the Meeting, a notice of meeting is published in the French *Bulletin des Annonces Légales Obligatoires* (BALO). Notifications to attend are published at least fifteen (15) days before the date of the Meeting via a notice published in the BALO and inserted into a newspaper accepting legal announcements for the department in which the head office is located.

However, shareholders owning shares in their own name for at least one (1) month on the date the convocation's notice is inserted into the newspaper shall be given notice individually, via an ordinary letter (or by registered letter if they request it and cover the related costs) sent to their last known address. This notification may also be sent via an electronic means of communication or remote data transmission, instead of by post, after obtaining the approval of the interested shareholders by post or by electronic means.

Notifications to attend must contain the following information:

- The identity of the Company,
- The date, place and time of the Meeting,
- The nature of the Meeting,
- The agenda for the Meeting.

When a Meeting is not able to deliberate due to a lack of the required quorum, a second Meeting must be convened at least ten (10) days in advance, in the same form as the first one. Notifications or letters inviting members to attend this second Meeting should reproduce the date and agenda of the first meeting.

ARTICLE 29 - Agenda

The agenda of the Meetings is determined by the author of the notification to attend.

One or more shareholders representing at least the share of the company's capital fixed by the Law and acting under and within the legal terms and deadlines, have the right to call for, by registered letter with a form for acknowledgement of receipt or by electronic means or remote data transmission, points or draft resolutions to be included in the agenda for the Meeting.

The Meeting may not deliberate on a question that is not included in the agenda, which cannot be altered for a second convocation. It can, however, in all circumstances, revoke the appointment of one or more directors of the Board of Directors and proceed with their replacement.

ARTICLE 30 - Participation of Shareholders in General Meetings

The right to participate in Meetings is defined and justified in accordance with the provisions of article R.225-85 of the French Commercial Code.

For the calculation of the quorum and the majority, the Shareholders participating, as the case may be, to the Meeting by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in accordance with applicable laws and regulations and as set out below.

Each shareholder may vote by postal ballot or by proxy (including by electronic means) in accordance with the applicable legislation, and notably by means of a form filled in and sent to the Company in the conditions set by law and by regulations.

Any shareholder may also participate in and vote at meetings by videoconference or any other means of telecommunication or electronic transmission (including by the transmission of an electronic voting form or a proxy form) allowing him/her to be identified, under the conditions and in accordance with the procedures stipulated in the legal and regulatory provisions in force. The decision of the Board of Directors to use telecommunication facilities or videoconferencing will be published in the meeting notice and the notice of summons.

The submission and signature of the electronic form may be directly performed on a dedicated website with a login and a password. The proxy or vote, thus expressed prior to the Meeting by this electronic means, and the confirmation of receipt given thereof, shall be considered as irrevocable written instructions and binding on all parties, it being specified that, in the event of a transfer of ownership prior to the legal period for the purpose of recording the shares, the Company will consequently invalidate or modify, as applicable, the proxy or vote expressed prior to this date and this time.

ARTICLE 31 – Presidency – *Bureaux* - Attendance sheet

Meetings are chaired by the President of the Board of Directors, or in his/her absence, by a director specially appointed for this purpose by the Board of Directors. Failing this, the Meeting elects a President itself.

Two shareholders, present and willing, representing, both for themselves as well as representatives, the largest number of votes act as tellers.

The *Bureau* appoint a Secretary who may be chosen from outside the shareholders.

An attendance sheet should be completed for each Meeting containing the information prescribed by the Law.

ARTICLE 32 - Quorum - right to vote

In Ordinary and Extraordinary General Meetings, a quorum is calculated based on all the shares comprising the Company's capital and, in Special Meetings, based on all the shares in the relevant category, reduced by shares deprived of voting rights in accordance with the Law.

The right to vote attached to shares is proportional to the share of the capital they represent. Each capital or dividend share gives the right to one vote.

As an exception to the above provisions, any shareholder, regardless of nationality, whose shares are fully paid-up and have been registered in a nominative account in the name of the same holder for at least two years, enjoys a double voting right in accordance with the Law.

Forms that do not indicate a vote in any particular direction or that express an abstention are considered as votes against.

For the calculation of the quorum and the majority, the shareholders participating, as the case may be, to the meeting by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in compliance with applicable legal and statutory provisions and article 30 above.

ARTICLE 33 - Minutes

Meetings' deliberations are recorded in minutes prepared in a special register kept at the head office and signed by the members of the *bureau* of the General Meeting.

Copies or extracts of the minutes of the deliberations are certified either by the Chairman of the Board of Directors, or by a director of the Board of Directors, or by the Meeting's Secretary. In the event of dissolution, they can be certified by the liquidator(s).

ARTICLE 34 - Communication of documents

All shareholders have the right to obtain communication of, and the Board of Directors has an obligation to send them or provide them with, the documents they need to make an informed decision and judgement on the management and operation of the Company.

The nature of these documents and the terms of their dispatch or their availability to shareholders are determined in accordance with applicable legislation.

In order to exercise their right of communication, shareholders or their representatives may obtain the assistance of an expert registered in one of the lists drawn up by the Courts and Tribunals.

Exercising the right of communication carries with it the right of copying, except where this concerns inventories.

B - Provisions specific to Ordinary General Meetings

ARTICLE 35 - Ordinary General Meeting

Ordinary General Meetings can take all decisions, other than those with the effect of directly or indirectly modifying the Articles of Association.

They meet at least once a year, within six (6) months of the end of each financial year, to rule on the accounts for this financial year, unless this period of time is extended by order of the President of the Commercial Tribunal ruling at the Board of Directors' request.

They meet on an extraordinary basis each time the Company's interests require it.

The Ordinary General Meetings can only deliberate validly, when convened the first time, if the quorum, as calculated pursuant to article 32 above, is at least one fifth of the shares with voting rights.

The second time the Meeting is convened, no quorum is required as long as the original agenda has not been modified.

The Ordinary General Meetings shall act on the basis of a majority of votes of the shareholders participating to the Ordinary General Meetings in accordance with the conditions listed in article 30 above.

C - Provisions specific to Extraordinary General Meetings

ARTICLE 36 - Extraordinary General Meeting

Extraordinary General Meeting is the sole authorized to modify all the provisions of the Articles of Association and to decide in particular the conversion of the Company into a Company of another form. It may not however increase shareholders' commitments, subject to transactions resulting from a consolidation of shares carried out legally.

Extraordinary General Meeting can only deliberate validly, when convened the first time, if the quorum as calculated pursuant to article 32 above, is at least, a quarter of the shares with voting rights and, the second time as calculated pursuant to article 32 above, one fifth of the shares with voting rights. Where this latter quorum is not reached, the second Extraordinary General Meeting may be postponed to a later date being no more than two (2) months after it had been convened.

It shall act on the basis of a two thirds majority of votes of the shareholders participating to the Extraordinary General Meeting, in accordance with the conditions listed in article 30 above.

As a legal exception to the above provisions, a General Meeting that decides a capital increase by incorporation of reserves, profits or issue premiums, may rule under the terms of a quorum and a majority of an Ordinary General Meeting.

In addition, when an Extraordinary General Meeting is called on to deliberate concerning the approval of a contribution in kind or the granting of a special benefit, shares belonging to the contributor or the beneficiary are not taken into account when calculating the majority. The contributor or the beneficiary does not have voting rights, either for themselves or as representatives.

D - Provisions specific to Special Meetings of holders of shares of a particular category

ARTICLE 37 - Special Meeting

If several categories of shares exist, no modification may be made to the rights attributable to shares in one of these categories without a valid vote at an Extraordinary General Meeting open to all shareholders and, in addition, without a valid vote at a Special Meeting which is opened to owners of shares in the relevant category alone.

Special Meetings can only deliberate validly, when convened the first time, if the quorum, as calculated pursuant to article 32 above, is at least one-third of the shares with a voting right, whose right is due to be modified and, the second time as calculated pursuant to article 32 above, a fifth of the shares carrying a voting right, whose right is due to be modified. Where this latter is not reached, the second Special Meeting may be postponed to a later date being no more than two (2) months after it had been convened.

They shall act on the basis of a majority of two thirds of the votes of the shareholders participating to the Special Meeting, in accordance with the conditions listed in article 30 below.

PART VI
COMPANY YEAR - ANNUAL ACCOUNTS - ALLOCATION AND DISTRIBUTION OF PROFITS

ARTICLE 38 - Company year

The Company year starts on 1 January in each year and ends on 31 December.

ARTICLE 39 - Accounts

Official accounts of the Company's transactions should be kept in accordance with the laws and normal business practices.

At the end of each financial year, the Board of Directors should draw up an inventory of the various assets and liabilities existing on this date. It should also prepare a balance sheet describing the assets and liabilities, a profit and loss account summarizing income and expenditure for the financial year, as well as an appendix supplementing and commenting on the information given in the balance sheet and profit and loss account.

All these documents should be made available to the Auditors in accordance with legal regulations.

ARTICLE 40 – Terms of dividends distribution

The profit and loss account which summarizes income and expenditure for the financial year reveals by difference, after deduction of depreciation costs and provisions, the profit or loss for the financial year.

From profits, reduced if need be by previous losses, is first deducted five per cent to constitute the legal reserve fund; this deduction ceases to be mandatory when the aforesaid fund reaches a tenth of share capital; it is resumed when for any particular cause the reserve drops below this figure of a tenth.

Distributable profit is composed of the profit for the financial year, less previous losses and amounts allocated to reserves under the Law or the Articles of Association, increased by accumulated profits.

In addition the General Meeting may decide to distribute sums taken from the reserves that are available to it, specifically indicating the reserve accounts from which such distributions should be taken. However, as a priority, dividends are taken from the financial year's distributable profits.

Excluding circumstances of a reduction in capital, no distribution may be made to shareholders when shareholders equity is or following the distribution would become, less than the amount of capital increased by reserves at which level the Law or the Articles of Association do not permit a distribution.

After approval of the accounts and the existence of distributable sums has been ascertained, the General Meeting determines the share allocated to shareholders, in respect of a dividend, proportionally to the number of shares belonging to each of them.

However, after deduction of the sums allocated to the reserve, under the Law, the General Meeting may decide to allocate all or part of the distributable profit to the deferral account or to any general or special reserve accounts.

Losses, if such exist, are allocated to profits carried forward from previous financial years until they are absorbed or carried forward.

Interim dividends may be distributed, as decided by the Board of Directors before approval of the accounts for the financial year under the terms set out or authorized by the Law. The amount of these interim payments may not exceed the amount of profit as defined by the Law.

ARTICLE 41 - Dividends

I. Procedures for the payment of dividends or interim dividends are set out by the General Meeting or, failing that, by the Board of Directors. However payment must occur within a maximum period of nine (9) months after the close of the financial year, unless an extension is granted by court order.

No dividends may be claimed back from shareholders, unless the distribution was carried out in violation of the legal provisions

Unclaimed dividends within five years of their payment are lapsed.

II. The General Meeting ruling on the accounts for the financial year has the option of granting shareholders for all or part of the dividend distributed or interim payments made against the dividend, an option between payment of the dividend or interim payments in cash or in shares issued by the Company, under the terms set out or authorized by the Law.

PART VII
SHAREHOLDERS EQUITY BECOMING LESS THAN HALF THE CAPITAL

ARTICLE 42 - Early dissolution

If, due to losses recorded in the Company's accounts, shareholders' equity in the Company is reduced to less than half of the share capital, the Board of Directors must, within four (4) months following approval of the accounts in which this loss is recorded, convene an Extraordinary General Meeting in order to decide whether an early dissolution of the Company is necessary.

If dissolution is not decided on, the capital must be, within the deadline set out by the Law, reduced by an amount equal to that of the losses recorded if within this period, shareholders' equity has not returned to a value at least equal to half the Company's share capital.

In both circumstances, the Meeting's decision must be published under the regulatory requirements.

A decision to reduce capital to an amount lower than the legal minimum can only be agreed under the condition precedent of a capital increase designed to raise it to an amount at least equal to this minimum amount.

In the event of a breach of the requirements of one or more of the above paragraphs, any interested party may apply to the courts for the dissolution of the Company. The same applies if the shareholders have not been able to hold valid deliberations.

Nevertheless, the Court cannot pronounce dissolution if, on the day it is due to issue its ruling concerning the substance, the situation is rectified.

PART VIII
DISSOLUTION - LIQUIDATION

ARTICLE 43 - Dissolution

The Company is dissolved on expiry of the term set out by the Articles of Association, except where the term has been extended, or by a decision of the Extraordinary General Meeting.

The dissolution may also be ordered through a decision of the Courts at the request of any interested party, when the number of shareholders is reduced to less than seven for more than a year. In these circumstances, the Court may grant the Company a maximum period of six (6) months to rectify the situation; it may not order the Company's dissolution if, on the day when it rules on the substance, the situation has been rectified.

The Company is in liquidation, from the very moment of its dissolution, regardless of the cause, except in the event of dissolution carried out in accordance with article 1844-5 para. 3 of the French Civil Code.

Dissolution ends the duties of the directors of the Board of Directors, the Chief Executive Officer, and as the case may be, the Deputy Chief Executive Officers; however, the Auditors continue their mission.

The General Meeting retains the same powers as during the life of the Company.

The General Meeting that orders dissolution determines the method of liquidation and appoints one or more liquidators, whose powers it determines and who exercise their duties in accordance with the applicable law.

The Company's legal personality persists for the needs of its liquidation and until the liquidation process is complete, but its name must be followed by the reference "Company in liquidation" as well as the name or names of the liquidators on all deeds and documents issued by the Company and intended for third-parties.

Its shares remain negotiable up to the end of the liquidation process.

The net proceeds of liquidation, after liabilities have been settled, are used in full to reimburse paid-up and non-depreciated share capital.

The surplus, if there is one, shall be distributed among the shareholders in proportion to the number of shares held by each of them.

PART IX
DISPUTES

ARTICLE 44 - Disputes

All disputes that may arise during the life of or the liquidation of the Company, either between the shareholders and the Company, or between the shareholders themselves, concerning the Company's affairs, will be judged in accordance with the Law and subject to the jurisdiction of the competent Courts covering the district in which the headquarters is located.

To this end, in the event of a dispute, all shareholders are required to elect domicile in the jurisdiction of the Court covering the district in which the Company's head office is located and all summons or notifications will be legally served at this domicile.

In the absence of such election of domicile, summons or notifications will be validly served at the Office of the Public Prosecutor of the Republic to the District Court in the district in which the Company's head office is located.

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the ordinary shares, the American Depositary Shares and the articles of association, or bylaws, of GENFIT S.A. ("Genfit" or the "Company") is a summary and does not purport to be complete. This summary is subject to, and qualified in its entirety by reference to, the complete text of the Company's bylaws, which are incorporated by reference as Exhibit 1.2 of the Company's Annual Report on Form 20-F to which this description is also an exhibit. The Company encourages you to read the Company's bylaws carefully.

As of December 31, 2020, GENFIT S.A. had the following series of securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, nominal value €0.25 per share*	*	The Nasdaq Global Select Market*
American Depositary Shares, each representing one ordinary share, nominal value €0.25 per share	GNFT	The Nasdaq Global Select Market

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

I. ORDINARY SHARES

The Company is a *société anonyme* organized under the laws of France and registered at the Register of Commerce and Companies of Lille Métropole (*Registre du commerce et des sociétés*) under the number 424 341 907.

As of December 31, 2020, the Company's outstanding share capital consisted of a total of 38,888,379 issued ordinary shares, fully paid and with a nominal value of €0.25 per share.

Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares

The description below reflects the terms of our bylaws and summarizes the material rights of holders of our ordinary shares under French law. Please note that this is only a summary and is not intended to be exhaustive. For further information, please refer to the full text of our bylaws, a copy of which has been filed as Exhibit 1.2 of the annual report on Form 20-F of which this description is also an exhibit.

Corporate Purpose (Article 4 of the Bylaws)

Our corporate purpose in France and abroad includes the research concerning the production and sale, at different stages of development, of biological molecules and all other activities regardless of what they may be, linked to the pharmaceutical industry, and more generally, to carry out all commercial, industrial, financial, securities or real estate transactions and operations linked directly or indirectly to its activity or capable of its facilitation.

Directors (Articles 14-25 of the Bylaws)

Duties of the Board. Our board of directors determines the orientations of the company's activity and ensures their implementation. Subject to the powers expressly assigned to the general meetings, and within the limits of the corporate purpose of our company, it shall deal with all issues pertaining to the proper functioning of the company and settle by its decisions our company's business. In relation to third parties, the company will be committed even by the actions of the board of directors which do not fall within the scope of our company's purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that they could not be unaware thereof given the circumstances.

Appointment and Term. Our board of directors must be composed of at least three members, but may not exceed 15

members, subject to the dispensation established by law in the event of merger, in which case the number may be increased to 24. In appointing and electing directors, we seek a balanced representation of women and men. The term of a director is 5 years, and directors may be re-elected at our annual ordinary shareholders meetings; however, a director over the age of 75 may not be appointed if such appointment would result in the number of directors over the age of 75 constituting more than one-third of the board. The number of directors who are also our employees cannot exceed one-third of the board. Directors may be natural persons or legal entities except for the chairman of the board who must be a natural person. Legal entities appointed to the board must designate a permanent representative. If a director dies or resigns between annual meetings, the board may appoint a temporary director to fill the vacancy, subject to ratification at the next ordinary general meeting, or, if such vacancy results in a number of directors below three, the board must call an ordinary general meeting to fill the vacancy.

Organization. The board of directors must elect a chairman from among the board members. The chairman must be a natural person, age 80 or younger, and may be removed by the board at any time. The board may also elect a natural person as deputy chairman who will fulfill the functions of the Chairman in his absence and may designate one or more non-voting board observers, whether companies or individuals, shareholders or not.

Deliberations. At least half of the number of directors in office must be present to constitute a quorum. Decisions are made by a majority of the directors present or represented and, if there is a tie, the vote of the chairman will carry the decision. Meetings may be held as often as required; however, the chairman is required to call a meeting with a determined agenda upon the request of at least one-third of the directors if the board has not met for more than two months. French law and our charter and bylaws allow directors to attend meetings in person or, to the extent permitted by applicable law and with specified exceptions in our bylaws, by videoconference or other telecommunications means allowing them to be identified and ensuring an effective participation in accordance with applicable laws and regulations.

Directors' Voting Powers on Proposal, Arrangement or Contract in which any Director is Materially Interested. Under French law, any agreement entered into, directly or through an intermediary, between us and any director that is not entered into in the ordinary course of our business and upon standard market terms is subject to the prior authorization of the board of directors. The interested director cannot vote on such decision. All agreements entered into between our company and one of our director, our chief executive officer, one of its deputy chief executive officer, an observer or a shareholder that holds over 10% of the voting rights, or further, if a legal person, a controlling company within the meaning of article L.233-3 of the French Commercial Code holding over 10% of the voting rights, must be subject to prior authorization from the board of directors. The chairman will in turn gives notice to our statutory auditors of all authorized regulated agreements and submits them to the general meeting for approval.

Directors' Compensation. Director compensation for attendance at board meetings (*jetons de présence*) is determined at the annual ordinary general meeting. Independent directors have a right to a fixed amount of compensation for their duties as director and, if applicable, as member or chair of one or more board committees and to a variable amount of compensation depending on their actual participation at board meetings and, if applicable, committee meetings.

Board of Directors' Borrowing Powers. Subject to any limitation set up by the general meeting of shareholders, there are currently no limits imposed on the amounts of loans or borrowings that the board of directors may approve.

Directors' Share Ownership Requirements. Our directors are not required to own any of our shares.

Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)

Dividends. We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.

"*Distributable Profits*" consist of our statutory net profit in each fiscal year, calculated in accordance with accounting standards applicable in France, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to applicable French laws and regulations.

Legal Reserve. Pursuant to French law, we must allocate 5% of our statutory net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. However, it is resumed when for any particular cause the reserve drops below 10%.

Approval of Dividends. Pursuant to French law, our board of directors may propose a dividend for approval by the shareholders at the annual ordinary general meeting.

Upon recommendation of our board of directors, our shareholders may decide to allocate all or part of any distributable profits to special or general reserves, to carry them forward to the next fiscal year as retained earnings or to allocate them to the shareholders as dividends. However, dividends may not be distributed when our net assets are or would become as a result of such distribution lower than the amount of the share capital plus the amount of the legal reserves which, under French law, may not be distributed to shareholders.

Our board of directors may distribute interim dividends after the end of the fiscal year but before the approval of the financial statements for the relevant fiscal year when the interim balance sheet, established during such year and certified by an auditor, reflects that we have earned distributable profits since the close of the last financial year, after recognizing the necessary depreciation and provisions and after deducting prior losses, if any, and the sums to be allocated to reserves, as required by law or the bylaws, and including any retained earnings. The amount of such interim dividends may not exceed the amount of the profit so defined.

Pursuant to French legislation, if a dividend is declared we may be required to pay a dividend tax in an amount equal to 3% of the aggregate dividend paid by us. However, the European Court of Justice, or ECJ, has ruled that the 3% dividend tax may not be applied to redistribution of dividends we receive from our subsidiaries established in another Member State of the EU, in that it creates double taxation of profits made within the EU as prohibited by Article 9 of the Parent-Subsidiary directive (ECJ, 1st ch. May 17, 2017, case C-365/16 AFEP).

Distribution of Dividends. Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our board of directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Shareholders may be granted an option to receive dividends in cash or in shares, in accordance with legal conditions. The conditions for payment of dividends in cash shall be set at the shareholders' meeting or, failing this, by the board of directors.

Timing of Payment. Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

Voting Rights. Each share shall entitle its holder to vote and be represented in the shareholders' meetings in accordance with the provisions of French law and of our bylaws. Ownership of one share implies, ipso jure, adherence to our bylaws and the decisions of the shareholders' meeting.

In general, each shareholder is entitled to one vote per share at any general shareholders' meeting. Pursuant to our bylaws, however, a double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years.

Under French law, treasury shares or shares held by entities controlled by us are not entitled to voting rights and do not count for quorum purposes.

Rights to Share in Our Profit. Each share entitles its holder to a portion of the corporate profits and assets proportional to the amount of share capital represented thereby.

Rights to Share in the Surplus in the Event of Liquidation. If we are liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of our shares. Any surplus will be distributed pro rata among shareholders in proportion to the number of shares respectively held by them, taking into account, where applicable, of the rights attached to shares of different classes.

Repurchase and Redemption of Shares. Under French law, we may acquire our own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for one of the following purposes:

- to decrease our share capital, provided that such a decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at an extraordinary general meeting; in this case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;

- to meet obligations arising from debt securities that are exchangeable into equity instruments;

- to provide shares for distribution to employees or managers under a profit-sharing, free share or share option plan; in this case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or

- we benefit from a simple exemption when the acquisition is made under a liquidity contract complying with the general regulations of, and the market practice accepted by the French Financial Markets Authority (AMF).

All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article L.225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.

Under MAR and in accordance with the General Regulations of the AMF (*Réglement Général de l'AMF*), a corporation shall report to the competent authority of the trading value on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of shares may result in us holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

Sinking Fund Provisions. Our bylaws do not provide for any sinking fund provisions.

Liability to Further Capital Calls. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Requirements for Holdings Exceeding Certain Percentages. Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code coming to directly or indirectly own, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater than or equal to 2% or a multiple of this percentage, must inform us of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds. This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In addition, any shareholder required the above information shall inform us of its objectives it intends pursuing over the following 12 months, when the thresholds are crossed, either upwards or downwards, of a tenth, a fifth, or third of the capital or voting rights, including notably whether it acts alone or in concert, it intends to continue acquiring

our shares, it intends to acquire or transfer control of the company, its intended management strategy for the company.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

These requirements apply without prejudice to requirements described below under the sections titled “Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)” and “Form, Holding and Transfer of Shares (Articles 13 and 15 of the Bylaws)—Ownership of Shares by Non-French Persons.”

Actions Necessary to Modify Shareholders’ Rights

Shareholders’ rights may be modified as allowed by French law. However, the extraordinary shareholders’ meeting is authorized to amend any and all provisions of our bylaws. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

Special Voting Rights of Warrant Holders

Under French law, the holders of warrants of the same class (i.e., warrants that were issued at the same time and with the same rights), including founder’s warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

Rules for Admission to and Calling Annual Shareholders’ Meetings and Extraordinary Shareholders’ Meetings (Part V of the Bylaws)

Access to, Participation in and Voting Rights at Shareholders’ Meetings. The right to participate in shareholders’ general meetings is defined and justified in accordance with the provisions of article R.225-85 of the French Commercial Code. For the calculation of the quorum and the majority, the shareholders participating, as the case may be, to the shareholders’ general meetings by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in accordance with applicable French laws and regulations. Each of our shareholders may vote by postal ballot or by proxy (including by electronic means) in accordance with applicable legislation, and notably by means of a form filled in and sent to our company in the conditions set by applicable French laws and by regulations. Any shareholder may also participate in and vote at meetings by videoconference or any other means of telecommunication or electronic transmission (including by the transmission of an electronic voting form or a proxy form) allowing him/her to be identified, under the conditions and in accordance with the procedures stipulated in the legal and regulatory provisions in force. The decision of the board of directors to use telecommunication facilities or videoconferencing will be published in the meeting notice and the notice of summons.

Participation in shareholders’ general meetings, in any form whatsoever, is subject to registration of shares under the conditions and time limits provided for applicable French laws and regulations.

The final date for returning voting ballots by correspondence is set by the board of directors and disclosed in the notice of meeting published in the French Journal of Mandatory Statutory Notices, or BALO *(Bulletin des Annonces Légales Obligatoires)*. This date cannot be earlier than three days prior to the meeting.

A shareholder who has voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which we send to such shareholder either at the shareholder's request or at our initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.

A shareholder may vote by correspondence by means of a voting form, which we send to such shareholder either at the shareholder's request or at our initiative, or which we include in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on our website at least 21 days before the date of the meeting. The voting form must be recorded by us three days prior to the shareholders' meeting, in order to be taken into consideration. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

Notice of Annual Shareholders' Meetings. Shareholders' meetings are convened by our board of directors, or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances. Meetings are held at our registered offices or at any other location indicated in the convening notice (*avis de convocation*). A meeting announcement (*avis de réunion*) is published in the BALO at least 35 days prior to a meeting, as well as on our website at least 21 days prior to the meeting. In addition to the particulars relative to the company, it indicates, notably, the meeting's agenda and the draft resolutions that will be presented. The requests for recording of issues or draft resolutions on the agenda must be addressed to the company under the conditions provided for in the current legislation.

Subject to special legal provisions, the convening notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the BALO. Further, the holders of registered shares for at least a month at the time of the insertion of the convening notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder after obtaining their agreement by post or by electronic means in accordance with legal and regulatory requirements. The latter may expressly request by post or by electronic means to the Company at least 35 days prior to the date of the insertion of the convening notice in a legal announcement bulletin and in the BALO that the aforementioned means of telecommunication should be replaced in the future by a mailing.

The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.

When the shareholders' meeting cannot deliberate due to the lack of the required quorum, the second meeting must be called at least ten days in advance in the same manner as used for the first notice.

Agenda and Conduct of Annual Shareholders' Meetings. The agenda of the shareholders' meeting shall appear in the convening notice of the meeting and is set by the author of the notice. The shareholders' meeting may only deliberate on the items on the agenda except for the removal of directors and the appointment of their successors which may be put to vote by any shareholder during any shareholders' meeting. Pursuant to French law and our current share capital, one or more shareholders representing 5% of our share capital may request the inclusion of items or proposed resolutions on the agenda. Such request must be received at the latest on the 25th day preceding the date of the shareholders' meeting, and in any event no later than the 20th day following the date of the shareholders' meeting announcement.

Shareholders' meetings shall be chaired by the Chairman of the board of directors or, in his or her absence, by a director elected for this purpose. Failing that, the meeting itself shall elect a Chairman. Vote counting shall be performed by the two members of the meeting who are present and accept such duties, who represent, either on their own behalf or as proxies, the greatest number of votes.

Ordinary Shareholders' Meeting. Ordinary shareholders' meetings are those meetings called to make any and all decisions that do not amend our bylaws. An ordinary meeting shall be convened at least once a year within six

months of the end of each fiscal year in order to approve the annual and consolidated accounts for the relevant fiscal year or, in case of postponement, within the period established by court order. Upon first notice, the meeting may validly deliberate only if the shareholders present or represented by proxy or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission in accordance with the applicable laws and regulations, represent at least one-fifth of the shares entitled to vote. Upon second notice, no quorum is required. Decisions are made by a majority of the votes held by the shareholders present, or represented by proxy, or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission. Abstentions will have the same effect of a "no" vote. In addition, pursuant to the AMF recommendation applicable from June 15, 2015, French listed companies may be required to conduct a consultation of the ordinary shareholders' meeting prior to the disposal of the majority of their assets, under certain circumstances.

Extraordinary Shareholders' Meeting. Our bylaws may only be amended by approval at an extraordinary shareholders' meeting. Our bylaws may not, however, be amended to increase shareholder commitments without the approval of each shareholder. Subject to the legal provisions governing share capital increases from reserves, profits or share premiums, the resolutions of the extraordinary meeting shall be valid only if the shareholders present, represented by proxy or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission represent at least one-fourth of all shares entitled to vote upon first notice, or one-fifth upon second notice. If the latter quorum is not reached, the second meeting may be postponed to a date no later than two months after the date for which it was initially called. Decisions are made by a two-thirds majority of the votes held by the shareholders present, represented by proxy, or voting by correspondence, by videoconference or electronic transmission. Abstentions will have the same effect of a "no" vote.

Provisions Having the Effect of Delaying, Deferring or Preventing a Change in Control of Our Company

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. 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 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 sections below titled "Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)—Requirements for Holdings Exceeding Certain Percentages" and "Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)";

- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and

- pursuant to French law, the sections of the bylaws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)

Set forth below is a summary of certain provisions of the French Commercial Code applicable to us. This summary is not intended to be a complete description of applicable rules under French law.

Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code coming to directly or indirectly own, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater or equal to 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% and 95% shall inform us as well as the French Financial Markets Authority (AMF) of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds.

This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code.

In addition, any shareholder crossing, alone or acting in concert, the 10%, 15%, 20% or 25% threshold shall file a declaration with the AMF pursuant to which it shall expose its intention over the following 6 months, including notably whether it intends to continue acquiring shares of the company, it intends to acquire control over the company, its intended strategy for the company.

Further, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 30% threshold shall file a mandatory public tender offer with the AMF. Also, any shareholder holding directly or indirectly a number between 30% and 50% of the capital or voting rights and who, in less than 12 consecutive months, increases his/her/its holding of capital or voting rights by at least 1% company's capital or voting rights, shall file a mandatory public tender offer.

Pursuant to the provisions of Article 11 of our bylaws, such individual or legal entity acquiring directly or indirectly, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater than or equal to 2% or a multiple of this percentage, must inform us of the total number of shares and voting rights and securities giving access to capital and voting rights it owns immediately or subsequently within a period of four trading days from the crossing of the said holding thresholds.

The individual or company required to provide the above information shall inform us of the objectives it intends pursuing during the next 12 months when the thresholds are crossed, either upwards or downwards, of a tenth, fifth or third of the capital or voting rights. This declaration specifies whether the purchaser is acting alone or in concert, if it intends stopping its purchases or sales or continuing them, or whether it intends acquiring or transferring control of our company, requesting its nomination or that of one or more other persons, or its registration, as a director of the Board of directors.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared in accordance with the provisions of Article 11 of our bylaws, such share shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

Changes in Share Capital

Increases in Share Capital (Article 7 of the Bylaws). Pursuant to French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; and
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;

- by conversion of previously issued debt instruments;

- by capitalization of profits, reserves or share premium; and

- subject to certain conditions, by way of offset against debt incurred by us.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings.

Reduction in Share Capital. Pursuant to French law, any reduction in our share capital requires shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

Preferential Subscription Right. According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights to these securities on a *pro rata* basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe *pro rata* based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, our share capital by means of a cash payment or a set-off of cash debts. The preferential subscription rights are transferable during the subscription period relating to a particular offering. Pursuant to legislation that went into effect on October 1, 2016, the preferential subscription rights will be transferable during a period starting two days prior to the opening of the subscription period and ending two days prior to the closing of the subscription period.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of our shareholders or individually by each shareholder. Our board of directors and our independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

In the future, to the extent permitted under French law, we may seek shareholder approval to waive preferential subscription rights at an extraordinary general shareholders' meeting in order to authorize the board of directors to issue additional shares and/or other securities convertible or exchangeable into shares.

Form, Holding and Transfer of Shares (Articles 9 and 10 of the Bylaws)

Form of Shares. The shares are in registered form, until their full payment. When they are fully paid up, they may be in registered form or bearer, at the option of the shareholders.

Further, in accordance with applicable laws, we may request at any time from the central depository responsible for holding our shares, the information referred to in Article L. 228-2 of the French Commercial Code. Thus, we are, in particular and at any time, entitled to request the name and year of birth or, in the case of a legal entity, the name and the year of incorporation, nationality and address of holders of securities conferring immediate or long-term voting rights at its general meetings of shareholders and the amount of securities owned by each of them and, where applicable, the restrictions that the securities could be affected by.

Holding of Shares. In accordance with French law concerning the "dematerialization" of securities, the ownership rights of shareholders are represented by book entries instead of share certificates. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions.

Ownership of Shares by Non-French Persons. Neither the French Commercial Code nor our bylaws limit the right of non-French residents or non-French shareholders to own or, where applicable, to vote our securities. However,

non-French residents must file a declaration for statistical purposes with the Bank of France (Banque de France) within twenty working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross of such 10% threshold. Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

Assignment and Transfer of Shares. Shares are freely negotiable, subject to applicable legal and regulatory provisions. French law notably provides for standstill obligations and prohibition of insider trading.

Forum Selection Provision (Article 44 of the Bylaws)

Our bylaws also include a provision that applies to actions between shareholders and us and between shareholders themselves that are predicated on French corporate law. The competent court is the Commercial Court of Lille. This provision does not apply to actions arising under U.S. federal securities laws. In addition, it is possible that a court could find this provision in our bylaws inapplicable or unenforceable.

Differences in Corporate Law

We are a *société anonyme*, or S.A., incorporated under the laws of France. The laws applicable to French *sociétés anonymes* differ from laws applicable to Delaware corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to us and the Delaware General Corporation Law relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and French law.

	FRANCE	**DELAWARE**
Number of Directors	Under French law, a *société anonyme* must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the bylaws. In addition, the composition of the board of directors endeavors to seek a balanced representation of women and men. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied as well as the deliberations taken by the director irregularly appointed will be null and void. The directors are appointed at the shareholders' general meetings.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the Chairman of the board of directors), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.

	FRANCE	DELAWARE
Removal of Directors	Under French law, directors may be removed from office, with or without cause, at any shareholders' general meeting without notice or justification, by a simple majority vote of the shareholders present and voting at the meeting in person or by proxy.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death, resignation or removal, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification by the shareholders by the next shareholders' general meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors.
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months after the end of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing which, by the statutory auditors, or by a court appointed agent (*mandataire ad hoc*) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	A meeting announcement is published in the French Bulletin of Mandatory Legal Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the meeting. Subject to special legal provisions, the meeting notice is sent out at least fifteen days prior to the date of the meeting, by means of a notice inserted both in a newspaper for legal notices (*journal d'annonces légales*) of the registered office department and in the BALO. Further, shareholders holding registered shares for at least a month at the time latest insertions of the notices shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice to registered shareholders may also be transmitted by electronic means of telecommunication, in place of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. When the shareholders' meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice. The notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Commerce and Companies (*registre du commerce et des sociétés*), the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

	FRANCE	DELAWARE
Proxy	Each shareholder has the right to attend the meetings and participate in the discussions (1) personally, or (2) by granting proxy to his/her spouse, his/her partner with whom he/she has entered into a civil union or to another shareholder or to any individual or legal entity of his choosing; or (3) by sending a proxy to the company without indication of the mandate, or (4) by voting by correspondence, or (5) by videoconference or another means of telecommunication in accordance with applicable laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of fifteen days.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period.

	FRANCE	DELAWARE
Shareholder Action by Written Consent	Under French law, shareholders' action by written consent is not permitted in a *société anonyme*.	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.
Preemptive Rights	Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a *pro rata* his/her share ownership unless such rights are waived by a two-thirds majority of the votes held by the shareholders present at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights have not been waived by the extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period cannot be less than five trading days in duration. Preferential subscription rights are transferable during the subscription period, but starting two business days prior to the start of the subscription period and ending two business days prior to its closing.	Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.

	FRANCE	DELAWARE
Sources of Dividends	Under French law, dividends may only be paid by a French *société anonyme* out of "*distributable profits*" (*bénéfices distribuables*) plus any distributable reserves and "*distributable premium*" that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law. "*Distributable profits*" (*bénéfices distribuables*) consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years. "*Distributable premium*" refers to the contribution paid by the shareholders in addition to the par value of their ordinary shares for their subscription that the shareholders decide to make available for distribution. Except in case of a share capital reduction, no distribution can be made to the shareholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the bylaws.	Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus or (2) in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.
Repurchase of Ordinary Shares	Under French law, a corporation may acquire its own ordinary shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes: •to decrease its share capital, provided that such decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at the extraordinary general meeting deciding the capital reduction, in which case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer; •with a view to distributing within one year of their repurchase the relevant shares to employees or managers under a profit-sharing, free share or share option plan; not to exceed 10% of the share capital, in which case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or •to meet obligations arising from debt securities, that are exchangeable into equity instruments. All other purposes, and especially share buy-backs for external growth operations by virtue of Article L. 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulations and insider dealing rules. Under the MAR and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form. No such repurchase of ordinary shares may result in the company holding, directly or through a person acting on its behalf, more than 10% of its issued share capital.	Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.

	FRANCE	DELAWARE
Liability of Directors and Officers	Under French law, the bylaws may not include any provisions limiting the liability of directors. Civil liabilities of the directors may be sought for (1) an infringement of laws and regulations applicable to a company, (2) breach of the bylaws and (3) management failure.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: •any breach of the director's duty of loyalty to the corporation or its stockholders; •acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; •intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or •any transaction from which the director derives an improper personal benefit.
Voting Rights	French law provides that, unless otherwise provided in the bylaws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder. As from April 2016, double voting rights are automatically granted to the shares held in registered form for more than two years, unless provided otherwise in the bylaws.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.
Shareholder Vote on Certain Transactions	Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: •the approval of the board of directors; and •approval by a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant shareholders' meeting or, in the case of a merger with a non-EU company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the Board of Directors authority to decide a merger-absorption or to determine the terms and conditions of the merger plan).	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: •the approval of the board of directors; and •approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

	FRANCE	DELAWARE
Dissent or Dissenters' Appraisal Rights	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock. Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of merger or consolidation requires the holders to accept for their shares anything other than: •shares of stock of the surviving corporation; •shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders; •cash in lieu of fractional shares of the stock described in the two preceding bullet points; or •any combination of the above. In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.

	FRANCE	DELAWARE
Standard of Conduct for Directors	French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest (*intérêt social*). In addition, directors shall take into account social and environmental implications of the Company's business.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.
Shareholder Suits	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 corporate interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders. The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.	Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must: •state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and •allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or •state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

	FRANCE	DELAWARE
Amendment of Certificate of Incorporation	Under French law, corporations are not required to file a certificate of incorporation with the French Registry of Commerce and Companies (*registre du commerce et des sociétés*) and only have bylaws (*statuts*) as organizational documents.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: •its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and •the amendment is adopted by the affirmative votes of a majority (or greater percentage as may be specified by the corporation) of the outstanding shares entitled to vote on the amendment and a majority (or greater percentage as may be specified by the corporation) of the outstanding shares of each class or series of stock, if any, entitled to vote on the amendment as a class or series.
Amendment of Bylaws	Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws.	Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal bylaws. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors.

Listing

Our ordinary shares are currently listed on Euronext Paris under the symbol "GNFT."

Transfer Agent and Registrar

BNP Paribas Securities Services is our transfer agent and registrar and currently maintains our share register for our ordinary shares.

II. AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, registers and delivers American Depositary Shares, or ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with BNP Paribas Securities Services, as custodian for the depositary in France. Each ADS will also represent any other securities, cash or other

property that may be held by the depositary. The depositary's office at which the ADSs are administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

An investor may hold ADSs either (A) directly (i) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs, registered in the investor's name, or (ii) by having uncertificated ADSs registered in the investor's name, or (B) indirectly by holding a security entitlement in ADSs through the investor's broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If an investor holds ADSs directly, he or she is a registered ADS holder, or an ADS holder. The description below assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. French law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will you receive dividends and other distributions on the ordinary shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

Cash. We do not expect to declare or pay any cash dividends or cash distributions on our ordinary shares for the foreseeable future. The depositary will convert any cash dividend or other cash distribution we pay on the ordinary shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Ordinary Shares. The depositary may distribute additional ADSs representing any ordinary shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell ordinary shares which would require it to deliver a fraction of an ADS (or ADSs representing those ordinary shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new ordinary shares. The depositary may sell a portion of the distributed ordinary shares (or ADSs representing those ordinary shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional ordinary shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in

each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse unexercised. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of ordinary shares, new ADSs representing the new ordinary shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, ordinary shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited ordinary share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of France and the provisions of our articles of association or similar documents, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date and we confirm to the depositary that

- we wish to receive a discretionary proxy;
- as of the instruction cutoff date we reasonably do not know of any substantial shareholder opposition to the particular question; and
- the particular question would not be materially adverse to the interests of our shareholders,

then the depositary will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs as to that question.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your ordinary shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

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.

Holders of ADSs who wish to obtain double voting rights will need to surrender their ADSs at the depositary's office. The depositary will in turn deliver the ordinary shares underlying such ADSs to you, and you must then inscribe those shares directly in registered form within the books of our transfer agent and registrar for the ordinary shares for two consecutive years in order to be entitled to double voting rights.

Except as described above, you will not be able to exercise your right to vote unless you withdraw the ordinary shares. However, you may not know about the shareholder meeting enough in advance to withdraw the ordinary shares.

Fees and Expenses

What fees and expenses will you be responsible for paying?

Pursuant to the terms of the deposit agreement, the persons depositing or withdrawing ordinary shares or holders of ADSs will be required to pay the following fees:

Persons depositing or withdrawing ordinary shares or ADS holders must pay:	For:
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	•Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property •Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	•Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs	•Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	•Depositary services
Registration or transfer fees	•Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares
Expenses of the depositary	•Cable and facsimile transmissions (when expressly provided in the deposit agreement) •Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	•As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	•As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your American Depositary Shares to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes. Your obligation to pay taxes and indemnify us and the depository against any tax claims will survive the transfer or surrender of your ADSs, the withdrawal of the deposited ordinary shares as well as the termination of the deposit agreement.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our ordinary shares from an exchange on which they were listed and do not list the ordinary shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, *but*, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;.
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of ordinary shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Ordinary Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our ordinary shares;
- when you owe money to pay fees, taxes and similar charges; or
- 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.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Each holder of ADSs may be required from time to time to provide certain information, including proof of taxpayer status, residence and beneficial ownership (as applicable), from time to time and in a timely manner as we, the depositary or the custodian may deem necessary or proper to fulfill obligations under applicable law.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary 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 in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed by agreeing to the terms of the deposit agreement to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Exhibit 4.8

Summary of the 2020 Stock Options Plans

Stock options (*options de souscription et/ou d'achat d'actions*) are granted for free and entitle each holder to subscribe for new shares and/or purchase existing shares of our Company at an exercise price set at the time of grant.

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors determines the exercise price, the aggregate number of stock options granted and the terms and conditions of the stock options, including the number of shares underlying each stock option, their vesting schedule and exercise period and delegates to the Chief Executive Officer the determination of the list of the beneficiaries and the number of stock options granted to each beneficiary, with the exception of the grant to the Chief Executive Officer, which is decided our board of directors.

Grants. Our stock options were granted to our Chief Executive Officer, executive officers and employees of our Company. A total of 195,000 stock options have been granted and accepted by the beneficiaries under three (3) plans in 2020, with different terms and conditions as set out below. We have one (1) stock option plan for French beneficiaries (SO 2020 C), one (1) stock option plan for our Chief Executive Officer (SO 2020 D) and one (1) stock option plans for U.S. beneficiaries that was designed to benefit from the "Incentive Stock Options" status (SO US 2020).

Underlying shares. The securities to which our stock options give rights are new ordinary shares of our Company. The number of ordinary shares to which each stock option gives right is one (1) new ordinary share.

The number of ordinary shares to which each stock option gives right can be adjusted, upwards or downwards, as a result of certain corporate transactions, such as rights issues.

Standard terms. Our stock options are exercisable during a period of seven (7) years following a three (3) year vesting period at the end of which the beneficiary must be effectively present in our Company or its consolidated subsidiaries (subject to exceptions) and subject to meeting the performance conditions that are assessed by our board of directors.

The terms and conditions of our stock options in respect of each of our plans are as follows:

	Performance conditions	Assessment date(s) of presence and performance conditions	Lock-up period end date	Exercise price
SO 2020 C	Internal performance (1)	December 31, 2023	January 1, 2024	€ 3.50
SO 2020 D	Internal performance (1) External performance (2)	December 31, 2023	January 1, 2024	€ 4.38
SO US 2020	Internal performance(1)	December 31, 2023	January 1, 2024	€ 4.52

(1) Based on the achievement of milestones in the development of our Company.
(2) Based on the evolution of the share price of our Company.

Exhibit 12.1

Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Pascal Prigent, certify that:

1. I have reviewed this annual report on Form 20-F of GENFIT S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 23, 2021

/s/ Pascal Prigent

Name: Pascal Prigent
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas Baetz, certify that:

1. I have reviewed this annual report on Form 20-F of GENFIT S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 23, 2021

/s/ Thomas Baetz

Name: Thomas Baetz
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

Certification by the Principal Executive Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of GENFIT S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Pascal Prigent, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 23, 2021

/s/ Pascal Prigent

Name: Pascal Prigent
Title: Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 13.2

Certification by the Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of GENFIT S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Baetz, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 23, 2021

/s/ Thomas Baetz

Name: Thomas Baetz
Title: Chief Financial Officer
(*Principal Financial Officer*)