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, 2019

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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Tel: +33 (0)3 2016 4000 / Fax: +33 (0)2 2016 4001
(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

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: 38,858,617 shares outstanding as of December 31, 2019**

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

EXPLANATORY NOTE

Genfit S.A. (the "Company") previously disclosed in a Form 6-K furnished with the Securities and Exchange Commission (the "SEC") on April 29, 2020 that it was delaying the filing of this Annual Report on Form 20-F for the year ended December 31, 2019 in reliance on the order issued by the SEC on March 4, 2020 in SEC Release No. 34-88318, as extended and amended on March 25, 2020 in SEC Release No. 34-88465 (the "SEC Order"). The SEC Order provides conditional relief to public companies that are unable to timely comply with their filing obligations as a result of the novel coronavirus ("COVID-19") outbreak, allowing for the postponement of certain filings required under the Securities Exchange Act of 1934, as amended.

As a result of staffing constraints, remote work transitions, mobilization of our finance, legal and clinical teams normally involved in the drafting of our Annual Report on Form 20-F on key business continuity efforts and coordination of the Company's response to the COVID-19 pandemic, especially as it relates to the impacts on the clinical development of elafibranor and our other product candidates, and reliance on certain third-parties to assist us in the production of the Annual Report who were also impacted by COVID-19, the filing of this Annual Report on Form 20-F was delayed.

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INTRODUCTION

Unless otherwise indicated, "GENFIT," "the company," "our company," "we," "us" and "our" refer to GENFIT S.A. and its consolidated subsidiaries.

"GENFIT," the GENFIT logo, "RESOLVE-IT", "NIS4", "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, NIS4 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 diagnostic test;
- 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 successful 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 propriety 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 is generally reliable, such information is inherently imprecise.

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

The following selected consolidated statement of operations data for the years ended December 31, 2017, 2018 and 2019 and selected consolidated statement of financial position data as of December 31, 2017, 2018 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this annual report. 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, as of and for the years ended December 31, 2017, 2018 and 2019.

The following selected consolidated financial data for the years and as of the dates indicated should be read together with, and is qualified in its entirety by reference to, "Item 5. Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this annual report. Our historical results are not necessarily indicative of our results to be expected for any future period.

Selected Consolidated Statement of Operations Data:

	Year ended		
(in € thousands, except earnings per share data)	**2017/12/31**	**2018/12/31**	**2019/12/31**
	(*)	**(*)**	
Revenues and other income			
Revenue	118	69	30,839
Other income	6,737	7,425	10,122
Revenues and other income	6,856	7,494	40,961
Operating expenses and other operating income (expenses)	—	—	—
Research and development expenses	(54,189)	(67,024)	(66,170)
General and administrative expenses	(9,421)	(9,076)	(17,265)
Marketing and market access expenses	—	(717)	(13,708)
Other operating income (expenses)	60	(162)	(1,649)
Operating income (loss)	(56,695)	(69,484)	(57,832)
Financial income	642	728	5,221
Financial expenses	(3,096)	(11,118)	(13,110)
Financial profit (loss)	(2,453)	(10,391)	(7,889)
Net profit (loss) before tax	(59,148)	(79,875)	(65,721)
Income tax benefit (expense)	3,420	354	576
Net profit (loss)	**(55,728)**	**(79,521)**	**(65,144)**
Basic and diluted earnings (loss) per share			
Basic and diluted earnings (loss) per share (€/share)	(1.79)	(2.55)	(1.76)

(*) IFRS16 was adopted on January 1, 2019 using the modified retrospective method and 2017 and 2018 have not been restated

Selected Consolidated Statement of Financial Position Data:

(in € thousands)	As of 2017/12/31 (*)	2018/12/31 (*)	2019/12/31
Cash and cash equivalents	273,820	207,240	276,748
Total - Assets	293,183	229,478	309,853
Total - Shareholders' equity	101,457	20,939	84,065
Total - Current liabilities	27,106	39,248	43,657
Total - Non-current liabilities	164,620	169,291	182,132
Total - Shareholders' equity & liabilities	293,183	229,478	309,853

(*) IFRS16 was adopted on January 1, 2019 using the modified retrospective method and 2017 and 2018 have not been restated

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

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

Our business currently depends substantially on the successful development and commercialization of elafibranor. 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. This ability to generate revenue is also dependent on the future of the development and marketing of an IVD test using our NIS4 technology.

We have been developing elafibranor in several clinical trials, including a pivotal Phase 3 clinical trial, RESOLVE-IT, for the treatment of non-alcoholic steatohepatitis or NASH, and have initiated a Phase 3 clinical program for the treatment of primary biliary cholangitis or PBC, following promising results in a Phase 2 trial.

In parallel, we are also developing NIS4 to identify patients with NASH and fibrosis who may be appropriate candidates for drug therapy in a context where these patients are difficult to identify based on the currently available diagnostic methods. A successful development of NIS4 as a diagnostic technology used in clinical care could have a significant impact on the development and marketing of product candidates currently under development for the treatment of NASH, including elafibranor.

In May 2020, we published the top line results of the interim analysis of our Phase 3 RESOLVE-IT trial. In the trial, elafibranor did not demonstrate a statistically significant effect on the trial's primary endpoint of NASH resolution without worsening of fibrosis nor did it achieve the key secondary endpoints.

Although the results of the interim analysis of our Phase 3 RESOLVE-IT clinical trial do not support our application for accelerated marketing approval from the U.S. Food and Drug Administration or FDA under Subpart H and conditional approval from the European Medicines Agency or EMA, as of the date of this annual report, we are conducting additional analyses of the interim data. Following these analyses and further discussions with regulatory authorities, we will determine whether to discontinue, amend or continue the RESOLVE-IT trial Even if we decide to continue the trial, there is not guarantee that we would be able to obtain marketing approval from the FDA or EMA for elafibranor in NASH.

We currently have no products approved for sale and we cannot guarantee that we or any of our current and collaborators will ever have marketable products. 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. 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 and MAAs must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a NDA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval.

We have received a fast track designation from the FDA for the development of elafibranor for the treatment of NASH. While the fast track designation for elafibranor in NASH permits close and regular contact between us and the FDA, the FDA and the EMA review processes can take more than one year to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing, before even reviewing the scientific basis. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA or the EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of 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. In particular, we are actively reviewing the full interim dataset from our Phase 3 RESOLVE-IT trial of elafibranor in NASH and will be conducting additional analyses. If, following these analyses, we decide to continue the trial, we cannot predict whether regulators will agree with the conclusions from, or request additional clinical data following, our Phase 3 NASH study to support an application for marketing approval of elafibranor in NASH.

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 and our partner Terns Pharmaceuticals in some territories and for some indications are developing our lead product candidate, elafibranor for the treatment of NASH, a condition for which no drug has yet been commercialized and for which there is little clinical experience. In PBC, the other major indication for which we and our partner Terns Pharmaceuticals are developing elafibranor, only two treatments have been approved and are currently marketed and they do not fulfill the medical needs of all patients. As a result, our development approach and that of our partner involve new endpoints and methodologies. The outcome of our clinical trials may not be favorable or , even if favorable, regulatory authorities may not find the results of the clinical trials collaborators to be sufficient for marketing approval.

For the last several years, we have been focused, and more recently along with Terns Pharmaceuticals in some territories, on developing therapeutics for the treatment of NASH, a disease for which there are currently no approved drug treatments. Similarly, only two treatments have been approved and are currently marketed for the treatment of PBC and they do not fulfil the medical needs of all patients. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

The FDA and EMA generally require two pivotal clinical trials to approve an NDA or MAA. Furthermore, for full approval of an NDA or MAA, the FDA or EMA, respectively, require a demonstration of efficacy based on a clinical benefit endpoint. The FDA can grant accelerated approval for a new drug if it complies with the following criteria: (1) it treats a serious condition, (2) it provides a meaningful advantage over available therapies and (3) it demonstrates an effect on an endpoint reasonably likely to predict clinical benefit.

Similarly, 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.

Although we have obtained Fast Track designation from the FDA for elafibranor in the treatment of NASH, which permits more frequent contact between us and the FDA, the potential approval of elafibranor for the treatment of NASH, if we were to decide to continue the RESOLVE-IT trial following the interim results, would depend upon the clinical results from the RESOLVE-IT trial and the review by the FDA and EMA of our or our collaborators applications. As a result, if we decide to continue the trial in view of obtaining regulatory approval of elafibranor in NASH, we or our collaborators may face difficulty in designing an acceptable registration strategy around RESOLVE-IT or any other trials in different subpopulations of NASH patients.

It may be expensive and time consuming to conduct and complete additional preclinical studies and clinical trials that the FDA, EMA and other regulatory authorities may require us to perform. As such, any requirement by the FDA, EMA or other regulatory authorities that we conduct additional preclinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we, our partner Terns Pharmaceuticals, or a future collaborator receives regulatory approval of elafibranor for the treatment of NASH, the labelling for our product candidates in the United States, Europe or other countries in which we, our partner Terns Pharmaceuticals, or a future collaborator have received or seek approval may include limitations that could impact the commercial success of our products.

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 our 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 have 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 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.

We are currently considering the development of some of our drug candidates in combination with other treatments, which exposes us to additional risks.

Depending on our decision whether or not to continue development of elafibranor in NASH, we may also consider the development of elafibranor in combination with one of our drug candidates or other approved drugs or drugs in development.

Combinations of some of our drug candidates with other treaments may not provide the expected synergistic outcomes or other complementary effects or patients may not be able to tolerate our drug candidates in association with other treatments. Even if any product candidate that we develop was able to receive market approval or to be marketed to be used in combination with other existing treatments, we would still be exposed to the risk that the FDA, the EMA or other foreign regulatory authorities may withdraw approval for the treatment in combination with our drug candidate or that issues related to safety, efficiency, production or supply occur with these existing treatments.

We may also evaluate elafibranor or all other future drug candidates in combination with one or more treatments in NASH or PBC that have not yet received market approval from the FDA, the EMA or other similar regulatory authorities. We, our current partner or a future partner may not be able to market and sell elafibranor or any other product candidate that we would develop in combination with these treatments that have not received approval in NASH or PBC if in the end they did not receive market authorization.

Delays in the commencement, enrollment and completion of clinical trials 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 a future collaborators to obtain regulatory approval for elafibranor and our other drug candidates.

Delays in the commencement, enrolment 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 the regulatory approval of our drug candidates. We currently have underway a number of trials including our pivotal Phase 3 RESOLVE-IT clinical study of elafibranor in NASH and are planning to initiate a Phase 3 pivotal trial in PBC. We may also be required to conduct additional clinical trials of elafibranor or our other drug candidates. In the past, we have experienced some delays in enrolment in our clinical trials and our RESOLVE-IT clinical trial in particular. We continue to work towards expanding our overall elafibranor development program with additional trials and studies, including in pediatric patients and product combinations and we plan on conducting additional development activities with elafibranor in other diseases. Terns Pharmaceuticals, our partner for the development of elafibranor in certain territories and for some indications will also launch new trials recruiting specific patient populations.

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 elafibranor as a treatment for the relevant indication. 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 enrolments 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, enrolment 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;
- our 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 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 is a large and complex Phase 3 clinical trial in 2,000 patients, in a disease without any approved therapies and the diagnosis of which generally involves invasive procedures such as liver biopsies. Additionally, there are a number of companies developing product candidates for the treatment of NASH, and, as a result, there may be increased patients in clinical trials involving the treatment of NASH. Furthermore, if one of our competitors' products is approved by the FDA or another regulatory body for the treatment of NASH before elafibranor is approved, we may experience difficulties enrolling patients in our clinical trials and retaining patients in any of our existing clinical trials. .

As we engage in other large and complicated trials and trials in advanced disease populations, including our planned Phase 3 pivot trial evaluating elafibranor in PBC and a Phase 2 trial evaluating NTZ in liver fibrosis, we may experience a number of complications that may negatively affect our plans or our development programs. Our Phase 3 pivotal trial evaluating elafibranor in PBC in particular is made complex by the 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, which may compromise our ability to retain or recruit patients or finalize 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 NASH or PBC, such as the approval of a drug therapy for the treatment of NASH or 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 the validity of our clinical trials may have a material adverse effect on our business or decrease our competitive position relative to other biotechnology or pharmaceutical companies.

In addition, if we or our collaborators are required to conduct additional clinical trials or other preclinical studies of our drug candidates beyond those contemplated, our ability or that of our collaborators to obtain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate that we or our collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

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. 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 NASH and 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. Elafibranor did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis nor on the key secondary endpoints. In addition, if a decision is made to continue the trial to evaluate clinical outcomes,

we cannot assure you that our RESOLVE-IT trial will achieve positive results. Furthermore, regulators may request additional clinical data to support regulatory approval.

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 RESOLVE-IT trial of elafibranor or our planned Phase 3 trial evaluating elafibranor in PBC do not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of elafibranor would be materially and adversely affected in these two therapeutic indications.

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 investor 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.

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

Changes in regulatory requirements, FDA guidance or guidance from the EMA or other European or foreign regulatory authorities, or unanticipated events during our clinical trials, may force us or our current or future collaborators to amend clinical trial protocols or to otherwise alter the regulatory approval or clearance process and timeline for our drug candidates and/or NIS4. Regulatory authorities could also impose additional clinical trial requirements. Amendments to our clinical trial protocols or those of or our current or future collaborators would require resubmission to the FDA, EMA, national clinical trial regulators and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed.

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 must decide which product candidates to pursue and the amount of resources to allocate to each. As such, we are currently primarily focused on the development of elafibranor for the treatment of NASH and PBC, and the parallel development of NIS4 for identifying patients with NASH and fibrosis who may be appropriate candidates for drug therapy. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, programs, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from more promising opportunities. We may not choose the right product candidates or programs to develop, or may be required to collaborate with third parties to advance a particular product candidate at terms that are less than optimal to us. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, our business prospects could be harmed.

Our product candidates may have undesirable side effects 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 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 may need to either restrict our use of such product to a smaller population or abandon our development of elafibranor for NASH, PBC and other potential indications.

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, NASH patients may suffer from other co-morbidities such as diabetes, cardiovascular disease and obesity 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 that we would intend for this patient population will not develop in current or future clinical trials or commercial use, which could delay or preclude their regulatory approval or limit their commercial use. However, DSMBs have been constituted in our main trials and are tasked on the one hand with evaluating side effects observed during our studies at regular intervals defined in our study protocols and with issuing recommendations regarding their continuation or the conditions of their continuation on the other hand.

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.

We or our potential future collaborators may not receive the necessary regulatory approvals to market NIS4, our in-vitro diagnostic test (IVD test) for use in clinical care.

Concurrently with our drug candidates development, we are also developing NIS4 in order to identify patients with NASH and fibrosis who may be eligible for therapeutic intervention.

In order to be allowed to market NIS4 as an IVD 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. We have licensed NIS4 to LabCorp to enable them to promote, sell, and run NIS4 testing within their Covance laboratory network within the context of research or clinical trial use. LabCorp/Covance thus independently operates NIS4. This operation is conducted within the framework of the CLIA and 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/Covance has received.

We currently do not have any IVD test that has been approved for marketing through such a 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 the FDA approval process for our IVD test, we are collecting data to obtain CE Mark and the subsequent market authorization on 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 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 similar regulatory authorities. 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 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.

We intend for NIS4 to be marketed as a clinical IVD and as such, NIS4 remains a product in development subject to the hazards of diagnostic product development, and there is no assurance that we will be able to achieve commercialization of this product candidate for this market.

In January 2019, we entered into a license agreement with Labcorp to allow them to deploy NIS4 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 our test, result in third party publication and provide additional evidence of its clinical utility. We intend to benefit from these advantages to support the next step of the deployment of NIS4 for diagnostic use in clinical care.

This second step will nevertheless require us to keep gathering clinical data within the framework of trials in which NIS4 is currently being evaluated or within the framework of potential additional clinical trials to come. Like for the clinical trials evaluating our drug candidates, delays in launching, advancing or in the final phase of our clinical trials could result in increased costs, delaying or limiting our ability or that of our collaborators to obtain market authorization for NIS4 for use in clinical care. The results of these trials may not be available at the desired time or we or our collaborators may be required to conduct additional clinical trials that we do not currently plan in order to obtain market authorization for NIS4 for clinical care. Besides, these trials are subject to numerous variable factors and hazards, such as the results of other trials, patient recruitment or discussions with regulatory authorities that may result in schedule changes. Therefore, we do not know if these trials will start or end according to the planned schedule, nor even if they will be launched.

In these trials, 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. The strength of the test 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 and sensitivity in order to allow for the development of a competitive test for clinical care that would be adopted by the medical community. Access to these samples could necessitate the implementation of collaborations or partnerships with hospitals or opinion leaders and we may not be in a position to conclude these collaboration or partnerships within a satisfactory timeframe or under satisfactory conditions.

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. A failure may occur at any time during one of these clinical developments. The results of earlier clinical trials does not allow predicting future results and NIS4 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 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 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, 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 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 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, which may result in higher costs and delays in the development schedule of NIS4. If delays occurred in the completion of these clinical trials, or if they were terminated, or if additional clinical trials were required besides the planned ones, this would impact the commercial perspectives of NIS4 and our ability to generate direct or indirect industrial revenue from this product would be delayed.

We are developing NIS4 to diagnose NASH patients eligible for therapeutic intervention in a field where no 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.

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

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

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

- being subject to proprietary rights held by others;

- failing to obtain or otherwise manufacture commercial supply of our approved products;
- failing to obtain clearance from regulatory authorities on the manufacturing of our products;
- failing to establish sales, marketing and distribution capabilities to effectively market and sell elafibranor and NIS4 in the United States, Europe and other territories;
- having adverse side effects that make their use less desirable;
- difficulties in negotiating and securing coverage and adequate reimbursement, or the failure to do so, from third-party payors for elafibranor, NIS4 or any of our other drug candidates, if approved or cleared;
- inability to secure market acceptance by patients and the medical community of elafibranor, NIS4 or any of our other drug candidates, if approved or cleared;
- failing to compete effectively with products or treatments commercialized by competitors; or
- failing to show that the long-term benefits of our products exceed their risks.

Even if 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, 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 no products are currently approved for the treatment of NASH and a limited number of products for the treatment of PBC, we do not know the degree to which elafibranor would be accepted as a therapy, if approved. There are, however, a number of products being developed by other companies for the treatment of NASH, and elafibranor may compete with these products for market acceptance in the future, if any of them are approved. Additionally, we cannot be assured that NIS4 will be accepted by the medical community as a means of identifying NASH patients who may be appropriate candidates for drug intervention, and even if NIS4 is used, a physician may still require additional testing (e.g. liver biopsy) to confirm diagnosis. The degree of market acceptance of elafibranor, 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 NASH and PBC or an alternative to liver biopsy for the diagnosis of NASH;
- 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 under-diagnosed NASH market or the PBC market;
- for NIS4, our ability, that of our partner, Covance/Labcorp or of a potential future collaborator to access the clinical research market and, if applicable, develop 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 partners are unable to establish sales, marketing and distribution capabilities for elafibranor or our 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 partner and/or specialized local distributor. 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, we entered into a license agreement with LabCorp to allow them to develop and deploy NIS4 in the clinical research space through their subsidiary Covance. 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 NIS4 in the clinical research space. 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, 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, 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. In addition, even if we or our collaborators obtain accelerated or conditional marketing approval for one of our product candidates, as we had envisioned for elafibranor in NASH on the basis of an interim analysis, like all companies using the Subpart H and conditional approval pathway, we or our collaborators would be required to continue the trial post-marketing in order to demonstrate the efficacy of the drug candidate on clinical benefit based on a composite endpoint of clinical outcomes. 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 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 NASH and 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 no drug has yet been commercialized in NASH and few have been 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 judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two 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, 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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA 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 December 31, 2020 due to the COVID-19 pandemic. 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's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, on March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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 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 collaboraters to commercialize 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 NIS4, if commercialized for clinical care. We will also likely experience volatility in the coverage and reimbursement of the 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 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 NIS4 or if third-party payors change their coverage or reimbursement policies with respect to the 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, 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 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 NIS4 as a LDT on the clinical research market. 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 contract manufacturing organizations, or CMOs, especially with regard to our Phase 3 RESOLVE-IT trial and our Phase 3 clinical 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 the NIS4 test kit for the clinical care 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 fail to do so at acceptable quality levels or prices.

We do not intend to manufacture the drug products nor the NIS4 test kits that we plan to sell if the latter is approved on the routine care market. 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 the RESOLVE-IT study and for our planned Phase 3 study evaluating elafibranor in PBC, in the process of being initiated, 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 and 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 agreements with third parties for the development and eventual commercialization of our product candidates, which may affect our ability to generate revenues.

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. 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. 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. 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 pose a number of risks, including that the collaborators may:

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

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. For example, although we have entered into a license agreement with LabCorp/Covance to use NIS4 for clinical research 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 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.

We depend on LabCorp/Covance for the development of NIS4 for the clinical research market.

We depend on LabCorp (through its subsidiary, Covance) for the development of NIS4 in the clinical research market.

Even though we have no reason to expect a failure at this time, any failure of LabCorp/Covance may have a significant unfavorable effect both on the development and commercialization of NIS4, and therefore on our activity, perspectives, financial situation and results.

This collaboration exposes us to the following risks:

- the means and resources used within the framework of this agreement remain for the most part at the discretion of LabCorp/Covance;
- LabCorp/Covance might not fulfill its contractual obligations;
- LabCorp/Covance might interrupt the commercialization or decide to interrupt or not renew the 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;
- LabCorp/Covance might develop, independently or with the assistance of third parties, in-vitro tests that are in direct or indirect competition with NIS4 if it believes that it is easier to successfully commercialize competing products under more attractive economic conditions than ours;
- LabCorp/Covance, as exclusive holder of the commercialization and distribution rights on NIS4 on the clinical research market for a set time period, might not allocate sufficient resources to these activities;
- LabCorp/Covance 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;
- LabCorp/Covance 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 LabCorp/Covance, which could result in delays or suspension of the commercialization of NIS4, 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 this partnership, 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 NIS4;
- LabCorp/Covance 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 NIS4 in an optimal fashion or never fulfill its objectives. and
- if LabCorp/Covance 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.

We depend on Terns Pharmaceuticals for the development and commercialization of elafibranor on the Greater China territory in NASH and PBC

Our only drug candidate licensed to date is elafibranor, whose development and commercialization rights in Greater China in NASH and PBC have been licensed to Terns Pharmaceuticals in June 2019.

Terns Pharmaceuticals is the only decision-maker for the development and commercialization of elafibranor in the defined indications and territories. Even though we have no reason to expect a failure at this time, any failure of Terns Pharmaceuticals may have a significant unfavorable effect both on the development and commercialization of elafibranor, and therefore on our activity, its perspectives, financial situation and results.

This collaboration exposes us to the following risks:

- the means and resources used within the framework of this agreement remain significantly at the discretion of Terns Pharmaceuticals;
- Terns Pharmaceuticals might not fulfill its contractual obligations;
- Terns Pharmaceuticals might interrupt the commercialization or decide to interrupt or not renew the 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;
- Terns Pharmaceuticals might develop, independently or with the assistance of third parties, products that are in direct or indirect competition with elafibranor if they believe that it is easier to successfully commercialize competing products under more attractive economic conditions than ours;
- Terns Pharmaceuticals, as holder of the commercialization and distribution rights on elafibranor in certain territories, might not allocate sufficient resources to these activities;
- Terns Pharmaceuticals 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;
- Terns Pharmaceuticals 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 Terns Pharmaceuticals, which could result in delays or suspension of the commercialization of elafibranor in the relevant territories, 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 this collaboration, notably in the case of change of control of our company;
- this collaboration might be terminated, and in that case, would require additional financing to continue the development or commercialization of elafibranor in the relevant territories and indications;
- Terns Pharmaceuticals 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 future collaborators or potential acquirers;
- the partnership might not result in the development and commercialization of elafibranor in the relevant territories and indications in an optimal fashion or never fulfill its objectives.
- If Terns Pharmaceuticals 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; and
- Terns Pharmaceuticals might not receive the required market approvals.

The manufacturing facilities of our third-party manufacturers of drug candidates as well as the central testing laboratories of LabCorp/Covance. If these third-parties 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 NIS4 as an LDT depends on the ability of the central laboratories of our partner LabCorp/Covance that conduct the diagnostic test to retain their 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 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.

Our production costs may be higher than we currently estimate.

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

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

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

In addition, a rise in the cost of raw material or in direct or indirect energy rates, a shortage of raw material used to make our drug candidates may increase or stopped product manufacturing and increase logistical costs. Any of these risks, should they occur, could disrupt our activities and compromise our financial position, results, reputation or growth.

Risks Related to Our Operations

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

The success or lack thereof of our research and development programs will have a significant impact on our headcount, and the scope of our operations, as will the potential commercialization of our drug candidates in Europe, the United States and other territories. In the event of commercialization, we would need to continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be successful in conducting these activities.

We could also need to reduce our headcount and scope of our operations. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these activities. Due to our limited resources, we may not be able to effectively manage these tasks. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. 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. 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 regarding our Phase 3 RESOLVE-IT trial. 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 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 if we are unable to successfully integrate them with our existing operations and company culture.

We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

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 or those of 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 if the United Kingdom and the European Union are not able to come to an agreement regarding the modalities of the withdrawal of the United Kingdom.

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 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. If, following Brexit, the United Kingdom and the European Union are not able to come to an organized withdrawal agreement, there may be a significant uncertainty regarding the continued application of such regulations in the United Kingdom. We are currently conducting the RESOLVE-IT clinical trial on elafibranor in NASH in the United Kingdom and plan to open new investigation sites in the United Kingdom for our trial evaluating elafibranor in PBC and other indications. In that context, we may not be certain that these trials will not be affected it 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, could 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 continues to spread globally and, as of May 2020, has spread to a number of countries, including 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 subcontrators – 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, there is no guarantee that governments will not take additional measures in the event there is a new outbreak of the disease in certain regions.

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

- putting all of our Phase 1 clinical trials on hold;
- suspending the initiation of combination studies and 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 a result of the COVID-19 pandemic, we may experience disruptions that 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, 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. 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 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 we are evaluating 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 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 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 address clearly 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.

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

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

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

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

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- us having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

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

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

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

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, physicians 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 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, including the civil False Claims Act, which impose criminal and civil 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 covered entities and their business associates 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, as defined by such law, and teaching hospitals, and certain ownership and investment interests held by physicians or their immediate family members;

- 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 such as our US subsidiary Genfit Corp. 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 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 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 partners, 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 and 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 recurring revenue from product sales. As a result, our ability to reduce our losses and reach profitability 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. We have incurred net losses over the last years, including a net loss of €65.1 million for the year ended December 31, 2019. Our revenue and other income in 2019 resulted principally from the $35 million upfront payment we received under our collaboration and license agreement with Terns Pharmaceuticals and from tax credits, including research tax credits, in France. Until June 30, 2018, we had nominal revenues from the sublease of a portion of our corporate headquarters to a third party. 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 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 NIS4. With the exception of the upfront payment under the collaboration and licensing agreement with Terns Pharmaceuticals, 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 and 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, until a decision is taken with respect to the discontinuation, amendment or continuation of our RESOLVE-IT trial in NASH, in the Fall 2020, we will continue to have expenses for this trial.

We also plan to seek FDA, marketing authorization of NIS4 and CE marking in Europe with the EMA. During the regulatory development process for NIS4, our expenses could increase if we are required by the FDA or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

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

Our ability to be profitable in the future will depend on our ability to obtain marketing approval for and commercialize our product candidates, particularly our lead product candidate, elafibranor and a diagnostic test using NIS4 technology 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 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 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 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 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 NIS4; and
- expanding our contract manufacturing for the commercial supply of elafibranor and the manufacturing under license under the diagnostic kit accompanying the potential commercialization of 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 NIS4 will facilitate the diagnosis and identification of NASH patients who may be well suited for drug therapy. If a test using our NIS4 technology does not obtain marketing authorization, we may not be able to reach enough NASH patients to successfully generate significant revenues.

If elafibranor, NIS4 or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if elafibranor, NIS4 or any of our other product candidates 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 commercialize our products, if approved, which may not be available to us 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.

We are currently advancing elafibranor through clinical development for multiple indications and other drug candidates through preclinical development. Additionally, we are also planning formal validation studies of 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 NIS4, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate incurring significant expenses as we prepare for the potential commercialization of elafibranor in NASH, including significant expenses relating to our sales, marketing and distribution capabilities and increasing our drug manufacturing activities. We also anticipate incurring significant expenses in connection with our planned commercialization of 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. 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 the bondholders will deem conversion economically viable, in which case we would need to repay the nominal amount at maturity in October 2022. 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. As of the date of this Annual Report, our stock price has decreased significantly following the announcement that elafibranor did not demonstrate a statistically significant effect on the RESOLVE-IT trial's primary endpoint of NASH resolution without worsening of fibrosis nor did it achieve the key secondary endpoints. 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 2022.

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.

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 €8.1 million for the year ended December 31, 2019. 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.

The French tax authorities, with the assistance of the Research and Higher Education Ministry, may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR benefit. In 2014, we were subject to such an audit, at the end of which, the French tax authorities questioned part of the CIR benefit received by us as a result of certain of our expenditures incurred in 2010. The audit continued for our 2011 and 2012 CIR returns. We received proposed adjustments in December 2014 (for the 2010 CIR) and in December 2015 (for the 2011 and 2012 CIR). This tax audit was also extended to the 2014 CIR as part of a documentary audit, the purpose of which was to determine whether we were acting as a sub-contractor in our collaborative research alliances with companies in the pharmaceutical industry, which would reduce the basis on which the CIR is computed. The French tax authorities contend that in these alliances we were acting as a sub-contractor. However, we have disputed this finding. Although the tax authorities have partially granted some of our arguments, the Ministry of Finance appealed the decision and prevailed. We elected not to appeal that decision in order not to engage further legal fees on a matter that cannot be decided by the *Cour de Cassation* (French supreme court). We cannot guarantee that the French tax authorities will not challenge the basis of the calculation of our CIR for future years, which could have an adverse effect on our results of operations and our financial position.

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 may be volatile or 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, 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.

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

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

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the EMA, FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds and raw materials used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

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

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 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. In this respect, 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 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, and 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. We 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 December 31, 2019, we had 38,858,617 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, 2020. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. 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. In addition, it is uncertain if and to what extent various states will conform to the Tax 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, 2019, we believe that we were not classified as a passive foreign investment company, or PFIC, for the taxable year ended December 31, 2019. 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 year. 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 will require, among other things, that we assess the effectiveness of our internal control over financial reporting beginning with our annual report for the fiscal year ending December 31, 2020 that we intend to file in 2021.

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. We are in the process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation. This process is time-consuming, costly, and complicated. 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 as of and for the year ended December 31, 2018, our independent registered public accounting firm identified a control deficiency in our internal control over financial reporting that constituted a material weakness in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

Our independent registered public accounting firm identified the material weakness attributable to our lack of expertise regarding complex and unusual IFRS accounting treatment for our convertible bonds and their associated deferred tax impacts. As such, our controls over financial reporting were not designed or operating effectively, and as a result there was an error in our previously issued financial statements for the year ended December 31, 2017 that required us to restate our financial statements for that year.

We have historically retained the services of an external consultant to assist us with complex and unusual IFRS accounting treatment, such as in the case of our convertible bonds. In an effort to remediate our material weakness, we have engaged additional personnel, both internal and external, with appropriate training, and have redesigned our supervision controls, including with respect to the documentation of assumptions used and the development of accounting positions, and we have reassessed the necessary qualifications for any external consultants. We will continue to enhance our controls in this regard. In connection with the audit of our financial statements for the year ended December 31, 2019, no material weaknesses have been identified. However, there can be no assurance that we will be successful in maintaining the remediation measures described above. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses.

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 our efforts to remediate the material weakness identified are not sustainable, or 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.

The Public Company Accounting Oversight Board, or PCAOB, is currently unable to inspect the audit work and practices of auditors operating in France, including our auditor.

Our auditors, Ernst & Young et Autres, are registered with the Public Company Accounting Oversight Board (PCAOB). The PCAOB's cooperative arrangement with the French audit authority expired in December 2019, preventing inspections of registered firms in France until a new arrangement is concluded. Such inspections assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. As a result, our investors may not realize the potential benefits of such inspections until such new arrangement, which is under negotiation, is concluded and inspections in France resume.

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, 2017, 2018 and 2019 amounted to €2.8 million, €3.0 million and €2.1 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 NIS4 and our other drug candidates, in the United States, Europe and elsewhere. We anticipate our capital expenditures in 2020 to be financed from our existing cash and cash equivalents and/or new bank loans. 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. Based on the preliminary results of this interim readout, we do not see a path for accelerated approval under Subpart H or conditional approval by the FDA and EMA. However, before taking a final decision about the future of RESOLVE-IT, we are actively reviewing the full dataset and will conduct additional analyses, including some aimed at understanding why response rates in the placebo arm of the trial were higher than expected. Depending on insights gained from these additional analyses, and after alignment with regulatory authorities, we will make the decision whether to discontinue altogether, amend or continue the previously planned extension phase of the RESOLVE-IT trial.

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. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial in PBC, and presented the full dataset at ILC-EASL in April 2019. In the first quarter of 2020, the Phase 3 PBC program was launched, with an expected trial initiation later in 2020. Our drug discovery efforts are based on selecting appropriate nuclear receptors as targets and utilizing rational drug design to optimize our drug candidates. 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. After a first licensing agreement signed with LabCorp in January 2019 to make our NIS4 technology available through their subsidiary Covance in clinical research, we are now implementing a dual-track commercial approach. 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.

NASH is a liver disease that affects millions of people and for which there are currently no approved therapies. NASH is characterized by an accumulation of fat, inflammation and degeneration of hepatocytes, and may ultimately lead to life-threatening conditions like cirrhosis, liver failure or liver cancer requiring liver transplant. The global market for the treatment of NASH is growing rapidly and is projected to reach $20 billion by 2025. With no approved treatment, NASH can ultimately lead to potentially life-threatening complications like cirrhosis, hepatic impairment, liver cancer or death. It is the second cause of liver transplant in the U.S. after hepatitis C, and is expected to become the leading cause in the near future. A study published in *Journal of Hepatology* indicated that 17.3 million people may have NASH in the United-States in 2016, and suggested that the total could reach 27 million by 2030. In the five major European markets (France, Germany, Italy, Spain and United Kingdom) this population is estimated at 12.6 million in 2016 and expected to reach 18.3 million by 2030.

Elafibranor, a dual agonist of the nuclear receptors PPARα and PPARδ, is currently in Phase 3 development for the treatment of NASH. We reported interim results from the RESOLVE-IT Phase 3 trial on May 11, 2020. Elafibranor did not meet the predefined primary endpoint of NASH resolution without worsening of fibrosis in the intend-to-treat or ITT population of 1,070 patients. Elafibranor also did not achieve statistical significance with respect to the other key secondary endpoints of the trial related to metabolic parameters. It is too early to conclude on the exact consequences of the trial outcome, but at this stage we do not expect to be able to pursue accelerated approval under Subpart H (FDA) or conditional approval (EMA) for elafibranor patients in NASH. Further analyses will be conducted following the recommendations from the RESOLVE-IT Steering Committee. In June 2019, we signed a strategic collaboration and licensing agreement with Terns Pharmaceuticals for the development and commercialization of elafibranor in NASH and PBC in Greater China.

Despite the interim results from the RESOLVE-IT trial, we are continuing with our other advanced development programs, which are independent of our elafibranor in NASH development program:

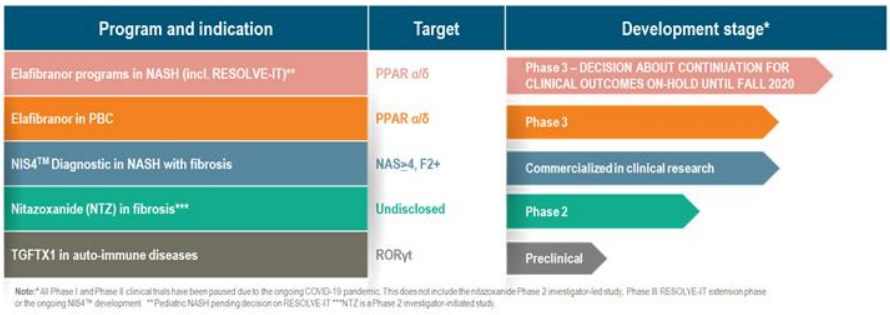
NIS 4 program: NASH is a silent disease. Patients often have no symptoms until the first signs of liver failure, and the lack of an accurate, non-invasive diagnostic tool contributes to under-diagnosis. Currently, liver biopsy is the standard for diagnosis, and variation in clinical practice and physician reluctance lead to under-diagnosis. Our blood-based NIS4 is a novel, standalone diagnostic technology that we believe can address the urgent need for a non-invasive, cost-effective, accessible and validated test to identify NASH patients who may be appropriate candidates for drug intervention, thereby decreasing the need for liver biopsy. We believe NIS4 has the potential to benefit patients, improve overall clinical care and facilitate the identification of NASH patients to be treated. Following the first agreement signed with LabCorp in January 2019, we are now developing a two-fold commercial strategy. First, we anticipate marketing NIS4 as a laboratory-developed test or LDT in the second half of 2020, via a licensing agreement with one or more central lab partner(s). Such deployment aims at expanding the use of NIS4 beyond the clinical research field only. In parallel, we intend to advance the program with the submission of NIS4 as an IVD (*In Vitro Diagnostic*), with an FDA marketing submission targeted in the first half of 2021.

- PBC: We are also developing elafibranor for the treatment of PBC, 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, lack of patient response and 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. We presented the full dataset of the Phase 2 clinical trial evaluating elafibranor for the treatment of PBC at the International Liver Congresses organized by EASL in 2019, showing that elafibranor met the primary endpoint of the trial with statistical significance compared to placebo in both doses evaluated, and also achieved with high statistical significance compared to placebo, the composite endpoint which has been used for drug registration of the second line treatment. In 2019, elafibranor received breakthrough therapy designation from the FDA for the treatment of PBC, and orphan drug designation from both FDA and EMA. Based on the positive Phase 2 results, we launched our Phase 3 PBC development program in early 2020 and are preparing for trial initiation later in 2020.

We are also advancing a clinical-stage program based on drug repositioning to develop an anti-fibrotic drug. Our lead drug candidate in this program, nitazoxanide, or NTZ, is an approved anti-parasitic agent that has shown promising activity against fibrosis in our preclinical disease models. See "Nitazoxanide Program for the Treatment of Fibrosis—Preclinical and Clinical Program." In December 2018, we announced the initiation of an investigator-initiated Phase 2 proof-of-concept trial to evaluate NTZ for the treatment of NASH patients with significant or severe fibrosis. That trial is ongoing.

Our TGFTX1 preclinical program is focused on the discovery and development of innovative drug candidates targeting RORγt, a nuclear receptor involved in certain inflammatory and autoimmune diseases. We are currently conducting pre-IND studies for a topical treatment of mild to moderate psoriasis.

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. We have now almost 200 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 are 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, with the exception of our RESOLVE-IT Phase 3 trial of elafibranor in NASH (until a decision regarding its discontinuation, amendment or potential continuation is taken in the Fall 2020) and our NIS4 program, as well as the investigator-initiated NTZ trial, we have suspended or put on-hold all of our other 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:

- **Our Phase 3 program in PBC was launched in the first quarter of 2020, and we anticipate trial initiation later in 2020, subject to ongoing impacts of the COVID-19 pandemic on the timing. Positive results from our Phase 2 clinical trial formed a strong rationale for further evaluation of elafibranor in this indication.** PBC is an autoimmune disease, and as such, this program is independent from our investigations of elafibranor in NASH..We disclosed topline results of the Phase 2 trial of elafibranor in PBC in December 2018 and presented the full Phase 2 dataset in April 2019, showing that elafibranor met the primary endpoint of our Phase 2 clinical trial, which was the change at week 12 in serum alkaline phosphatase or ALP from baseline. Compared to placebo, treatment with 80 mg and 120 mg elafibranor resulted in mean decrease from baseline of –52% and –44%, respectively, each with high statistical significance. With respect to the composite endpoint used for registration of the second line treatment, the elafibranor 80 mg and 120 mg treatment groups achieved with high statistical significance mean response rates of 67% and 79%, as compared to 6.7% for the placebo group. We also observed a beneficial trend on pruritus – a major symptom of PBC –but remains to be confirmed in a larger Phase 3 trial as these results were not statistically significant.
- **Our diagnostic program has the potential to expand market opportunity through better patient identification and stratification.** Our NIS4 technology is designed to identify patients with NASH and fibrosis who 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 not only help address the unmet need of under-diagnosed NASH, but could also provide physicians with a tool to identify patients who may potentially benefit from drug treatment. NIS4 has the potential to also allow stronger engagement of diabetologists, endocrinologists, cardiologists and primary care physicians in the identification and clinical management of patients with NASH and fibrosis. In January 2019, we entered into a license agreement with LabCorp to deploy NIS4 in the clinical research space, and LabCorp has moved forward with several large pharmaceutical companies to incorporate NIS4 testing within the scope of their NASH clinical trials. Later in 2019, at the Liver Congress organized by AASLD, we presented additional data about NIS4 suggesting that it was also able to outperform other non-invasive diagnostics in identifying NASH with fibrosis in the specific population of patients with type 2 diabetes, a known risk factor for NASH.
- **We remain a pioneer in the NASH field.** Our early move into this specific therapeutic area and our focus on the challenges associated with this emerging field and its complicated pathology 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, and we believe it represents a major asset. Our long-standing position and the experience acquired over the years could make us a valuable partner for any pharmaceutical company willing to develop an ambitious plan in NASH, regardless of its development stage: 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. We are actively involved in the NASH stakeholder community, and play an active role within The Liver Forum, an international institution bringing together the most prominent stakeholders in the field and key opinion leaders. We also participate in academic consortia, such as the biomarkers consortia in the United States and Europe, which are dedicated to improving diagnosis. We also work with patient advocacy groups including the Global Liver Institute, American Liver Forum and the European Liver Patient Association. We also spearhead disease awareness through The NASH Education Program, which is a GENFIT public health initiative. In 2018, after having established a large and diversified coalition of key stakeholders, The NASH Education Program organized the first edition of the International NASH day (June 12 of each year). The Global Liver Institute and other prominent patient advocacy groups, built upon this inaugural success to take the lead in organizing the second edition held on June 12, 2019.
- **Our pipeline includes other compounds and combination approaches.** In December 2018, we announced the initiation of an investigator-initiated Phase 2 proof-of-concept trial to evaluate NTZ for the treatment of NASH patients with significant or severe fibrosis. If this Phase 2 trial demonstrates anti-fibrotic activity in these patients, we plan to develop NTZ as a combination therapy as part of our strategy in NASH, in addition to development as a standalone monotherapy in fibrotic diseases. Our TGFTX1 program is in preclinical development in certain inflammatory and

autoimmune diseases. The strategic partnership signed with Terns Pharmaceuticals or Terns in 2019 also increased our capacity to expand our NASH program, as a result of the research and development agreement between both parties. Backed by experienced investors in the pharmaceutical industry, Terns has a robust pipeline of early-stage candidates that we believe present interesting opportunities for our collaboration as a result of the diversity of their mechanisms of action.

- **Our experienced team is comprised of industry leaders in metabolic and liver-related diseases with global expertise in science, regulatory affairs, market access and commercialization.** In September 2019, we announced the appointment of Pascal Prigent as CEO, and Jean-François Mouney's decision to transition to full-time Chairman of the Board. Mr. Prigent joined us in May 2018 as Executive Vice President of Marketing and Commercial Development, had been a key member of our Executive Committee, and instrumental in achieving several major corporate objectives including the collaboration with Terns Pharmaceuticals . In 2019, we added Dr. Carol L. Addy as our Chief Medical Officer. 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.
- **We have entered into major collaborations with the potential to deliver value for patients, physicians and shareholders.** With two strategic deals signed in 2019, we has demonstrated its ability to identify high value partners the we believe can maximize the potential of our key assets and their value. Our collaborator Terns Pharmaceuticals: its profile – with key investors like Orbimed, Vivo Capital or Lilly Asia Ventures and management with deep experience at companies like Gilead and Novartis – provides assurance of great leadership, and the R&D collaboration paves the way to generate further value in the future. Our collaborator LabCorp is well known in diagnostics worldwide and we believe their involvement in several on-going NASH trials make them the right collaborator to make our NIS4 technology available for as many patients as possible, as early as possible.

Our Strategy

Our goal is to become a leader in the development and commercialization of innovative therapies and diagnostics in metabolic and liver-related diseases. The key elements of our strategy to achieve this goal include:

- **Evaluate the full Phase 3 RESOLVE-IT dataset (72-week, 1,070 patients) to engage discussions with regulatory agencies, and inform our decision on the future of the program.** We believe it is necessary to better understand the high response rate observed in the placebo arm of the interim results of RESOLVE-IT. Placebo response rates for NASH resolution across most NASH trials were historically within the range of 5 to 9%. However, in the RESOLVE-IT trial, the response rate among the placebo group was nearly 15%, even though placebo patients had the same disease, similar baseline characteristics and were enrolled at the same centers, and were following largely similar protocols. This variability across trials raises a fundamental question for experts in the NASH field, and remains unexplained. We have therefore decided to follow recommendations from the RESOLVE-IT Steering Committee and plan to have all of the trial biopsies re-read, in order to inform our decision regarding RESOLVE-IT trial continuation. We believe this new data will also be useful for the whole NASH ecosystem given that accelerated approval by the FDA under Subpart H and conditional approval from the EMA are based on this type of histological criteria. Beyond these analyses, we will also conduct further analyses in various sub-populations. While these additional analyses are not expected to affect the current regulatory outcome in the short term, they will assist us in informing a decision as to whether there is an opportunity to continue development of elafibranor in NASH.
- **Rapidly advance the Phase 3 clinical development of elafibranor for the treatment of PBC.** We are advancing clinical development of elafibranor for the treatment of adult patients with PBC who have had inadequate response to ursodeoxycholic acid, or UDCA. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial evaluating elafibranor for the treatment of PBC, and later presented the full dataset during the International Liver Congress organized by EASL in April 2019. We have now launched the Phase 3 program and are continuing to discuss the clinical development strategy with the FDA to be in a position to initiate the clinical trial later in 2020.
- **Progress our diagnostic program in NASH, with a dual-track commercialization strategy for NIS4 technology.** In 2017, we began the product and regulatory development phases for our novel, blood-based technology designed to identify patients with NASH and fibrosis who may be appropriate candidates for drug therapy. The objective is to offer an attractive means of decreasing the need for liver biopsies, and address a well-known and significant unmet need in the field. Today, the clinical reference to diagnose and stage NASH is liver biopsy, which is an invasive and costly procedure that may be associated with procedural complications. It is also a non-scalable option, while the prevalence of

the disease and the number of suspected patients in need of further evaluation are high. Therefore, a non-invasive diagnostic solution optimized for use in NASH remains a high unmet need. NIS4 technology is already deployed in the clinical research field through our commercial partner LabCorp-Covance, and expansion plans are underway, with a goal to commercialize this technology as an LDT beyond the clinical research environment.

- **Continue to assess our combination program in NASH, and advance other drug candidates in our pipeline**. In addition to developing our other drug candidates to independently target metabolic and liver-related diseases, we believe elafibranor's unique approach in targeting PPARα and PPARδ creates opportunities to explore combination therapies, either with our other drug candidates, third-party drug candidates or approved drugs. We believe combining mechanisms could offer optimal benefits through complementary pathways. The program that would be aimed at evaluating the potential synergies between elafibranor and antidiabetic drugs from the GLP-1 agonist class, and from the SGLT2 inhibitor class, will be reevaluated in the coming months, in light of the conclusions derived from the full Phase 3 interim dataset analyses, including in sub-populations. In our development program for fibrotic diseases, we have chosen to initially advance NTZ into Phase 2 clinical development. In December 2018, we announced the initiation of an investigator-initiated Phase 2 proof-of-concept trial to evaluate NTZ for the treatment of fibrosis in NASH patients with significant or severe fibrosis. We believe NTZ could be developed as an anti-fibrotic monotherapy but also as combination therapy.
- **Reinforce the strategic collaboration with Terns Pharmaceuticals in the development of joint R&D projects.** In June 2019, we signed a strategic collaboration agreement with Terns Pharmaceuticals for the development of elafibranor for the treatment of NASH and PBC in Greater China, and we also undertook to develop joint R&D projects in liver disease, including the development of combinations with Terns' proprietary compounds. The potential of this program in NASH will be reevaluated following the conclusions of the analysis of the full dataset of the RESOLVE-IT interim results.
- **Leverage business development opportunities in our main therapeutic areas** and remain open to opportunities that could create value for the Company, whether through forging new strategic partnerships or new scientific collaborations; and
- **Refocus our public awareness effort in NASH, and concentrate our activity on challenges related to diagnostic tools.** The NASH Education Program, a public health initiative we created in 2016, is dedicated to the development and funding of NASH awareness and education activities aimed at the medical community and the general public. We believe that this program, through the production and dissemination of essential medical knowledge, can increase early diagnosis of NASH patients and provide physicians and patients with critical information about diagnostic and therapeutic solutions in development.

Our Drug Candidates and Diagnostic Development Programs

NASH—A Silent, Serious and Widespread Disease with No Approved Treatments

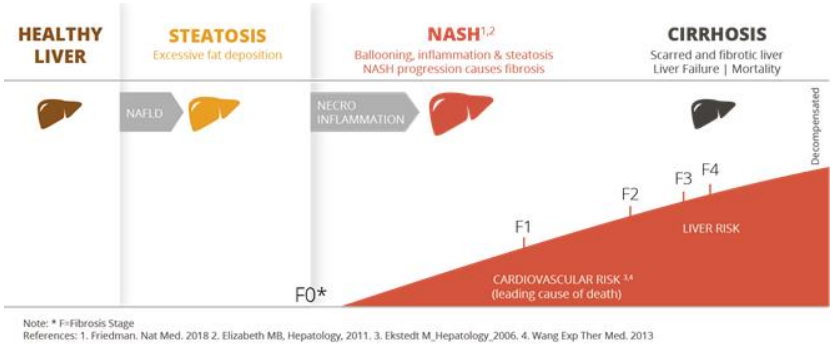
Overview

NASH is a silent disease, meaning patients have no symptoms until first signs of liver failure appear, and is notably under-diagnosed. With no approved drug treatments, NASH can lead to life-threatening conditions like cirrhosis, liver failure, liver cancer and death. NASH is the second leading indication for liver transplantation in the United States, behind hepatitis C, but is also the most rapidly growing indication and is expected to eventually become the primary cause. A study published in the *Journal of Hepatology* estimates that there were approximately 17.3 million adults with NASH in the United States in 2016 and projects that this number will grow to approximately 27.0 million by 2030; in the five major European markets, France, Germany, Italy, Spain and the United Kingdom, these numbers were estimated to be 12.6 million in 2016 and 18.3 million by 2030. NASH is a critical public health concern and an area with high unmet medical need.

We are developing our lead drug candidate, elafibranor, for the treatment of NASH, a severe form of non-alcoholic fatty liver disease, or NAFLD. NAFLD is the buildup of fat in the liver, called hepatic steatosis, that is not caused by alcohol consumption. As the disease progresses, the liver is exposed to chronic inflammation and liver cell degradation (manifested as hepatocyte "ballooning"). A patient has NASH when the three components—steatosis, inflammation and damage—are all present. Without treatment, NASH leads to fibrosis, which is the accumulation of non-functional scar tissue, as the body tries to heal itself. Because the accumulation of scar tissue leads to tissue remodeling, development of fibrosis leads to progressive loss of liver function which may ultimately lead to life-threatening conditions like cirrhosis, liver failure or liver cancer. Approximately 20% of NASH patients will go on to develop cirrhosis, and almost half of patients with cirrhosis will develop liver failure. Studies

show that NASH patients have a 10 times greater risk of dying from a liver-related disorder than the general population. In addition to its serious effects on the liver, NASH multiplies the risk of a patient developing cardiovascular problems, such as myocardial infarction, stroke and peripheral vascular accident, which also contribute to higher mortality rates in NASH patients. In fact, cardiovascular disease is the leading cause of death in NASH patients.

The following image depicts the progression of a normal liver through the development of NASH and its eventual consequences.



Note: * F=Fibrosis Stage
References: 1. Friedman. Nat Med. 2018 2. Elizabeth MB, Hepatology, 2011. 3. Ekstedt M_Hepatology_2006. 4. Wang Exp Ther Med. 2013

Causes, Diagnosis and Assessment of NASH

Although experts are still studying the multiple possible causes, it is generally accepted that NASH is a consequence of high-sugar, high-fat diets and insufficient physical exercise. As such, the disease is closely associated with metabolic disorders and NASH patients can have some or all of the following disorders: obesity, type 2 diabetes, hyperglycemia and abnormal levels of triglycerides and cholesterol. As the obesity and type 2 diabetes pandemic has increased, so too has the number of NASH cases worldwide.

Today, the clinical standard to formally diagnose NASH and stage fibrosis in a patient suspected of having NASH is the liver biopsy. When a liver biopsy shows steatosis, ballooned cells and inflammation, with or without fibrosis, the patient is diagnosed with NASH. Physicians use various scoring scales to assess the extent of disease severity and fibrosis in NASH patients:

- The NAFLD Activity Score, or NAS, provides a numerical score and assesses the severity of the disease for patients who have NASH. The NAS includes three sub-score components—steatosis (0-3), hepatocellular ballooning (0-2) and inflammation (0-3).
- The NASH Clinical Research Network fibrosis staging system ranks a patient's level of fibrosis on a scale of F0 to F4. No fibrosis is F0; mild, significant and severe fibrosis is F1, F2 and F3, respectively, and cirrhosis is F4.

The histological spectrum of NAFLD is quite large and both NAS and fibrosis stage can be used to define a patient's risk of developing cirrhosis, liver failure, liver cancer, liver transplant and liver death. The presence of NASH is the underlying cause of fibrosis, and fuels the fibrosis progression from stage to stage. Not surprisingly, the higher the fibrosis stage, the more advanced the disease, the greater the risk of developing major liver complications.

Although the natural history of the disease is not fully understood, a consensual definition of a NASH patient at risk of liver complications has emerged. According to this definition, a patient presenting with active NASH (NAS≥4) and significant fibrosis (F≥2) should be considered "at risk" and may be an appropriate candidate for drug intervention.

Market Opportunity

The treatment of NASH is an urgent public health challenge. Despite the growing burden of NASH on public health systems resulting from high prevalence and morbidities and mortality associated with the disease, there are currently no FDA-approved therapies for the treatment of NASH. Existing drugs have been tested off-label for assessing potential efficacy on NASH and liver fibrosis but have failed because of lack of efficacy, unacceptable side effects or both.

As the global epidemic of obesity fuels NAFLD prevalence, NASH has become one of the most common liver disorders. Global Data estimates the NASH market in the seven major markets (France, Germany, Italy, Japan, Spain, the United Kingdom and the United States) at approximately $143 million as of 2017, with the potential to reach up to $18.3 billion by 2026.

Our Solution: Elafibranor for the Treatment of NASH

Our two-pronged strategy for developing solutions for NASH patients consists of developing drug candidates for patients with NASH and developing an IVD test to aid in the diagnosis of at-risk NASH patients.

Elafibranor is a dual-agonist acting simultaneously on two nuclear receptors, PPARα and PPARδ, that control expression of key genes of inflammation, lipid metabolism, glucose metabolism and insulin sensitivity, oxidative stress and fibrosis. These two receptors play an important role in numerous processes involved in the development of NASH and its co-morbidities, as outlined below.

- The activation of PPARα as well as PPARδ confer anti-inflammatory activities through the repression of independent and complementary pathways. Thus, the dual activation of PPARα and PPARδ is thought to be advantageous over single agonism of either of the targets alone.
- PPARα and PPARδ in the liver increase mitochondrial β-oxidation which can lead to fatty acid degradation, or catabolism, and the decrease of liver fat.
- The activation of PPARα decreases oxidative stress, which occurs in part through the upregulation of anti-oxidant genes.
- PPARα activation leads to a beneficial cardioprotective lipid profile which includes a decrease in total cholesterol, remnant cholesterol, LDL-cholesterol and triglycerides, and an increase in HDL-cholesterol.
- The activation of PPARδ increases insulin sensitivity, which can occur in part by its activity to increase mitochondrial function and energy expenditure. This increased insulin sensitivity improves glucose homeostasis, lowers the elevated plasma free fatty acid levels associated with obesity and decreases hyperinsulinemia, which in turn decreases lipogenesis.
- PPARα activation has shown a beneficial effect on the microvasculature. It is reasonable to hypothesize that this effect would also be operative in the liver, reducing inflammation and improving vascular activity in NASH patients.
- The combined activation of PPARα and PPARδ, leading to decreased inflammation, oxidative stress, liver fat and insulin resistance, has a beneficial impact on the liver as is evidenced by the activity of elafibranor to decrease markers of liver dysfunction, including alanine aminotransferase, or ALT, aspartate aminotransferase, or AST, and gamma-glutamyl transferase, or GGT.

An important distinction between elafibranor and some of the other third-party programs targeting PPARs in NASH is that elafibranor does not have any pharmacological PPARγ activity as shown by studies in disease models and in clinical trials. Elafibranor has not shown the unwanted side effects most commonly associated with PPARγ activation, such as weight gain, edema, and fluid retention, which are associated with increased risk of heart failure.

NASH is closely associated with obesity and type 2 diabetes and is considered to be the liver manifestation of the metabolic syndrome. Similar to many metabolic diseases such as type 2 diabetes, NASH is a multifaceted disease with multiple components, including insulin resistance, inflammation, oxidative stress, increased liver fat and dyslipidemia. A therapeutic intervention that can address multiple NASH components may provide optimal clinical benefit and have the best probability to attain the histological endpoints required for drug registration for the treatment of NASH patients.

Our Clinical Program for Elafibranor in the Treatment of NASH

RESOLVE-IT—Our Pivotal Phase 3 Clinical Trial

Based on the results obtained in our Phase 2b clinical trial of elafibranor in treating NASH patients, we are currently evaluating elafibranor for the treatment of NASH in a global pivotal Phase 3 clinical trial, RESOLVE-IT. The trial began in the first quarter of 2016 and is expected to enroll approximately 2,000 patients at approximately 270 sites throughout the world. In May 2020, we announced the results of the interim analysis of the first 1,070 enrolled patients after 72 weeks of treatment in

order to evaluate the efficacy of elafibranor, based on a single primary histological endpoint, resolution of NASH without worsening of fibrosis, as a basis for accelerated marketing approval from the FDA and conditional marketing approval from the EMA.

RESOLVE-IT is a randomized, double-blind, placebo-controlled (2:1) Phase 3 clinical trial enrolling patients with NASH (NAS≥4) and fibrosis (F2 or F3, stages at which fibrosis is significant but has not yet reached cirrhosis). Patients will receive either elafibranor 120 mg or placebo once daily. The primary endpoint at the interim analysis, which has been performed on the interim cohort comprised of the first 1,000 patients enrolled and after 72 weeks of treatment, is the proportion of elafibranor-treated patients achieving NASH resolution without worsening of fibrosis as compared to placebo. The trial also had a key secondary histological endpoint on fibrosis and key secondary endpoints on metabolic parameters..

In April 2018, we announced that we had achieved enrollment of the first 1,000 patients in the interim cohort, which was planned to support the Subpart H approval pathway. This pathway requires continuation of the trial through the extension period for all 2,000 patients, at which time the full patient population will be evaluated for a composite endpoint of clinical outcomes. The trial also aimed to evaluate improvement of cardiometabolic profiles in patients treated with elafibranor versus patients treated with placebo. Throughout the duration of the trial, the safety is continuously monitored by the Data Safety Monitoring Board, or DSMB, an independent committee that provides recommendations on continuation of the trial.

During the recruitment, we focused on the balanced distribution of treatments across all sites and countries, based on stratification according to gender, presence of diabetes and disease severity. We have enrolled patients in more than 270 sites across North America, Europe, Australia, Latin America, Turkey and South Africa. Interim baseline data on the initial cohort show that the patients recruited into the trial to date have the expected metabolic co-morbidities which include type 2 diabetes, hypertension, dyslipidemia and obesity. Thus, the baseline characteristics of the trial population are consistent with the expected associated risk factors for patients with NASH and fibrosis.

Seven pre-planned safety reviews of the data have been performed by the DSMB. In each of the reviews, including the most recent one in November 2019, the DSMB recommended continuation of the trial without any modification after analysis of the safety data set, including adverse events and laboratory data. This recommendation, taking into account an increasing number of patients exposed to treatment for longer periods of time, is consistent with our observations in previous Phase 1 and Phase 2 clinical trials that support elafibranor's favorable tolerability profile and lack of demonstrated safety concerns.

Interim results

The RESOLVE-IT Phase 3 trial evaluated the effect of elafibranor compared to placebo in 1,070 patients (ITT population) with biopsy proven NASH as defined by 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). Patients with no biopsy results at week 72 were considered as non-responders in the efficacy analysis.

Elafibranor did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis.

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 and tolerability profile of elafibranor continues to be supportive of ongoing clinical investigation.

We plan to the conduct additional analyses of the interim data set so that we may better understand the totality of the data. Specifically, we seek to better understand the higher than anticipated placebo response rate and, importantly whether elafibranor may provide benefit in specific NASH patient sub-populations. We anticipate presenting the data at a major hepatology congress in the second half of 2020. Furthermore, we intend to discuss the full dataset with regulatory authorities so we may make an informed decision about the future of elafibranor in NASH while ensuring that the decision will be in the best interests of NASH patients.

GOLDEN-505—Our Phase 2b Clinical Trial

The efficacy and safety of elafibranor was has been evaluated in an extensive preclinical program which included multiple disease models. Prior to our GOLDEN-505 Phase 2b clinical trial in NASH patients, our Phase 2a program in elafibranor included trials performed in different populations of metabolic disease patients, including patients with atherogenic dyslipidemia, prediabetes or type 2 diabetes. In these Phase 2a trials, we observed that treatment with elafibranor promoted a cardioprotective lipid profile, promoted glucose homeostasis, increased insulin sensitivity, was anti-inflammatory and decreased markers of liver injury. Each of these activities are important targets in the treatment of NASH patients and we believe the combined multiple activity profile of elafibranor observed in the Phase 2a trials warranted its further clinical development in a Phase 2b trial.

In 2012, a consensus definition of NASH resolution had not yet been adopted by regulatory authorities or the medical community and little was known about the target NASH population to be included in clinical trials. As a result, we designed the GOLDEN-505 trial with the input of key opinion leaders and the FDA to identify the therapeutic dose for elafibranor and the most appropriate NASH population for drug therapy. For this purpose, GOLDEN-505 enrolled a patient population covering almost the entire histological spectrum of NASH (from NAS=3 to NAS=8 and fibrosis stage from F0 to F3). Patients with fibrosis stage F4 were excluded, as this would indicate that the patient had already progressed to cirrhosis. This trial, which began in 2012, was one of the largest interventional trials and first true international study ever conducted in NASH, enrolling 276 patients, 274 of whom were treated, at 56 sites throughout the United States and seven countries in Europe.

Patients were enrolled if they had NASH defined as NAS≥3 with at least one point in steatosis, ballooning and inflammation scores, and fibrosis stage from F0 to F3. Patients were divided into three treatment groups, receiving either elafibranor 80 mg, elafibranor 120 mg or placebo once daily for 52 weeks. The primary endpoint of the trial was to evaluate the efficacy of elafibranor doses compared to placebo on reversal of NASH without worsening of fibrosis. We also evaluated the effect of elafibranor on secondary endpoints including changes in NAS, morphometric parameters, insulin resistance, cardiovascular risk parameters and safety markers.

Efficacy Results

Topline results were announced in March 2015 and detailed results were presented at the 2015 American Association for the Study of Liver Diseases, or AASLD, Annual Meeting. Complete results of the trial were published in the peer-reviewed *Gastroenterology* journal.

After the end of the 52-week treatment period, there was no difference between the elafibranor arms and placebo according to the protocol-defined definition of the primary endpoint. We conducted a post hoc analysis of the data using a definition recommended by the FDA for use as the primary endpoint in our Phase 3 trial. Applying this definition to our Phase 2b data, elafibranor 120 mg resolved NASH without the worsening of fibrosis in the intent-to-treat population, defined as all patients who took at least one treatment: 19% of patients receiving elafibranor 120 mg experienced NASH resolution without worsening of fibrosis, compared to only 12% in the placebo group, a statistically significant difference. The following table shows the percentage of patients in the placebo and elafibranor 120 mg groups who reached NASH resolution without the worsening of fibrosis, broken down by the patient's NAS. The elafibranor 80 mg group did not perform better than placebo using the FDA-recommended definition of the primary endpoint.

Percentage of Patients with NASH Resolution without Worsening of Fibrosis
(Primary Endpoint of Trial (FDA recommended post hoc definition))

Total Number of Patients	NAS Score	Placebo	Elafibranor 80mg	Elafibranor 120mg	p-value[(1)]
274	All patients (ITT)	12% (n=92)	13% (n=93)	19% (n=89)	0.045
234	NAS≥4	9% (n=76)	13% (n=83)	19% (n=75)	0.013
204	NAS≥4 with fibrosis (any stage)	11% (n=66)	15% (n=67)	20% (n=71)	0.009

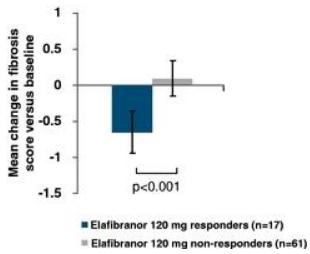
(1) P-value represents the statistical significance between two groups. A p-value <0.05 denotes significant difference and means that there is < 5% likelihood that the observed results occurred by chance. The p-values in the table are comparisons between the elafibranor 120 mg and placebo groups. The p-values comparing the elafibranor 80 mg and placebo groups each exceeded 0.05, meaning that such results were not statistically significant.

The statistical difference between the elafibranor and the placebo groups increased with the extent of initial histological lesions. In the subpopulation of patients with active NASH (NAS≥4), 19% of patients receiving elafibranor 120 mg experienced NASH resolution, compared to only 9% in the placebo group, with a p-value of 0.013. In the subpopulation of patients with active NASH (NAS≥4) and fibrosis (F≥1), these results increased to 20% and 11% in the elafibranor 120 mg group and placebo group, respectively, with a p-value of 0.009.

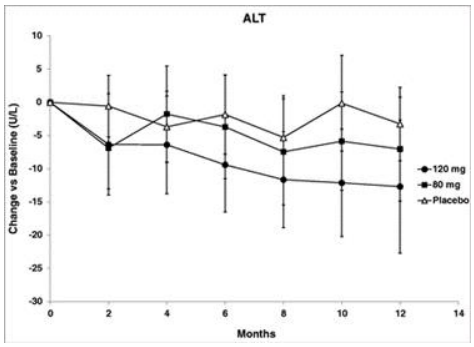
In addition, we conducted a post hoc analysis to take into account differences in the standard of care across centers and baseline severity. In patients recruited in centers with at least one patient with active NASH (NAS≥4) in the three treatment arms of the trial, 26% in the elafibranor 120 mg group, compared to 5% in the placebo group (p=0.02), experienced resolution of NASH without worsening of fibrosis. We believe this analysis provides a good assessment of the efficacy of elafibranor, taking into account the caveats of the Phase 2b trial design which recruited patients with mild disease and too low of a NAS (NAS=3) and included trial centers which did not have patients from each of the study arms present. Of the 274 patients enrolled and treated (the intent-to-treat population) in the Phase 2b trial, 40 patients had mild disease, defined as a NAS=3. In these patients with mild disease, there was an unexpectedly high placebo response rate, which we believe might have led to a lack of treatment effect in the pre-specified primary outcome assessment. The current practice for drug development in NASH, including in our ongoing RESOLVE-IT trial, is now to include only those patients with moderate or severe disease, defined by a NAS equal to or greater than 4.

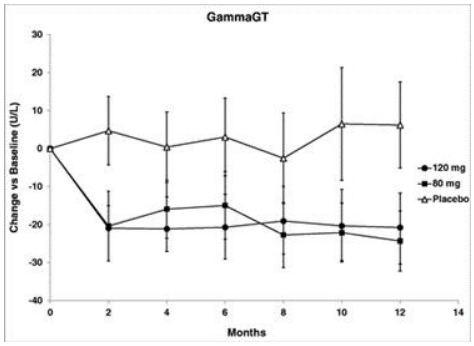
Importantly, patients who achieved NASH resolution when treated with elafibranor ("responders") experienced a parallel decrease in fibrosis score compared to elafibranor patients who did not achieve NASH resolution ("non-responders"), as depicted in the figure below. Although the trial was not designed for anti-fibrotic endpoints, we believe it provided proof-of-concept of an anti-fibrotic effect. This correlation between improvement in NASH activity and regression of fibrosis fits with the treatment paradigm that NASH resolution predicts long-term beneficial effects on prevention of negative clinical outcomes.

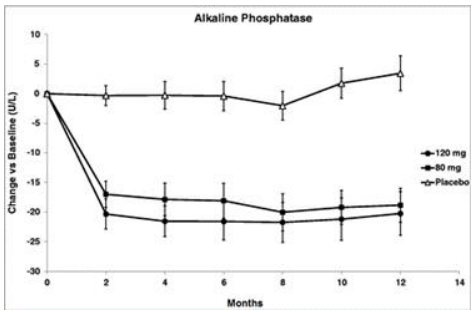
Fibrosis Change from Baseline
in Elafibranor 120 mg Responders v. Non-Responders



Patients treated with elafibranor experienced improvement in circulating markers of liver dysfunction such as ALT, GGT and alkaline phosphatase, or ALP. The charts below show the changes in ALT, GGT and ALP from baseline over the course of the treatment period of the trial. These results were published in *Gastroenterology* in 2016.

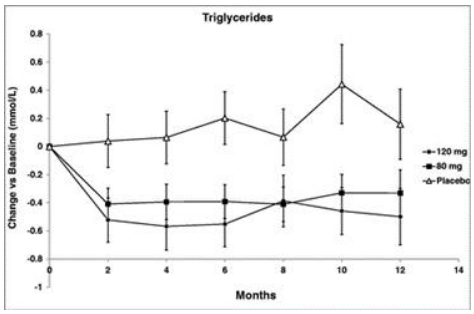


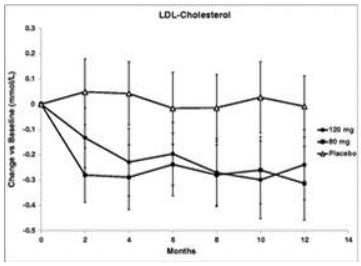


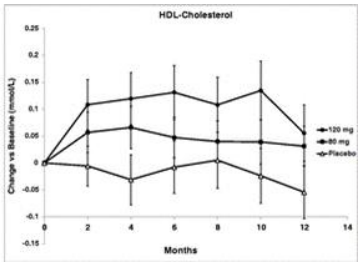


In addition, in our evaluation of the secondary endpoints, we observed therapeutic activity of elafibranor 120 mg on the following cardiometabolic risk factors associated with NASH, which we believe is commensurate with elafibranor providing a beneficial cardiometabolic profile:

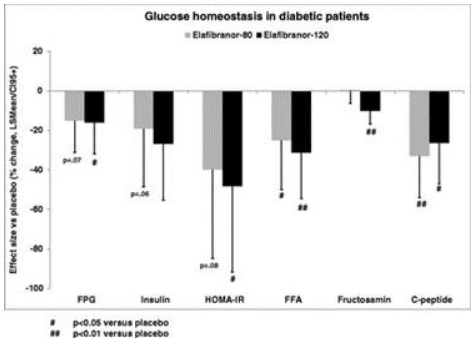
Improved levels of plasma lipids and lipoproteins. The charts below show the changes from baseline in triglycerides, LDL cholesterol and HDL cholesterol for each arm during the trial.



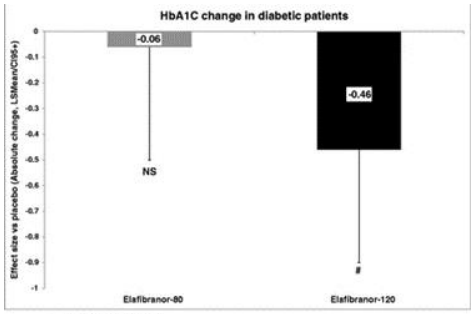




Improved insulin sensitivity and glucose metabolism in diabetic patients. The following charts show the effects of elafibranor compared to placebo on a number of insulin sensitivity and glucose metabolism measures observed during the trial.

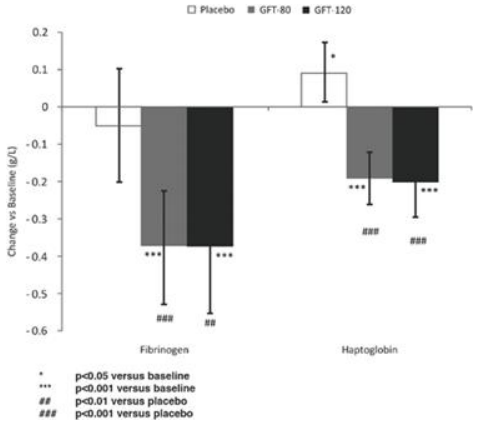


\# p<0.05 versus placebo
\## p<0.01 versus placebo



\# p<0.05 versus placebo

Anti-inflammatory effects. The following chart shows changes from baseline in fibrinogen and haptoglobin, two measures of inflammation, during the trial. In this chart, elafibranor 80 mg is noted as "GFT-80" and elafibranor 120 mg is noted as "GFT-120."



These results were published in *Gastroenterology* in 2016.

Safety Results

Periodic safety reviews were conducted throughout the Phase 2b clinical trial by the DSMB. These reviews did not generate any comments or additional requests highlighting the overall safety profile of elafibranor.

In the GOLDEN-505 trial, elafibranor was well tolerated at both dose levels. Over the 52-week treatment period, frequency of adverse events, or AEs, were similar between the treatment groups, including placebo, and the majority of the AEs were mild in intensity. During the trial, 4 patients in the elafibranor groups experienced possibly treatment related SAEs. In the elafibranor 80mg group, three SAEs occurred in one patient experiencing ataxia, fasciulation and tremor on the same day. A second patient, who had a preexisting risk profile for miscarriage, experienced a spontaneous abortion. In the elafibranor 120 mg group, one patient experienced mild acute pancreatitis. This patient had a historical cholecystectomy, was suspected of related biliary pancreatitis at the time of the adverse event, suffered from numerous concurrent conditions and was on confounding concurrent medications. A second patient was diagnosed with Parkinson's disease, deemed possibly treatment related by the investigator, although it was deemed not treatment related by the sponsor due to risk factors such as patient's age (76), sex (male) and family history of tremors (patient's father). Additionally, four patients in the placebo group experienced possibly treatment related SAEs (renal cancer, breast cancer, bladder cancer and pancreatic cancer).

In addition, there were no cardiac events, signals on cancer or deaths in the elafibranor treatment groups. Body weight remained stable. A statistically significant mild increase in creatinine of approximately five percent was observed in the elafibranor treatment group. An increase in creatinine is a known and generally reversible effect of elafibranor and other PPAR agonists, like fenofibrate, which has been on the market for decades. Several long-term studies with fenofibrate (DAIS, FIELD, ACCORD) have shown the preservation of renal function. This was illustrated by the rapid reversal of the observed increase in creatinine upon stopping treatment, which, even after several years of treatment, decreased to levels below those observed in the placebo groups, which is indicative of a renoprotective effect of PPAR agonist treatment. The most common adverse events were of gastrointestinal nature and of mild intensity, such as abdominal pain, transit disorders, nausea and vomiting, were similar between treatment groups. No safety concerns of elafibranor emerged from this trial.

Prior Clinical Trials and Preclinical Studies

Phase 2a Clinical Trials

We have also completed five Phase 2a clinical trials which were exploratory in nature to assess safety, type of efficacy and magnitude of efficacy of elafibranor in patients suffering from specific cardiometabolic disorders also frequently observed in NASH patients. These trials, involving an aggregate of 297 randomized patients assessed a variety of endpoints not specifically related to efficacy in NASH. However, we believe the results provided a scientific and clinical rationale for positioning of elafibranor as a suitable NASH therapeutic through our observations of:

- reduced markers of liver injury;
- reduced markers of inflammation;
- improved glucose metabolism and insulin sensitivity; and
- improved levels of plasma lipids and lipoproteins.

In all five Phase 2a clinical trials, we observed a favorable tolerability profile and did not demonstrate any safety concerns of elafibranor. Below are summaries of these five Phase 2a clinical trials.

- GFT505-207-1 was a Phase 2a, randomized, placebo-controlled, double-blind, two-parallel group clinical trial in patients presenting with Frederickson Type IIB dyslipidemia (high triglycerides and low HDL-cholesterol). In this trial, we evaluated a once-daily oral treatment of elafibranor 30 mg in 24 patients compared to a placebo group of 13 patients over the course of 28 days. We evaluated reduction in serum triglycerides and increases in HDL-cholesterol levels, as well as improvements in other related lipid markers. We observed that patients in the elafibranor treatment group experienced a decrease in triglycerides of 8.72%, an increase in HDL-cholesterol of 5.35%, a decrease in non-HDL-cholesterol of 4.65% and a decrease in LDL-cholesterol of 4.28%, each as compared to placebo. We also observed favorable trends in corresponding apolipoproteins, which are proteins that bind lipids to form lipoproteins. In the patients treated with elafibranor 30 mg, we observed good tolerability. No SAEs were reported and no subjects withdrew from the trial.
- GFT505-208-3 was a Phase 2a, randomized, placebo-controlled, double-blind, two-parallel group clinical trial in patients with atherogenic dyslipidemia (high triglycerides and low HDL-cholesterol). In this trial, we evaluated a once-daily oral treatment of elafibranor 80 mg in 63 patients compared to a placebo group of 31 patients over the course of 28 days. We evaluated reduction in serum triglycerides, increases in HDL-cholesterol levels and improvement in other lipid makers. We observed significant beneficial effects in the elafibranor group compared to the placebo group, including a reduction in serum triglycerides of 16.67% (p=0.008), an increase in HDL-cholesterol of 7.77% (p=0.004), and statistically significant reductions in pro-atherogenic lipoproteins, each as compared to placebo. In patients treated with elafibranor, we observed good tolerability. No SAEs were reported and no subjects withdraw from the trial due to adverse events. The results of this clinical trial were published in *Diabetes Care* in 2011.
- GFT505-209-4 was a Phase 2a, randomized, placebo-controlled, double-blind, two-parallel group clinical trial in patients with abdominal obesity and presenting with impaired fasting glucose and/or impaired glucose tolerance. In this trial, we evaluated a once-daily oral treatment of elafibranor 80 mg in 23 patients compared to a placebo group of 24 patients over the course of 35 days. We evaluated improvement in markers of glucose metabolism and lipid profile. We observed significant beneficial effects in the elafibranor group compared to the placebo group on changes in glucose homeostasis, including a reduction in fasting insulin of 24.8% (p=0.005), a reduction in fasting plasma glucose of 5.2% (p=0.01) and a reduction on the insulin resistance index of 31.4% (p=0.001). With respect to changes in plasma lipids and associated proteins, patients in the elafibranor group experienced significant improvements over placebo, including a decrease in triglycerides of 24.8% (p<0.001), an increase in HDL-cholesterol of 9.3% (p=0.009), a decrease in non-HDL-cholesterol of 13.3% (p<0.001), a decrease in total cholesterol of 8.7% (p<0.001) and statistically significant decreases in corresponding apolipoproteins. Additionally, in the elafibranor group we observed significant impact on markers of liver injury and inflammation compared to placebo, including a decrease in GGT of 15.1% (p=0.004), a decrease in ALP of 24.5% (p<0.001), a decrease in fibrinogen of 10.0% (p=0.01) and a decrease in haptoglobin of 15.8% (p=0.008). In patients treated with elafibranor, we observed good tolerability. There was one SAE in the elafibranor group that was deemed to be unrelated to treatment. No adverse events led to discontinuation of elafibranor treatment. The results of this clinical trial were published in *Diabetes Care* in 2011.

- GFT505-210-5 was a Phase 2a, randomized, placebo-controlled, double-blind, two-parallel group clinical trial in drug-naive patients with type 2 diabetes. In this trial, we evaluated the efficacy of once daily oral treatment of elafibranor 80 mg in 50 patients compared to a placebo group of 47 patients over a period of 12 weeks. We evaluated changes in HbA1c, fasting glucose, fasting insulin, HOMA-IR and other parameters measured during an oral glucose tolerance test. Patients in the elafibranor group experienced significant improvements from baseline, including a decrease in HbA1c of 0.31% (p=0.01). Patients experienced a decrease in fasting insulin of 2.02 mlU/L and a decrease in the HOMA-IR score of 1.10. In the elafibranor treatment group, but not in the placebo group, parameters derived from the oral glucose tolerance test were also significantly improved compared to baseline, like glucose AUC of –42.5 mg/dL (p=0.001) and a decrease in insulin AUC of 10.5 mlU/L (p=0.009) and a decrease in free fatty acid AUC of 0.17 mmol/L h (p<0.001), but not in the placebo group. Favorable trends persisted when comparing these glucose homeostasis marker changes between the two groups but were not statistically significant. Highly significant improvements over placebo were obtained on plasma lipids including a decrease in triglycerides of 0.60 mmol/L (p<0.001), a decrease in LDL-cholesterol of 0.37 mmol/L (p=0.002), a decrease in total cholesterol of 0.47 mmol/L (p=0.001), a decrease in non-HDL-cholesterol of 0.53 mmol/L (p<0.001), and decreases in corresponding apolipoproteins (p<0.001). Finally, significant effects could be seen over placebo on inflammatory markers like HsCRP (p=0.004), haptoglobin (p<0.0001), and on liver markers GGT (p<0.001) and ALP (p<0.001). In the trial, one patient experienced four SAEs deemed unrelated to treatment leading to premature treatment discontinuation. Another patient experienced an AE of mild to moderate intensity, which was judged not related to treatment with elafibranor, led to study drug discontinuation.
- GFT505-210-6 was a randomized, single-blind, placebo-controlled, crossover clinical trial in 22 male patients with insulin resistance and abdominal obesity. In this trial, we evaluated the efficacy of once daily oral treatment of elafibranor 80 mg over the course of eight weeks on insulin resistance using the hyperinsulinemic euglycemic glucose clamp procedure. This gold-standard technique allows assessment of the hepatic response to low dose of insulin and peripheral tissues response to high dose of insulin. In patients treated with elafibranor, we observed significantly improved hepatic response to a low dose of insulin compared to placebo. Similarly, the response of peripheral tissues was significantly increased compared to placebo. In addition, compared to placebo, patients treated with elafibranor experienced a significantly improved plasma lipid profile, including a decrease in serum triglycerides of 21% (p=0.003), a decrease in total cholesterol of 9.2% (p=0.004), a decrease in LDL-cholesterol of 13.2% (p=0.001) and statistically significant decreases in corresponding apolipoproteins. In addition, patients treated with elafibranor showed improvement in inflammation markers such as haptoglobin or fibrinogen and liver markers such as ALT (–20%, p=0.004), GGT (–30.4%, p=0.003) or ALP (–19.3%, p<0.001). In patients treated with elafibranor, we observed good tolerability. No SAEs related to treatment with elafibranor occurred and no AE led to discontinuation of elafibranor treatment. The results of this clinical trial were published in *Diabetes Care* in 2013.

Most of these Phase 2a clinical trial results have been reported in two publications in a peer-reviewed journal, *Diabetes Care*. Notably, in a trial using the gold standard method for measuring sensitivity to insulin, we showed that in patients with insulin resistance, elafibranor was able to increase insulin sensitivity of the liver and muscles. Knowing the essential role of insulin resistance in development of NASH, this Phase 2a trial was decisive for the decision to launch a biopsy-based Phase 2b trial in NASH patients.

Phase 1 Clinical Trials

The elafibranor Phase 1 program to assess the safety and tolerability as well as pharmacokinetic profile of elafibranor comprised 12 clinical trials performed in single Phase 1 clinical research centers. This Phase 1 program includes a total of over 600 volunteers including more than 500 healthy lean subjects, 60 healthy overweight or obese subjects and 12 subjects with type 2 diabetes. Among them, more than 400 were included in elafibranor treated groups and more than 150 in placebo or comparator treated groups. Below is a brief summary of these Phase 1 clinical trials:

- GFT505-106-1 was a placebo-controlled trial conducted in a total of 56 healthy volunteers (44 subjects in the elafibranor treatment group and 12 subjects in the placebo group) to assess the safety and the pharmacokinetic profile of elafibranor after single administrations at ascending doses of 10, 20, 30, 50 and 70 mg under fasting and fed conditions. No subject withdrew from the trial and no SAEs were reported.

- GFT505-106-2 was conducted in a total of 48 healthy volunteers (36 patients in the elafibranor treatment group and 12 patients in the placebo group) to assess the safety and pharmacokinetic profile of elafibranor after repeated administration for 14 days at ascending doses of 5, 10, 20 and 30 mg. No subject withdrew from the trial and no SAEs were reported.
- GFT505-108-3 was conducted in a total of 12 healthy volunteers, all treated with elafibranor, to compare safety and pharmacokinetics of two different formulations after single administration at 10 mg. No subject withdrew from the trial and no SAEs were reported.
- GFT505-108-4 was a placebo-controlled trial conducted in a total of 64 healthy volunteers (48 subjects in the elafibranor treatment group and 16 subjects in the placebo group) to assess the safety and pharmacokinetic profile of elafibranor after single administration of ascending doses of 100 and 120 mg and after repeated administration of ascending doses of 40, 60, 80 and 100 mg for 14 days. No subject withdrew from the trial. One SAE was reported at the 120 mg dose level but was not deemed related to elafibranor.
- GFT505-109-5 was an open label trial conducted in a total of 28 healthy volunteers, all treated with elafibranor, to assess potential drug-drug interaction between elafibranor at 80 mg for 14 days with simvastatin at 20 mg. One non-treatment related AE led to discontinuation and one non-treatment related SAE occurred prior to any administration of elafibranor.
- GFT505-109-6 was conducted in a total of 30 healthy volunteers (20 subjects in the elafibranor treatment group and 10 subjects in the comparator group) to assess potential drug-drug pharmacodynamic interaction between repeated administration of elafibranor at 100 mg for 14 days and single administration of sitagliptin at the end of the treatment period. No subject withdrew from the trial and no SAEs were reported.
- GFT505-111-7 was conducted in 24 healthy subjects, all treated with elafibranor, and in 60 overweight/obese subjects (45 subjects treated with elafibranor and 15 subjects in the placebo group) and in 12 type 2 diabetic subjects (9 subjects treated with elafibranor and 3 subjects in the placebo group). Our objectives in this trial were to (i) compare pharmacokinetic profile of two formulations of elafibranor at 120 mg after single administration in male and female healthy lean volunteers (open label phase), (ii) to assess safety and tolerability and pharmacokinetic profile of single administration of ascending doses of 180, 240 and 300 mg in overweight/obese otherwise healthy volunteers (double-blind, placebo controlled); (iii) to assess safety and tolerability and pharmacokinetic profile of repeated administration for 14 days of ascending doses of 120, 180 and 240 mg in overweight/obese otherwise healthy volunteers (double-blind, placebo controlled); and (iv) to assess safety and tolerability after multiple oral doses in patients with Type 2 diabetes. No subject withdrew from the trial and no SAEs were reported.
- GFT505-112-8 was an open label trial conducted in a total of 19 healthy volunteers, all treated with elafibranor, to assess potential drug-drug interaction between elafibranor at 120 mg for 13 days with Warfarin 15 mg. No subject withdrew from the trial and no SAEs were reported.
- GFT505-113-9 was a double-blind trial conducted in a total of 176 healthy volunteers (89 subjects in the elafibranor group, 42 subjects in the placebo group and 45 subjects in the positive control group) to assess the effects of repeated administration for 14 days of elafibranor at 120mg and 300 mg on QT/QTc interval. No subject withdrew from the trial and no SAEs were reported.
- GFT505-114-10 was an open label trial conducted in 6 healthy volunteers, all treated with elafibranor, to assess excretion balance and metabolic profile of elafibranor after single administration of 14C-labelled elafibranor at 120 mg. No subject withdrew from the trial and no SAEs were reported.
- GFT505-115-11 was an open label trial conducted in a total of 25 healthy volunteers, all treated with elafibranor, to assess potential drug-drug interaction between elafibranor at 180 mg for 14 days with atorvastatin 40 mg. No subject withdrew from the trial and no SAEs were reported.
- GFT505-115-12 was an open label trial conducted in a total of 25 healthy volunteers, all treated with elafibranor, to assess dose linearity of pharmacokinetic parameters after single administration of elafibranor (120, 180 and 240 mg) and time dependency of pharmacokinetic parameters and repeated administration of elafibranor for 16 days. Eight subjects withdrew from the trial due to AEs and no SAEs were reported.

We believe that the results from our Phase 1 program of elafibranor support a favorable tolerability profile up to 300 mg (which is 3-4 times higher than expected therapeutic doses of 80 mg/day and 120 mg/day), both under fed and fasting conditions, either after single administration or after repeated administration for at least 14 days (from 10 mg/day to 300 mg/day) in healthy, overweight/obese or diabetic volunteers. In this range of doses, no SAE related to elafibranor was reported. None of these Phase 1 trials revealed any serious safety signals and, notably, a 14-day regulatory cardiac safety study did not reveal an effect on QT/QTc, which is a measure of cardiac safety risk, at the high dose of 300 mg per day.

Adverse events were all of mild to moderate intensity with no apparent imbalance over placebo or comparator groups. Most of them resolved before study end. They consisted mainly of gastrointestinal disorders (diarrhea, abdominal pain, flatulence, constipation, vomiting, dyspepsia).

Furthermore, no clinically relevant changes were detected in biochemical and hematological parameters, vital signs (including arterial pressure) or electrocardiogram. There was no evidence of dose-related clinically potentially significant abnormalities (CPSA) and/or clinically potentially significant changes (CPSC).

Animal Models and Toxicology Studies

Several animal models have been used to assess efficacy of elafibranor on NASH resolution, liver fibrosis and comorbidities like dyslipidemia, type 2 diabetes or atherosclerosis. Results have been published in peer-review journals, including *Hepatology*, and/or presented at multiple international scientific meetings. Recently, we observed elafibranor's effect on liver cancer prevention and development in two mouse models. In the first mouse model, the effect of elafibranor was evaluated in mice that had been fed a diet that induced NASH and hepatocellular carcinoma, or HCC, referred to as the "CD/FF diet." The mice were divided into three groups: one group of eight mice received a "regular" diet, one group of seven mice received the CD/FF diet and one group of four mice received the CD/FF diet plus elafibranor at a dose of 30 mg/kg/day. At week 36, all of the mice that had received the CD/FF diet alone developed NASH and grade 3 fibrosis. In contrast, among the mice that received elafibranor, none developed NASH and all only developed grade 1 fibrosis. At the end of the study, we evaluated nodules present in the mice. All of the mice in the group that had received the CD/FF diet alone had between six to eight nodules present in their livers. In contrast, nodules were only present in half of the mice that were administered elafibranor, and even those only had one or two nodules. Liver sections from the mice were analyzed to determine the presence of tumors and whether any tumors were benign or malignant. In the group that received the CD/FF diet alone, 86% had developed at least one malignant lesion, whereas no tumor lesions—malignant or benign—were observed in the group that received elafibranor.

In the second mouse model, NASH and HCC were induced in mice through administration of the CD/FF diet for 19 weeks, following DEN (carcinogen) injection at 14 days post partum. The mice were divided into two groups—one group of six mice received the CD/FF diet alone and one group of seven mice received the CD/FF diet and, only for the last eight weeks of treatment, began to receive elafibranor at a dose of 30 mg/kg/day, once histological NASH lesions had already developed. A group of three mice that received a "regular" diet and no DEN injection was kept as comparator. Liver sections from the mice were analyzed to determine the presence of tumors and whether any tumors were benign or malignant. In the group that had received the CD/FF diet alone, half developed at least one HCC lesion. In contrast, in the group that received elafibranor for the last eight weeks of treatment, only 28% developed at least one HCC lesion. None of the mice on the "regular" diet had benign or malignant lesions. Also in this study, we measured the concentration of alpha fetoprotein, or AFP, a commonly used cancer marker, in the mice serum. In the group that had received the CD/FF diet alone, AFP serum concentration was significantly increased compared to that seen in healthy mice, whereas in the group that received elafibranor, AFP serum concentration was reduced by 47% as compared to the group receiving CD/FF alone, a result that was statistically significant with a p-value of less than 0.01.

We have also evaluated elafibranor in numerous regulatory toxicology studies in animals, with up to two years of treatment in rats and mice and up to one year of high-dose treatment in monkeys. These studies did not reveal any major signs of toxicity relevant to humans. In all animal studies, elafibranor did not cause weight gain, peripheral edema or increase heart weight which are side effects typically associated with drugs acting on PPARγ. This confirmed selectivity of elafibranor for the two other forms of PPARs: PPARα and PPARδ.

Regulatory Pathway for Treatment of NASH

In February 2014, the FDA granted fast track designation to elafibranor for the treatment of NASH; however, the results of the interim analysis of our Phase 3 clinical trial do not support our application for accelerated marketing approval from the FDA under Subpart H and conditional approval from the EMA. Nonetheless, this does not preclude the continuation of the trial, and we intend to make an informed decision regarding trial continuation after discussing the full data set with regulatory authorities. A decision to continue the trial would be supportive of evaluating the efficacy of elafibranor on clinical benefit within the full 2,000 patient population. The composite endpoint of clinical outcomes would include all-cause mortality, the progression to cirrhosis, and a full list of cirrhosis-related events such as liver transplantation, and Model for End-Stage Liver Disease, or MELD score >15, on the full trial population and would be aimed to support full marketing approval. The Phase 3 trial remains blinded. All patients will be maintained under treatment and followed until the occurrence of a pre-defined number of progressions to clinical outcomes or until a decision is made to discontinue to trial.

Pediatric NASH

As prevalence of obesity in children has increased, NAFLD has become a growing health concern in this population. A study published in 2016 estimates that NAFLD affects approximately 10-20% of the general pediatric population, with approximately 25% of these children progressing to NASH, and that within the next 10 years, pediatric NAFLD is expected to become the most prevalent cause of liver pathology, liver failure and indication for liver transplantation in childhood and adolescence in the Western world. In the United States, the prevalence of NAFLD in children is estimated to be approximately 10%. Thus, regulatory agencies strongly encourage parallel development of drugs to treat this specific population.

In November 2016, we initiated the first juvenile toxicology studies of elafibranor in rats as part of our Pediatric Investigation Plan, or PIP, in the treatment of NAFLD/NASH following agreement on our PIP from the EMA. In January 2018, we received agreement from the FDA on our Pediatric Study Plan, or PSP, after which we announced the official launch of the NASH pediatric program with elafibranor. In March 2019, the FDA indicated that the protocol for our Phase 2, 12-week randomized trial of 20 pediatric patients is acceptable to fulfill the requirements of the Pediatric Research Equity Act. This trial will evaluate the pharmacokinetic and pharmacodynamic properties of elafibranor in children and adolescents and is being conducted in U.S. clinical centers specializing in NASH pediatrics. As of the date of this Annual Report, approximately one-half of the patient cohort has been randomized, however further enrollment in this study is currently on-hold due to the COVID-19 pandemic. The continuation of this trial will be driven by a decision to continue the elafibranor program in NASH, pending a discussion of the RESOLVE-IT interim analysis data with regulatory authorities in the second half of 2020.

NASH Combination Therapies with Elafibranor

NASH is a complex and multifaceted disease and several drug classes with complementary mechanisms of action may be required for optimal management of NASH, liver fibrosis and comorbidities. Therefore, there is an increasing need for therapies based on drug combinations. To address this need, we are also considering the evaluation of combination therapy approaches combining elafibranor with molecules being developed in our other programs, molecules already marketed in other indications and certain molecules currently being developed by others for the treatment of NASH, with the goal of treating the largest possible number of NASH patients. The initiation of combination studies of elafibranor in NASH will be driven by a decision to continue the elafibranor program in NASH, pending a discussion of the RESOLVE-IT interim analysis data with regulatory authorities in the second half of 2020.

During the International Liver Congress in Amsterdam in 2017, we presented data on the therapeutic complementarity of elafibranor and an FXR agonist illustrating the potential for new combination treatments with elafibranor for the optimal care of NASH patients. We evaluated elafibranor in combination with obeticholic acid, or OCA, an FXR agonist, in a preclinical rat model. In this study, a total of 90 rats were divided into several groups of 10, with a control group receiving a “normal” diet and the rest receiving a CDAA/c diet. Of the rats receiving the CDAA/c diet designed to induce fibrosis, mice received either elafibranor alone (in doses of either 1, 3 or 10 mg/kg/day), OCA (in doses of either 10 or 30 mg/kg/day) or a combination of one of the three elafibranor doses plus OCA 10 mg/kg/day. At the end of the 12-week study period, the rat livers were analyzed for levels of liver fibrosis and hepatic collagen, a biochemical measure of fibrosis. Notably, significant reduction in fibrosis was observed in all rats that were given elafibranor of any dose level. In contrast, a significant reduction in fibrosis was only achieved by the rats receiving OCA at the higher 30 mg/kg/day dose level. In this study we observed a synergistic effect of elafibranor and OCA on fibrosis in the rats receiving combination therapy even at the low doses of elafibranor. Fibrosis was reduced by 71% and 81% in the groups receiving elafibranor 1 mg/kg/day plus OCA 10 mg/kg/day and elafibranor 3 mg/kg/day plus OCA 10 mg/kg/day, respectively. Rats administered with combination therapy also had significant decreases in hepatic collagen compared to decreases observed in the mice receiving only elafibranor or OCA alone. We believe this synergistic effect, even at submaximal doses, supports the potential of our combination therapy approach.

In April 2018, we presented data at the European Association for the Study of the Liver, or EASL, International Liver Congress from studies of combination therapy with elafibranor in which NTZ had a synergistic effect in primary human stellate cells and in a model of NASH with fibrosis. In this mouse model, a total of 39 mice were divided into five groups—one group of 4 mice received a "normal" diet, one group of 12 mice received only a diet designed to promote lipid accumulation and result in liver fibrosis, referred to as a CDAA/c diet, one group of eight mice received the CDAA/c diet plus elafibranor 1 mg/kg/day, one group of eight mice received the CDAA/c diet plus NTZ 100 mg/kg/day and the final group of seven mice received the CDAA/c diet plus elafibranor 1 mg/kg/day plus NTZ 100 mg/kg/day. At the end of the 12-week study period, the mice livers were analyzed for levels of liver fibrosis and hepatic collagen. The mice in the combination therapy group experienced a statistically significant attenuation of liver fibrosis of 52% (range of 25% to 63%), compared to 36% in the group receiving only elafibranor (range of 18% to 47%) and 27% in the group receiving only NTZ (range of –4% to 53%), each as compared to the CDAA/c only group. Similarly, in the combination therapy group, hepatic collagen was reduced by 41% (ranging from 26% to 56%), compared to 22% in the group receiving only elafibranor (ranging from 11% to 33%) and 23% in the group receiving only NTZ (ranging from 13% to 34%), each as compared to the CDAA/c only group. Altogether, these findings indicate that NTZ may be a good candidate for a NASH combination therapy with elafibranor, thus establishing the rationale for proof-of-concept studies in patients with NASH and advanced fibrosis.

At the annual meeting of the 2018 AASLD, we presented new data on anti-NASH treatment combinations, using elafibranor as backbone, in *in vitro* and *in vivo* NASH models, associating it with an ACC inhibitor. In this study, mice were divided into five groups—one group of four mice received a "normal" diet, one group of 12 mice received the CD/FF diet alone, one group of eight mice received the CD/FF diet plus elafibranor 1 mg/kg/day, one group of eight mice received the CD/FF diet plus GS-0976, an ACC inhibitor product candidate being developed by Gilead Sciences, Inc., at 10 mg/kg/day and the final group received the CD/FF diet plus elafibranor 1 mg/kg/day plus GS-0976 at a dose of 10 mg/kg/day. At the end of the eight-week study, the mice livers were analyzed for NAS and levels of hepatic triglycerides, an indicator of advancing liver disease. As compared to the group that received only the CD/FF diet, the groups receiving either elafibranor or GS-0976 alone showed subtle and non-significant decreases in NAS (3% and 9%, respectively) and hepatic triglycerides (6% and 2%, respectively). However, the group of mice that received the CD/FF diet and the combined therapy of elafibranor and GS-0976 showed statistically significant ($p<0.05$) decreases in both NAS (33%) and hepatic triglycerides (64%). These results suggest the potential of elafibranor, in combination with an ACC inhibitor, in reducing liver fat.

Finally, we have shown at the 2019 AASLD that elafibranor (ELA) synergizes with low doses of semaglutide (SEMA)(GLP-1 receptor agonist), to reduce NASH components in a model of high fat-induced insulin resistance and NASH (Gubra model). In this experiment, mice with advanced NASH phenotype (NAS between 5 and 7) and liver fibrosis ((stage between 2 and 3) were either exposed to elafibranor alone (12 mice), to semaglutide alone (14 mice) or to the combination of both agents (14 mice) for 12 weeks. In this model, semaglutide reduced body weight by 17% and steatosis (grade 3 to grade 2 in 60% of mice) but had no effect on fibrosis. In contrast, semaglutide and elafibranor cotreatment resulted in a significant reduction of all histological NASH features, i.e. reduction in steatosis, activity index and fibrosis. It is important to underscore that all these effects were observed in mice, which developed severe NASH phenotype before the pharmacological treatment was initiated. Transcriptomic analyses of tissue samples suggest that ELA/SEMA cotreatment effect in this study was explained by the synergistic action of both drugs on the inflammatory pathways in NASH-affected livers. Indeed, many inflammatory cells express both PPARs and GLP-1 receptors. By contrast, GLP-1 receptors are not expressed in hepatocytes, meaning that its effect on glucose and lipid metabolism in the liver is indirect. Inflammatory cells interfere with homeostatic signaling of metabolic hormones, such as insulin and glucagon in the liver. Gene expression studies in this experiment suggest that ELA and semaglutide work in concert to resolve inflammatory insults in NASH liver and to restore normal metabolic functions.

In light of the preclinical studies with elafibranor and considering that NASH is a multifactorial disease (like many if not all metabolic diseases), we believe combining multiple potentially synergistic mechanisms that target the underlying pathways of NASH could be a relevant way to optimize the clinical management of patients with NASH. Because of the common epidemiological and pathophysiological features between NAFLD/NASH and type 2 diabetes, antidiabetic drugs, including sodium glucose co-transporter 2 (SGLT2) inhibitors and GLP-1 agonists, have been evaluated in patients with NAFLD over the years. The effects of these anti-diabetes drugs include body weight or fat tissue reduction, improved glycemic control and reduction of inflammatory markers, decreased lipogenesis, increase in free fatty acid oxidation, and reduction in oxidative stress. Indeed, early clinical studies to evaluate the effects of SGLT2 inhibitors and GLP-1 agonists in patients with NASH have demonstrated reduction in liver injury and reduction in hepatic fat. Taken together, mechanistic, preclinical and clinical data point to potential synergistic effects of elafibranor if combined with an SGLT2 inhibitor or a GLP-1 agonist and are supportive of the launch of the combination program. Pending a decision to continue the development of elafibranor for NASH, the first studies in the program are planned to evaluate the effect of elafibranor and an SGLT2 inhibitor, and the effect of elafibranor when co-administered with a GLP-1 agonist. These studies are not planned to initiate until the resolution of the COVID-19 pandemic.

Hepatic Lipid Composition

A growing body of evidence indicate that the type of fatty acids, as opposed to simply the quantity of fatty acids, that are stored in hepatocytes play a central role in the risk for progressive liver disease. Triglycerides, which are stored in lipid droplets in the liver of NAFLD patients with insulin resistance are predominantly composed of saturated fatty acids, such as palmitic acid. Saturated fatty acids are more metabolically harmful for the human liver than unsaturated fat. In hepatocytes, the ratio of monounsaturated fatty acids (MUFA) to saturated fatty acids (SFA) determines whether liver cells are damaged by the flux of exogenous FFA, and thus the type rather than the quantity of FFA determines hepatic stress. Intracellular saturated fatty acids both stimulate the production and are substrates for ceramides formation. Ceramides impair insulin signaling, induce tissue inflammation and mitochondrial dysfunction, and increase the hepatic uptake of free fatty acids from the circulation, contributing to steatosis. Saturated fatty acids and ceramides are highly enriched in livers of patients with NAFLD and insulin resistance.

We hypothesize that the beneficial effects of elafibranor as seen in the Phase 2b study may be mediated in part by a decrease in the fatty acid saturation index. It is well-known that hepatic fatty acid desaturases are under the control of PPARs and desaturase activity is expected to be induced with elafibranor treatment. However, data investigating fatty acid composition in humans upon PPAR α/δ stimulation are currently lacking. Thus, the Phase 2 hepatic fat study was initiated and is aimed to get a better understanding about the mechanism of action of elafibranor on fat metabolism in the human fatty liver using state-of-the art Magnetic Resonance Spectroscopy (MRS) techniques. These non-invasive techniques will allow not only studying the total amount of hepatic fat, but can also give qualitative information about the hepatic fat pool (i.e. degree of saturated, monounsaturated and polyunsaturated fatty acids. The study is currently on hold pending resolution of the COVID-19 pandemic.

NIS4 for the Diagnosis of 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). This discovery kicked off a multi-year effort that has resulted in the development of NIS4, a blood-based molecular test for the identification of patients with NASH (NAS≥4) and significant fibrosis (F≥2), 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 NIS4 in the clinical research space.

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 pharmacotherapeutic intervention if the promising agents currently in late-stage clinical development obtain regulatory approval.

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 correlated 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 this report) 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.

The treatment of NASH being a pressing public health challenge, there is a large unmet need for an easy-to-access, non-invasive tool as an alternative to liver biopsy. The availability of such a test would help address NASH under diagnosis 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, addressing this clinical gap. We believe our diagnostic test, 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 can be used to not only identify but also monitor the progression, regression, or stability of disease.

miRNAs represent a 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.

Since our inception, we have developed a recognized expertise in transcriptomics, which is the study of the RNA transcripts in cells. We initially focused this expertise on mRNA and have expanded in recent years to the study of specific miRNAs. We have developed methods for the extraction and rapid and reliable measurement of miRNA in samples of blood, serum or plasma. In our miRNA biomarker research program, we use advanced technologies, such as next generation sequencing, or NGS, which allows us to perform sequencing of millions of small fragments of DNA in parallel.

Our Solution: The NIS4 Test Based on Our Biomarker Algorithm

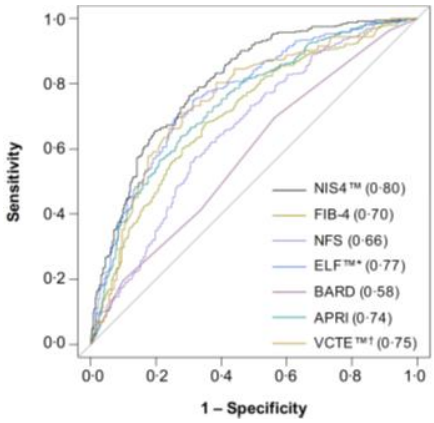
Aware of the challenges associated with diagnosing at-risk NASH, we initiated a research program to combine our technical expertise in informatics, machine learning and molecular biology with access to our extensive NASH clinical biobank, including cohorts from our GOLDEN-505 and RESOLVE-IT clinical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

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: alpha-2-macroglobulin, YKL-40, hemoglobin A1c, and microRNA-34a. Our lead technology, NIS4, integrates the outputs of four independent NASH-associated biomarkers through an algorithm to produce a 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 NIS4, 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 like elafibranor.

Development and validation of a diagnostic signature for at-risk NASH

To assess its clinical performance, NIS4 was first developed within a DISCOVERY cohort (N=239) to establish performance metrics and clinical cut-offs. We then validated the clinical performance of NIS4 against the liver biopsy in two independent cohorts comprising a total of 702 patients: the RESOLVE-IT-DIAG (N=475) and ANGERS cohorts (N=227). In testing NIS4, we utilized the initial liver biopsy and bloom sample from each patient. We compared the results of NIS4 on the blood sample to the patient's initial liver biopsy to evaluate whether NIS4 was an accurate predictor of the patient's severity of NASH and stage of fibrosis. We tested NIS4's ability to identify patients with at-risk NASH from patients without at-risk NASH. This was determined using the AUROC, or Area Under Receiver Operating Characteristic, curve, a type of analysis that gives an overall performance metric of a diagnostic test based on its ability to correctly identify those with the disease, or sensitivity, and its ability to correctly rule out those without the disease, or specificity with the maximum score being 1.0.

From our preliminary research, NIS4 outperformed other blood-based biomarkers when assessed in a head-to-head comparison from 702 patients with a full set of biochemical parameters from the combined external validation cohorts. As depicted in the figure below, NIS4 (AUROC = 0.80) outperformed other non-invasive NASH/fibrosis diagnostics (p<0·01), including FIB-4 (AUROC=0·70), NFS (AUROC=0·66), ELF™ (AUROC=0·77), APRI (AUROC=0·74), and BARD (AUROC=0·58) for the identification of at-risk NASH.



Subpopulation analyses were performed in 702 patients from the combined external validation cohorts to assess the overall performance of NIS4 compared with other diagnostics (FIB4, VCTE™, BARD, APRI, NFS, and ELF™) among specific subpopulations of clinical relevance in NASH as shown in the 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 impacted by patient age within the range studied, sex, BMI, or transaminase levels. The clinical performance of NFS was statistically better (p=0·013) in patients ≥55 (AUROC=0·69) vs <55 (AUROC=0·59) years of age, whereas FIB-4 exhibited higher performance (p=0·039) in females (AUROC=0·75) vs males (AUROC=0·67). Similarly, APRI also showed higher performance (p=0·004) in females (AUROC=0·79) than in males (AUROC=0·68). ELF™, on the other hand, showed higher performance (p=0·0288) in non-obese patients (BMI <30 kg/m2; AUROC=0·84) vs obese (BMI ≥30 kg/m2; AUROC=0·74), and (p=0·019) in females (AUROC=0·81) vs males (AUROC=0·71). BARD had consistent results across the categories explored, and VCTE™— while not statistically significant (p=0·055)—had directionally higher performance in patients without type 2 diabetes (AUROC=0·80) vs those with type 2 diabetes (AUROC=0·65).

We believe that these resultssuggest that NIS4 has the potential to be used in medical practice, as well as in a clinical research setting, to accurately identify patients with at-risk NASH (NAS≥4 and F≥2). In this context, we believe NIS4 could be deployed within the framework of clinical laboratories to achieve straightforward integration into future clinical care, and to be

more cost-effective, accessible, and acceptable for patients than liver biopsy. In doing so, 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 future therapeutic interventions.

Regulatory and Commercial Strategy

We began communications with the FDA in 2017 to discuss potential regulatory pathways for an IVD-version of the NIS4 test. 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 NIS4 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.

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. We believe this agreement will provide expanded access to, and further validation of NIS4 which should be supportive in our plans to seek marketing authorization from the FDA and European Notified Bodies. Initially, we will enable LabCorp through its subsidiary Covance to market and sell the 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. In 2020, we anticipate entering into a second license agreement with a major laboratory partner to enable them to develop, deploy, market, and sell NIS4 as a laboratory developed test (LDT) for use as a clinical diagnostic. We believe that licensing our technology to a large diagnostic company would enable them to launch the test to enable early adoption, result in third-party publications and provide additional evidence of the clinical utility of NIS4. We plan to use these benefits to further support the next stage of our commercial strategy, which is to seek FDA marketing authorization for a kit-based IVD version of NIS4 to allow us to commercialize the test within the United States.

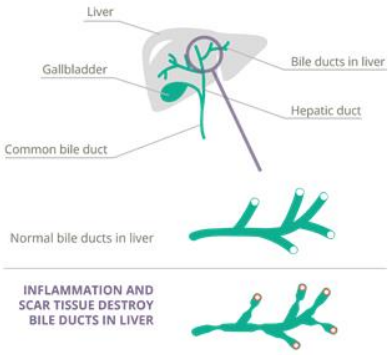
In parallel, we will progress towards submitting a data package to a European Notified Body to enable CE marking and associated marketing approval in key European markets in 2021. In Europe, if approved, we are still finalizing our plans but are considering selling the IVD-version of NIS4 through a distributor or commercial partner to independent, smaller laboratories, as there are fewer large central laboratories in these regions.

Elafibranor for the 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.

Primary Biliary Cholangitis



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. 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, ursodiol, a drug containing 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. Ursodiol, administered orally, is designed to help move bile through the liver and into the intestines. Although ursodiol 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 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 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 clinical trials, including our Phase 2 clinical trial in PBC.

Our Clinical Program for Elafibranor in the Treatment of PBC

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 pruritis, 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 with high statistical significance 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 VAS score in patients that reported pruritus (VAS ≥10 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 an 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.

Based on the strength of the Phase 2 results and following the end-of-Phase 2 meetings with the FDA and EMA in 2019, we have initiated the Phase 3 program of elafibranor for the treatment of patients with PBC. As of the first quarter of 2020, we have contracted with a CRO well versed in this disease area, and have selected 65 clinical trial sites in 12 countries.

While the COVID-19 pandemic has led us to a pause in the initiation of the Phase 3 study, we will pursue interactions with the FDA to further optimize the study plan for the development of elafibranor under the accelerated approval regulatory path. In the Phase 2 trial, elafibranor demonstrated highly significant efficacy results on the surrogate primary endpoint used to support regulatory approval of Ocaliva; however, it will also be important for our pivotal phase 3 trial to appropriately capture the clinical benefit that elafibranor may have on pruritus, which remains a major unmet need for patients with PBC, despite the current approved treatments. In addition to the pivotal phase 3 trial that will be used to support and seek regulatory approval, we plan for the program to also include a confirmatory study based on hard clinical endpoints.

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 the rights to develop and commercialize elafibranor in Greater China (mainland China, Hong Kong, Macau, and Taiwan), for the treatment of NASH and PBC. Preparation for the initiation of clinical studies with elafibranor in China is underway, with timelines to be dictated by the resolution of COVID-19 and discussions with regulatory authorities.

As part of the agreement, GENFIT and Terns will also undertake joint R&D projects in liver disease, including the development of elafibranor in combination with Terns' compounds.

Following the publication of the top line interim results and the conclusions of the analysis of the full dataset, we will reassess the potential of this collaboration with Terns and determine, with Terns' management a joint strategy to put in place for NASH. For more information, see Item 10.C – *Collaboration and License Agreement with Terns Pharmaceuticals, Inc.*

Nitazoxanide Program for the Treatment of Fibrosis

About Fibrosis

We are developing nitazoxanide or NTZ for the treatment of liver fibrosis. Progressive liver fibrosis can result from chronic liver injury of any etiology, including viral infection, alcoholic liver disease and NASH. Multiple studies have demonstrated that patients with NASH are at higher risk for adverse liver-related outcomes, with the degree of fibrosis contributing most significantly to this increased risk.

Cirrhosis is the terminal stage of progressive liver fibrosis, which results in over 1 million deaths annually worldwide. Lethal complications of cirrhosis include functional liver failure, portal hypertension-induced variceal bleeding, ascites, hepatic encephalopathy, systemic bacterial infection and liver cancer, especially HCC. Annual direct and indirect costs for the care of cirrhosis exceed $12 billion in the United States alone, and there is an urgent need for anti-fibrotic drugs to prevent progression towards hepatic decompensation and the associated morbidity and mortality.

Approved therapies directly targeting and reversing advanced fibrosis are still lacking, but clinical studies have indicated that liver fibrosis and even cirrhosis can be regressed by therapeutic intervention aimed at the primary disease etiology.

Our Solution: 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. Secondary objectives of this proof-of-concept trial include evaluating the anti-fibrotic effect of NTZ by several approaches, including a method to quantify hepatic fibrogenesis flux rates. Using heavy water labeling, de novo collagen-associated protein synthesis will be determined through Fractional Synthesis Rate of circulating proteins at baseline and at the end of treatment to assess the effect of daily oral administration of NTZ. Other non-invasive methods, including MRE and FibroScan, will be used to evaluate the liver stiffness changes after NTZ treatment. Results are expected during the course of 2020, based upon updates provided by the investigator and subject to progress in patient recruitment.

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 ELA 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 ELA 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 ELA 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 ELA/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.

TGFTX1 Program for the Treatment of IL-17-Dependent Autoimmune Diseases

We have designed our TGFTX1 preclinical program to allow us to identify and develop drug candidates for the treatment of certain IL-17-dependent autoimmune diseases, including psoriasis and certain inflammatory respiratory conditions such as neutrophilic asthma, chronic obstructive pulmonary disease, or COPD, or asthma-COPD overlap syndromes. Psoriasis is a chronic and debilitating autoimmune disease that affects approximately 125 million people globally, or 2 to 3% of the total population, and approximately 80% of psoriasis patients suffer from a mild-to-moderate form of the disease. Beyond the physical manifestations, psoriasis can have a significant impact on a patient's quality of life, often with profound psychosocial consequences.

There are three major forms of therapy: topical, phototherapy and systemic therapy. The treatment options are based on psoriasis severity. Recent advances in biologic agents have considerably expanded the treatment options, however, the prices of these newer treatments are higher than traditional systemic medications. Topical therapy remains the standard of care for treatment of mild-to-moderate disease and the biological agents are typically reserved for the small population of psoriasis patients with the most severe disease. The available topical therapies include the use of corticosteroids and vitamin D analogues, as monotherapies or in combinations. Although these treatments are still the standard of therapy for mild-to-moderate psoriasis, there are considerable side effects that have been documented.

IL-17 is produced by inflammatory lymphocytes upon the activation of RORγt, a key transcription factor that controls the function of IL-17-secreting lymphocytes. Recent data suggest that RORγt inhibition may be a straightforward and efficient way to curb exacerbated immune responses caused by IL17. In our TGFTX1 program, we have identified novel RORγt antagonists. One of our proprietary molecules is a potent and selective RORγt antagonist that inhibits IL-17 release from human primary Th17 lymphocytes. This topical drug candidate improved both disease score, as measured by the Psoriasis Area and Severity Index, or PASI, and skin histology in a mouse model of psoriasis and complies with a target product profile for topically delivered drugs. In this mouse model, we pre-treated a group of 10 mice with TGFTX1 for three days before applying a skin irritant, and treated another group of 10 mice with the skin irritant alone for a period of eight days. We assessed the severity of inflammation daily and then at the end of the study analyzed the skin samples to evaluate changes in psoriasis using a PASI score and measuring epidermal thickness. The group of 10 mice pre-treated with TGFTX1 had significant decreases in PASI score (40%, $p<0.001$), epidermal thickness score (41%, $p<0.001$) and in a direct measure of epidermal layer thickness (33%, $p<0.001$), compared to the group of 10 mice given the skin irritant alone. We have also completed several regulatory pre-IND studies of this drug candidate that are required for topically administered agents.

In parallel, we are developing a different RORγt drug candidate to treat certain inflammatory lung conditions, such as severe neutrophilic asthma, COPD and asthma-COPD overlap syndrome, conditions in which pathologic actions of IL-17 are postulated.

The drug profile of this highly potent and selective RORgt agonist is compatible with drug delivery to the lungs by inhalation, as required in respiratory diseases. Two patent applications were filed in 2019 to protect the API, its related chemical series and the prodrug form that enables efficacious drug delivery into the lungs.

To further these programs, we plan to leverage the expertise of specialized pharmaceutical companies with already established franchises in dermatology and/or respiratory diseases through collaborations or other strategic alliances that we may enter into in the future.

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.

NASH

Treatment

There are currently no approved drugs for the treatment of NASH; however, the NASH market has been attracting increasing interest from larger pharmaceutical companies over recent years.

We are aware of several companies, summarized below, that are currently in Phase 3 development of a drug candidate for the treatment of NASH:

- Intercept Pharmaceuticals, Inc., announced in February 2019 topline results for its Phase 3 clinical trial of obeticholic acid, or OCA, an FXR agonist for the treatment of NASH. OCA only achieved one of its two primary endpoints, demonstrating statistically significant improvement in liver fibrosis without worsening of NASH at 18 months, missing the other primary endpoint of NASH resolution without worsening of fibrosis. Intercept Pharmaceuticals has announced that their Prescription Drug User Fee Act (PDUFA) target action date for its NDA is June 26, 2020. OCA is not considered as a direct competitor of elafibranor, given the highly differentiated profiles of the two molecules.
- Allergan plc, following its acquisition of Tobira Therapeutics, Inc., which is developing its drug candidate cenicriviroc for the treatment of NASH. The current state of the program is not very clear, especially following Allergan's acquisition by Abbvie in 2019. In Phase 2, after 2 years of treatment, the main endpoints (NASH resolution without worsening of fibrosis, and fibrosis improvement without the worsening of NASH) were missed from a statistical perspective.
- Madrigal Pharmaceuticals, Inc., announced in December 2019 that the first patient had been dosed in MAESTRO-NAFLD-1, the second Phase 3 trial they conducted after MAESTRO-NASH, their first Phase 3 study in patients with NASH and fibrosis, that was initiated in March 2019. Madrigal's drug candidate resmetirom is a thyroid hormone receptor, or THR, β-selective agonist.
- Galmed Pharmaceuticals is developing aramchol, an oral therapy for the treatment of NASH and fibrosis, and announced in April 2019 the completion of its End-of-Phase 2 meeting with the FDA and a general agreement on the Phase 3/4 pivotal registration study ARMOR, to evaluate the efficacy, safety and tolerability of aramchol in subjects with NASH and fibrosis.
- Gilead Sciences, Inc. ran two Phase 3 trial of its drug candidate selonsertib, but targeting fibrosis only, and in patients with level F3 fibrosis due to NASH (STELLAR 3), and in patients with level F4 fibrosis due to NASH (STELLAR 4). In February and in April 2019, Gilead announced that selonsertib did not meet the pre-specified endpoint of one stage or greater histologic improvement in fibrosis without worsening of NASH in STELLAR 4 and STELLAR 3 respectively.
- Novo Nordisk announced in May 2020 that they had successfully completed a Phase 2 study evaluating semaglutide in NASH: 59% receiving semaglutide achieved NASH resolution with the highest dose (0.4 mg), vs. 17% for placebo, enabling further clinical trial development.

We are also aware of other companies that have drug candidates in earlier stages of development, including:

- NGM Biopharmaceuticals, Inc., which announced in February 2020 positive preliminary topline liver histology and biomarker data from a 24-week Phase 2 trial (Cohort 4) of aldafermin in NASH patients;
- Inventiva S.A., which is in Phase 2 development of its drug candidate lanifibranor, a drug targeting PPARα, PPARδ and PPARγ for the treatment of both NASH and systemic sclerosis; and
- Novartis AG, which is currently in Phase 2 development of its candidate emricasan.

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

PBC

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

We are aware of other companies developing drug candidates for the treatment of PBC with whom we would also compete, including, Zydus Cadila, Enanta Pharmaceuticals, Inc. and Eisai Inc.

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.

Other considerations

We believe that elafibranor's differentiated mechanism of action in targeting PPARα and PPARδ, the positive efficacy results from our Phase 2b clinical trial in NASH and our Phase 2 clinical trial in PBC and the favorable tolerability profile and demonstrated lack of safety concerns observed to date in clinical trials together suggest the potential for elafibranor to have competitive advantages over approved drugs and drug candidates in development by our competitors.

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 NIS4, we have entered into a license agreement with LabCorp to further develop and manufacture the test for clinical research use within IVD regulatory requirements.

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 May 1, 2020, we own or have rights to 29 issued U.S. patents, over 495 issued foreign patents, and 22 pending U.S. applications, and over 318 pending foreign patent applications. Our patent portfolio contains 49 different patent families, which are made up of over 800 patents and patents applications. Nineteen 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 May 1, 2020, we own three U.S. patents directed to the composition of matter of elafibranor, which are expected to expire in 2024, without taking a patent term extension 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 seven U.S. patents and one pending U.S. application directed to the treatment of liver diseases, including NASH, and using elafibranor. The granted patents and the pending patent applications, if issued, are expected to expire in 2030 and 2031, without taking a patent term extension into account. We also have counterpart patents granted in various countries or regions, including, Australia, Canada, China, Europe, Israel, and Japan. In addition, we own one U.S. patent application directed to the treatment of PBC, which, if issued, is expected to expire in 2037, without taking a patent term extension 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 May 1, 2020, we own four U.S. patent applications directed to the diagnosis of NASH, in particular our NIS4 diagnosis test, using certain biomarkers. The U.S. applications, if issued, would be expected to expire between 2036 and 2038.

We also have filed in 2019 several priority patent applications covering specific aspects of our NIS4 diagnostic test and on some other research tools.

Other Programs

We are pursuing patent protection for various molecules developed by our laboratories including molecules in our TGFTX1 program for the discovery of drug candidates relating to RORγt. As of May 1, 2020, we own one U.S. issued patent and 4 U.S. patent applications for the TGFTX1 program.

In addition, we are pursuing patent protection directed to our repositioning of nitazoxanide for treating cholestatic and fibrotic disease. As of May 1, 2020, four 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 loss 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 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 applying 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.

Pediatric extension

In the US and the EU it is possible to extend a product's regulatory exclusivity for an additional period of time, by providing data on pediatric studies.

Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements may result in the USPTO extending patent life by six months, to the extent that regulatory protections have not already expired.

In Europe, a Regulation on pediatric medicines provides for pediatric research obligations with potential rewards including extension of the Supplementary Protection Certificate for six months.

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 150 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 200 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 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.

Pediatric Exclusivity and Pediatric Use

Under the Hatch-Waxman Amendments, the FDA may not approve a generic (abbreviated NDA) until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting the filing of abbreviated NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product.

Under the Pediatric Research Equity Act of 2003, as amended, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or full or partial waivers from the pediatric data requirements if certain criteria are met.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent marketing and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the drug to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

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 approval; 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 the NIS4 test 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 2020, we anticipate entering into a second license agreement with a major laboratory partner to enable them to develop, deploy, market, and sell NIS4 as a laboratory developed test (LDT) for use as a clinical diagnostic.

As an LDT, the laboratory partner will be responsible for marketing the product to HCPs 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 version of NIS4 to allow us to commercialize the test within the United States. 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-version of 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. 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. Each Member State may approve a specific local price for the medicine. For example, in France, once a pharmaceutical product is granted marketing authorization by the EMA or the French Medicine Agency (ANSM), the company can file an application with HAS for national reimbursement. There are two lists of reimbursable pharmaceuticals:

- Drugs dispensed by retail pharmacies
- Drugs dispensed by hospitals

Drugs can appear on one or both of these lists. Reimbursement is based on the determination and assessment of three elements:

- The actual medical benefit, SMR
- The improvement in actual medical benefit, ASMR
- Target population eligible for treatment (in the reimbursement scheme)

To be placed on one (or both) of these reimbursement lists, companies must follow 3 steps:

- Choose which reimbursement list to be placed on, depending on the company’s strategy
- Technical assessment by the Transparency Committee (CT) and the economic assessment by the Committee for Economic and Public Health Assessment (CEESP), if needed
- Fixing the reimbursement rate by the National Union of Health Insurance Funds (UNCAM) and the pricing negotiation with the Economic Committee of Health Care Products (CEPS)

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 remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has 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. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a 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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will 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 December 31, 2020 due to the COVID-19 pandemic. 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's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a

"Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these, and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures 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.

Additionally, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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:

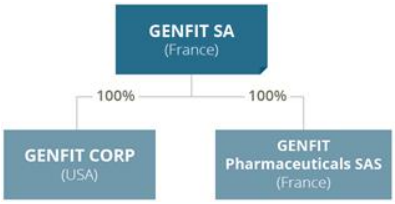
- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return 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 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;
- 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



D. Property, Plants and Equipment

Our corporate headquarters are located in Loos., France. We acted as agent of our lessor for the construction of an extension to the building leased to provide approximately 1,000 additional square meters of office space in April 2019. To date, the total surface occupied is approximately 6,500 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 have 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, and we are also evaluating elafibranor as a potential treatment for primary biliary cholangitis, or PBC, having announced positive preliminary results from a Phase 2 clinical trial in December 2018. On May 11, 2020, we published the topline data from the interim analysis.of the the RESOLVE-IT trial. In these interim results, elafibranor did not demonstrate a statistically significant effect on NASH resolution without worsening of fibrosis, which was the primary endpoint of the trial, nor did it achieve the key secondary endpoints. Based on the preliminary results of this interim readout , we don't expect to be able to obtain Subpart H or conditional approval of elafibranor in this indication by the FDA or the EMA. However, before we make a final decision about the future of RESOLVE-IT, we intend to review the full dataset and will conduct additional analyses, including some aimed at understanding why response rates among the placebo group in the RESOLVE-IT trial were higher than expected based on other late stage clinical trails using similar protocols. Depending on insights gained from these additional analyses, and after alignment with regulatory authorities, we will make a decision as to whether the extension phase should be continued, modified or discontinued.

As a result of this announcement, we are reviewing all of our non-essential expenses, with a first series of measures including terminating all marketing and commercialization readiness activities for elafibranor in NASH. However, since no immediate decision can be taken regarding the future of the RESOLVE-IT trial, the trial will continue and its associated costs will continue, including those related to CRO activities and patient monitoring, which cannot be interrupted abruptly due to ethical and regulatory concerns. In the event a decision is taken to discontinue the RESOLVE-IT trial in the Fall 2020, given the size and complexity of the study, residual costs are to be expected and the full impact of the decision on the Company's cash burn will not be noticeable until several months following the termination of the trial.

Our drug discovery efforts are based on selecting appropriate nuclear receptors as targets and utilizing rational drug design to optimize our drug candidates. A key differentiator of our development strategy is our NASH biomarker-based diagnostic program, called NIS4, in which we are developing a new *in vitro* diagnostic, or IVD, test to identify patients with NASH who may be appropriate candidates for drug therapy. 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 any 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 €65.1 million for the year ended December 31, 2019. We expect to incur significant expenses and substantial operating losses over the next several years as we continue our research and development efforts and advance the clinical development of elafibranor and potentially commercialize it as well as NIS4 and our other drug candidates, in the United States, Europe and elsewhere.

Financial Operations Overview

Revenue and Other Income

During the years ended December 31, 2017 and 2018, our revenue of €0.1 million in each period consisted primarily of revenue from the sublease of a portion of our corporate headquarters in Loos, France. We terminated this sublease effective as of June 30, 2018 and do not expect to receive any further sublease revenue. 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 Phamaceuticals, or Terns.

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 NIS4 for clinical development. 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). Under the LabCorp agreement, we expect to record revenues during the course of 2020. 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. In 2017, the tax credit was equal to 7% of wages paid to employees during the year in respect of salaries that do not exceed 2.5 times the French minimum wage. For 2018, the applicable tax credit was equal to 6% of eligible wages. The CICE was discontinued on January 1, 2019. We used this tax credit to finance the increases in our headcount and to purchase scientific equipment.

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.

Aide à l'embauche Grant

We recognize income related to *l'aide à l'embauche,* a subsidy granted in 2017 by French tax authorities to companies with less than 250 employees which hire new employees whose wages do not exceed 1.3 times the French minimum wage.

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;
- R&D-related grants to The NASH Epidemiology Institute (formerly The NASH Education Program) for the year 2017 and
- intellectual property fees related to the filing of patents.

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 trial. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain drug candidates, pursue later stages of clinical development of other drug candidates and progress the development of NIS4.

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, business development, 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 our general and administrative expenses 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, and investor relations costs. In particular, we will continue to incur additional accounting expenses to comply with the Sarbanes-Oxley Act of 2002 in the United States that will require us to test the effectiveness of our internal controls over financial reporting.

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.

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. 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, 2017, 2018 and 2019 are summarized in the table below.

	Year ended		
(in € thousands, except earnings per share data)	**2017/12/31**	**2018/12/31**	**2019/12/31**
	(*)	(*)	
Revenues and other income			
Revenue	118	69	30,839
Other income	6,737	7,425	10,122
Revenues and other income	6,856	7,494	40,961
Operating expenses and other operating income (expenses)	—	—	—
Research and development expenses	(54,189)	(67,024)	(66,170)
General and administrative expenses	(9,421)	(9,076)	(17,265)
Marketing and market access expenses	—	(717)	(13,708)
Other operating income (expenses)	60	(162)	(1,649)
Operating income (loss)	(56,695)	(69,484)	(57,832)
Financial income	642	728	5,221
Financial expenses	(3,096)	(11,118)	(13,110)
Financial profit (loss)	(2,453)	(10,391)	(7,889)
Net profit (loss) before tax	(59,148)	(79,875)	(65,721)
Income tax benefit (expense)	3,420	354	576
Net profit (loss)	**(55,728)**	**(79,521)**	**(65,144)**

(*) IFRS16 was adopted on January 1, 2019 using the modified retrospective method and 2017 and 2018 have not been restated.

Comparisons 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 in 2018. 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**

During the year ended December 31, 2019 we had foreign exchange gains related 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).

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, 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)	-
Other operating income (expenses)	(1,649)	-	-	-	(1,668)	-	19
TOTAL	**(98,793)**	**(2,202)**	**(41,568)**	**(20,984)**	**(28,807)**	**(5,251)**	**19**

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)	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
TOTAL	**(76,979)**	**(1,855)**	**(47,662)**	**(13,625)**	**(12,403)**	**(1,435)**	**2**

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 nitazoxanide or NTZ. 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.

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.

We expect our research and development expenses to continue to remain significant for the foreseeable future, as we initiate clinical trials for certain drug candidates, continue the later stages of clinical development for other drug candidates and progress in the development of our diagnostic test.

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. During the year ended December 31, 2018, we also donated €1 million to The NASH Education Program.

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.

We expect that our general and administrative costs will increase in the future, in parallel with the increase in our support functions, given the expected increase in research and development activities and of our regulatory obligations.

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.

We expect that our marketing and market access costs will increase in the future, in parallel with the increase in our support functions, given the expected increase in research and development activities and the potential commercialization of our drug and diagnostic candidates, and of our regulatory obligations.

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 interest payments on the OCEANEs are at a rate of 3.5% and the accretion of the discounting of the bond debt at an effective interest rate of 7.2%. 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.

Comparison for the Years Ended December 31, 2017 and 2018

Revenue

Revenue of €118,000 and €69,000 during the years ended December 31, 2017 and 2018, respectively, was primarily the result of our subleasing a part of our corporate headquarters in Loos, France.

Other Income

Other income for the years ended December 31, 2017 and 2018 consisted of the following:

Other income	**Year ended**	
(in € thousands)	**2017/12/31**	**2018/12/31**
CIR tax credit	6,545	7,295
CICE tax credit - Other operating income	171	130
Government grants and subsidies	21	—
TOTAL	**6,737**	**7,425**

Increase in the CIR between the years ended December 31, 2017 and 2018, 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, 2017 and 2018.

Operating Expenses for the Year Ended December 31, 2017

Operating expenses and other operating income (expenses) (in thousands of euros)	**Year ended 2017/12/31**	**Raw materials& consumables used**	**Contracted research & development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes)**	**Depreciation, amortization & impairment charges**	**Gain / (loss) on disposal of plant & property, equipment**
Research and development expenses	(54,189)	(2,117)	(35,088)	(7,915)	(7,973)	(1,095)	—
General and administrative expenses	(9,421)	(112)	(7)	(5,491)	(3,374)	(437)	—
Other operating income (expenses)	60	—	—	—	68	—	(8)
TOTAL	**(63,550)**	**(2,229)**	**(35,095)**	**(13,406)**	**(11,280)**	**(1,532)**	**(8)**

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)	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
TOTAL	**(76,979)**	**(1,855)**	**(47,662)**	**(13,625)**	**(12,403)**	**(1,435)**	**2**

Research and Development Expenses

Research and development expenses totaled €54.2 million, or 85% of our total operating expenses, for the year ended December 31, 2017. These expenses consisted primarily of €35.1 million in contracted research and development activities conducted by third parties, the substantial majority of which were incurred in connection with the advancement of our RESOLVE-IT Phase 3 clinical trial of elafibranor for the treatment of NASH. We also incurred €7.9 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. Other expenses of €8.0 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.

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.

General and Administrative Expenses

General and administrative expenses totaled €9.4 million, or 15% of our total operating expenses, for the year ended December 31, 2017. These expenses consisted primarily of €5.5 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, and as well as €3.4 million in costs and fees for third-party service providers.

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.

Marketing and Market Access Expenses

We did not incur specific marketing and market access expenses in 2017.

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.

Financial Income (Expense)

Our net financial income (expense) for the year ended December 31, 2017 was €(2.5) million, consisting primarily of €(2.3) million of interest expense on our convertible bonds and bank loans and a €(0.8) million net foreign currency exchange rate loss resulting from the translation of U.S. dollars generated by the operations of our U.S. subsidiary and subcontractors into euros, offset in part by €0.4 million of interest income on our cash and cash equivalents and €0.2 million of other financial income.

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.

B. Liquidity and Capital Resources

Overview

As of December 31, 2017, 2018 and 2019, we had €273.8 million, €207.2 million and €276.7 million, respectively, in cash and cash equivalents. At March 31, 2020, we had €252 million 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 €3.4 million, €3.2 million and €3.2 million associated with these types of arrangements as of December 31, 2017, 2018 and 2019, 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 €3.5 million, €4.0 million and €2.6 million in bank loans as of December 31, 2017, 2018 and 2019, 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.

As we continue to develop, and potentially commercialize, our drug candidates and diagnostic solutions in the coming years, 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.

Cash Flows

The table below summarizes our cash flows for the years ended December 31, 2017, 2018 and 2019:

(in € thousands)	**Year ended 2017/12/31 (*)**	**Year ended 2018/12/31 (*)**	**Year ended 2019/12/31**
Cash flows provided by (used in) operating activities	(49,856)	(56,081)	(47,680)
Cash flows provided by (used in) investment activities	(2,948)	(3,986)	327
Cash flows provided by (used in) financing activities	174,348	(6,514)	116,860
	121,544	**(66,580)**	**69,508**

IFRS16 "leases" was adopted on January 1, 2019 using modified retrospective method and 2017 and 2018 have not been restated.

Operating Activities

Cash used in operating activities was €49.9 million, €56.1 million and €47.7 million for the years ended December 31, 2017, 2018 and 2019, respectively.

With respect to the 2017 period, this amount primarily resulted from our net loss of €55.7 million, driven largely by our significant research and development efforts during the period, adjusted by €0.6 million in non-cash expenses and other adjustments and by €5.3 million in net cash flows from changes in working capital.

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 results 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.

Investing Activities

Cash used in investing activities was €2.9 million and €4.0 million for the years ended December 31, 2017 and 2018, respectively, and consisted primarily of equipment and other capital purchases and in 2018, acquisition of financial instruments. Cash provided in investing activities was €0.3 million for the year ended December 31, 2019 due to the reimbursement by the

landlord of the costs associated with the expansion of our corporate headquarters by the landlord when construction was completed in April 2019 More information is provided in Note 8 of our consolidated financial statements, included in this report).

Financing Activities

Cash provided by financing activities was €174.3 million for the year ended December 31, 2017 and consisted of gross proceeds of €180.0 million from our issuance of convertible bonds in October 2017, partially offset by bank fees, net repayments under bank loans, conditional advances, capital leases and interest paid.

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.

Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. Our net loss was €55.7 million, €79.5 million and €65.1 for the years ended December 31, 2017, 2018 and 2019, respectively. We expect to incur significant expenses and substantial 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 commercialization of NIS4 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 RESOLVE-IT trial of elafibranor for the treatment of NASH and our planned clinical trials of elafibranor for the treatment of PBC;
- 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 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, 2019 will be sufficient to fund our operations for at least the next 12 months.

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

The following table discloses aggregate information on a discounted basis about our material contractual obligations and the periods in which payments are due as of December 31, 2019. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

Contractual obligations (in € thousands)	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**	**Total**
Refundable and conditional advances	—	—	—	3,229	3,229
Convertible loans	1,312	164,142	—	—	165,454
Bank loans	1,105	1,486	54	—	2,645
Leases	2,112	3,692	2,254	4,223	12,281
Pension and employee benefits	—	—	—	1,408	1,408
Other	9	—	—	—	9
Total contractual obligations	**4,539**	**169,320**	**2,309**	**8,859**	**185,027**

The nominal amount of the convertible loan of €180.0 million is due in less than 3 years.

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 are cancellable contracts and are not included in the contractual obligations in the foregoing table.

In 2019, we signed a Memorandum of Understanding –(MoU) a CMO to be followed by an implementation contract with the CMO to set up a second supply and manufacturing source of elafibranor.

The costs related to the transfer of technology required for the establishment of the second source of supply and manufacturing, as well as the costs of manufacturing the registration lots will be borne by the CMO and serve as a basis for calculating the penalties that would be payable by the Group in certain cases of early termination of the MoU or its implementation contract. The amount of these penalties could reach a maximum of €1.4 million.

In February 2020, we entered into a MoU with another CMO, setting forth the general terms and conditions under which the CMO will undertake to establish a second source of manufacturing and supply of the active pharmaceutical ingredient or API in elafibranor, as well as the principal terms and conditions under which we will appoint the CMO for a determined period, as our non-exclusive manufacturer and supplier of minimum forecasted volumes of API in the United States of America, Canada and the European Union for a specified period.

If a market authorization is not obtained for all of the above countries, no manufacture and supply agreement will come into force and no compensation would be owed to the CMO.

If a market authorization is not be obtained in one or more of those countries, the minimum forecasted volumes of API to be manufactured and supplied shall be adapted to take into account, that the demand of end-product in which the API is used, might be below the initially forecasted minimum volumes.

If a market authorization is obtained, the manufacture and supply agreement will come into effect and we will have the right to terminate it for any reason, and at any time under the following cumulative conditions :

- sending a 24 months prior notification of our intent to terminate (although we may terminate immediately upon payment of an amount equal to 30% of the forecasted minimum volumes to be manufactured for the 24 months following the receipt of the termination notice) ; and the payment of the total amount of technology transfer costs actually incurred by the CMO from which we deduct, on a prorate basis, the amount of tons actually produced and sold to us as compared to the total forecasted minimum volumes remaining at the time of notification.

Agreement with a provider of commercial services for medical science liaisons

In January 2020,we entered into a services agreement with a provider of commercial services. Pursuant to this agreement, this provider shall appoint a field force of medical science liaisons to provide medical affairs services to us. Those medical science liaisons are being employed by the provider of commercial services for a determined period of 2 years starting in March 2020 .

Each party may terminate this agreement by providing with at least 90 days prior written notice to the other party; provided, however, that any such termination by us may not occur prior to the eighteen (18) month anniversary of the effective date of the agreement .

In the case of our termination of this agreement , a scale down, or at the end of the term, we will be obligated to pay or reimburse to the provider the amount due to any lessor or rental agent of the fleet vehicles and information technology equipment leased or owned by the provider and provided to medical science liaisons, or we may elect (i) to have transferred the IT equipment and pay an amount equal to the net book value of the equipment on the books of the provider at the time of the transfer event, or, (ii) the Company may elect to dispose of the IT equipment and pay the provider the net loss on such IT equipment or (iii) to dispose of the fleet vehicles and pay the provider the net loss on such fleet vehicles. Notwithstanding the foregoing options , we may terminate this agreement upon forty- five (45) days prior written notice to the provider in the event that the United States Food and Drug Administration does not approve elafibranor and/ or NIS4 (each a « product »), if there is a significant delay in receiving approval from the FDA of a product ; or the FDA has caused its withdrawal from the market of a Product, and such withdrawal causes or will cause this agreement and/or our commercialization of ourproduct candidates to no longer be commercially viable.

Agreement with a provider of commercial services for commercial leadership

In January 2020, the Company has entered into a services agreement with a provider of commercial services. Pursuant to this agreement, the provider shall appoint a commercial project team to support and facilitate elafibranor and NIS4 launch. This team consist of 3 full-time employee professionals, who are employed by the provider for a determined period of 2 years.

Each party may terminate this agreement by providing the other party with at least 90 days prior written notice.

In the case of termination of this agreement at the end of the term, we will be obligated to pay or reimburse to the provider the amount due to any lessor or rental agent of the fleet vehicles and information technology equipment leased or owned by the provider and provided to the team of commercial leadership, or we may elect (i) to have transferred the IT equipment and pay an amount equal to the net book value of that IT equipment on the books of the provider at the time of the transfer event, or, (ii) the Company may elect to dispose of the IT equipment and pay the provider the net loss on such IT equipment and (iii) to dispose of the fleet vehicles and pay the provider the net loss on such fleet vehicles. Notwithstanding the foregoing options, and except if we would receive a authorization under CLIA for NIS4, we may terminate this agreement upon forty- five (45) days prior written notice to the provider in the event that the FDA does not approve elafibranor, or if there is a significant delay in receiving approval from the FDA of a product ; the FDA has caused its withdrawal from the market of a product, and such withdrawal causes or will cause this agreement and/or our commercialization of our product candidates to no longer be commercially viable.

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

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, 2017, we had outstanding four repayable advances from BPI France with an aggregate remaining balance of €3.4 million. As of December 31, 2018, and as of December 31, 2019 we had outstanding one repayable advance with an amount 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 that is following patients at risk for type 2 diabetes. The program ended on December 31, 2014. The conditional advance is not refundable except 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 would be €14.8 million, inclusive of the €3.2 million advance to be repaid. 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. Following this letter, the parties met in March 2020 for the presentation of our arguments. 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.

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, and have a maturity date in October 2022. Beginning in November 2020, we may, at our option, redeem the bonds prior to maturity in the event that our share price exceeds a specified amount for a 20-day trading period.

Bank Loans

At December 31, 2017, 2018 and 2019, we had borrowed under multiple bank loans primarily intended to finance the acquisition of scientific and information technology equipment. The total principal amount outstanding was €3.5 million, €4.0 million and €2.6 million as of December 31, 2017, 2018 and 2019, 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. More information about our accounting for leases under IFRS 16 and the impacts of the adoption of this standard is provided in Note 8 to our consolidated financial statements included in this report.

Equipment Leases

From time to time we enter into lease agreements for scientific equipment that contain a purchase option and are considered financial leases. Amounts in the table above represent minimum principal payments.

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 above 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 and 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 based on the circumstances concerned. 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, and note 4.7.2 "Application of the new IFRS 16 standard".

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."

tellItem 6.Directors, Senior Management and Employees.

A. Directors and Senior Management

In September 2019, we announced the appointment of Pascal Prigent as CEO, and Jean-François Mouney's decision to transition from Chairman and CEO to full-time Chairman of the Board. The team also added Dr. Carol L. Addy as Chief Medical Officer, based in Cambridge, Massachusetts, announced the appointments of Dr. Dean Hum as President of GENFIT Corp. and Dr. Suneil Hosmane as Head of Global Diagnostics, both based at GENFIT's U.S. headquarters in Cambridge, Massachusetts.

At the Shareholders' Meeting planned for June 11, 2020, the Board of Directors has proposed that the shareholders vote on the addition of two new members to the Board. Mrs. Katherine Kalin and Mr. Eric Baclet, if approved, would bring significant experience in the pharmaceutical and diagnostic industries and would be considered independent directors under the criteria used by the Board of Directors.

The following table sets forth information concerning our senior management and directors as of May 1, 2020. 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	52	Chief Executive Officer
Dean Hum, Ph.D	57	Chief Operating Officer
Nathalie Huitorel	58	Executive Vice President and Chief Financial and Administrative Officer
Carol Addy, M.D.	60	Chief Medical Officer
Jean-Christophe Marcoux	43	Chief Strategy Officer
Suneil Hosmane, Ph.D	38	Head of Global Diagnostics
Laurent Lannoo	50	Corporate Secretary, Director of Legal Affairs
Non-Employee Directors		
Jean-François Mouney(1)(6)	64	Chairman of the Board
Xavier Guille des Buttes(2)(3)(7)	78	Vice-Chairman of the Board
Catherine Larue, Ph.D(1)	64	Director
Anne-Hélène Monsellato(4)	52	Director
Frédéric Desdouits-(7)	53	Director
Florence Séjourné(5)	48	Director
Philippe Moons(2)	67	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

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. He has also served as a member of the board of directors and Corporate Secretary of The NASH Education Program since July 2018.

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.

Nathalie Huitorel has served as our Executive Vice President and Chief Financial and Administrative Officer since October 2007 and as 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., the Management Committee of Genfit Pharmaceuticals SAS and a member of the board of directors and Treasurer of The NASH Education Program since its inception.

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.

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. He was also a member of the board of directors and Corporate Secretary of The NASH Education Program from its inception in 2017 until mid-2018.

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.

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.

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. He is also chairman of the board of directors of our wholly owned subsidiary, Genfit Corp., chairman of the Management Committee of our wholly owned subsidiary Genfit Pharmaceuticals SAS, and chairman of the board of directors of The NASH Education Program.

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. He is also vice chairman of The NASH Education Program.

Catherine Larue, Ph.D has served as a member of our board of directors since 2017. Since 2012, Dr. Larue has been CEO of the Integrated Biobank of Luxembourg (IBBL), where she leads the development of the bio banking strategy and new initiatives in the field of personalized medicine. 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. public 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. 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.

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 is Managing Director of Seqens CDMO Business Unit (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. 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.

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 of Da Volterra, a clinical-stage biotechnology company developing novel Microbiota Protective therapies for infection control and cancer supportive care. 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.

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. 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.

Family Arrangements and Selection Arrangements

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.

B. Compensation

Director Compensation

At our general meeting of shareholders held on June 13, 2019, 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 13, 2019 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, 2019, which consisted solely of attendance fees.

NAME	(€)
Jean-François Mouney(1)(2)	14,791
Xavier Guille des Buttes	68,016
Frédéric Desdouits	33,136
SAS Biotech Avenir	-
Philippe Moons	36,188
Anne-Hélène Monsellato	44,472
Catherine Larue	33,136

(1) Mr. Mouney was appointed as chairman of the board of directors by the shareholders at the Shareholders' Meeting on June 16, 2017. For the period from January 1, 2019 to September 15, 2019, while Mr. Mouney also served as our Chief Executive Officer, Mr. Mouney did not receive compensation for his service on the board of directors. The amount shown in the table reflects his compensation for service on the board of directors from September 16, 2019 through December 31, 2019. His compensation as Chief Executive Officer for the period from January 1, 2019 to September 15, 2019 is described in the section below titled "Chief Executive Officer Compensation."

(2) Mr. Mouney's compensation includes social security charges.

Chief Executive Officer Compensation

Our only executive officer under French law is our chief executive officer. During the year ended December 31, 2019, two individuals served in this role—Jean-François Mouney, through September 15, 2019, and Pascal Prigent, beginning September 16, 2019. The following table sets forth information regarding compensation earned during the year ended December 31, 2019 by Messrs. Mouney and Prigent.

NAME AND PRINCIPAL POSITION	FIXED COMPENSATION (€)	VARIABLE COMPENSATION (€)	DIRECTORS FEES (€)	EQUITY AWARDS (€)	ALL OTHER COMPENSATION (€)	TOTAL (€)
Jean-François Mouney, Chief Executive Officer(1)	441,182	750,524(2)	39,895(3)	108,522	7,200	1,347,323
Pascal Prigent, Chief Executive Officer(4)	94,694	-	-	-	408	95,102

(1) The compensation in this table is comprised of Mr. Mouney's compensation for his services as Chief Executive Officer from January 1, 2019 through September 15, 2019, as well as his gross fixed compensation as chairman of our board of directors for the period from September 16, 2019 to December 31, 2019.

(2) For the year ended December 31, 2019, Mr. Mouney was granted €750,524 as Chairman and CEO as variable compensation linked to performance under the Incentive Plan as applied following the capital increase as part of the Initial Public Offering on the Nasdaq Global Select Market. Three-quarters of that variable compensation, related to performance in 2018, in an amount of €562,893 was paid in 2019 following approval of the Shareholders Meeting on June 15, 2019. The remainder of his variable compensation, in an amount of €187,631, would have been subject to approval of the Shareholders Meeting on June 11, 2020, however, as described below, Mr. Mouney has elected to forgo receiving this amount

(3) Includes the gross annual directors fees of €29,479 for the performance of his office of chairman of the board of directors of our subsidiary, Genfit Corp., during the period from September 16, 2019 to December 31, 2019 and a gross compensation of €10,416 as Chairman of the Board of Directors for the period from September 16, 2019 to December 31, 2019 corresponding to directors' fees for his participation in certain Board committees.

(4) The compensation in this table is the compensation for Mr Prigent's services as our Chief Executive Officer for the period of September 16, 2019 through December 31, 2019.

Compensation of Mr. Mouney

The various component parts of the overall annual compensation of Mr. Mouney for his duties within the Genfit group during the fiscal year ended December 31, 2019 are summarized below:

Fixed Compensation

Through his executive officer contract (*contrat de mandat social*), Mr. Mouney received a gross fixed annual compensation of €384,892 for the duties carried out within Genfit S.A. as Chairman and CEO for the period from January 1, 2019 to September 15, 2019, and a gross fixed compensation of €56,290 for the period from September 16, 2019 to December 31, 2019 as Chairman of the Board of Directors of Genfit S.A. and a gross fixed annual compensation of €29,479 for the performance of his office of chairman of the board of directors of our subsidiary, Genfit Corp., during the period from September 16, 2019 to December 31, 2019.

Variable Compensation

For the year ended December 31, 2019, Mr. Mouney was granted €750,524 as Chairman and CEO as variable compensation linked to performance under the Incentive Plan as applied following the capital increase as part of the Initial Public Offering on the Nasdaq Global Select Market. Three-quarters of that variable compensation, related to performance in 2018, in an amount of €562,893 was paid in 2019 following approval of the Shareholders Meeting on June 15, 2019. The remainder of his variable compensation, in an amount of €187,631, was to be paid subject to approval of the Shareholders Meeting on June 11, 2020. However, in May 2020, Mr. Mouney has elected to forgo this amount; as a result, as noted by the Board of Directors, the balance of €187,631will not be paid.

The Incentive Plan provides that the Chairman and Chief Executive Officer's incentive bonus can represent up to 40% of the sums to be allocated under the plan; these sums vary in accordance with the conditions for carrying out the strategic and structuring operations for our development, and which reflect the beneficiary's performance.

Mr. Mouney also received a gross compensation of €10,416 as Chairman of the Board of Directors for the period from September 16, 2019 to December 31, 2019 corresponding to directors' fees for his participation in certain Board committees (Compensation and Nominations Committee and Strategy and Alliances Committee).

Equity Awards

During the year ended December 31, 2019, Mr. Mouney was granted equity awards in the form of stock options to purchase 15,130 shares and 3,000 free shares.

Other Compensation

The benefits in kind granted to Mr. Mouney for the year ended December 31, 2019 consisted of a company car valued at €7,200.

Severance Benefits

Until September 15, 2019, Mr. Mouney benefitted from a severance payment. No payments were made under that provision in his executive officer contract upon his resignation as CEO. As from September 16, 2019, he no longer benefits from a severance payment.

Compensation of Mr. Prigent

The various component parts 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, 2019 are summarized below:

Fixed Compensation

Through his executive officer contract (*contrat de mandat social*), Mr. Prigent received a gross fixed compensation of €94,694 for the duties carried out within Genfit S.A. as CEO for the period from September 16, 2019 to December 31, 2019. This amount represents the pro rata amount for the period during which he was CEO in 2019, calculated on the basis of a gross fixed annual compensation of €325,008.

Variable Compensation

For the year ended December 31, 2019, Mr. Prigent did not receive any variable compensation as CEO.

Equity Awards

During the year ended December 31, 2019, Mr. Prigent did not receive any equity compensation as CEO.

Other Compensation

The benefits in kind granted to Mr. Prigent as CEO for the year ended December 31, 2019 consisted of a company car valued at €408.

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 twelve months, increased, where applicable, by the amount of annual variable compensation due for the previous year 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 dachat 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) and redeemable share warrants (BSAAR) 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 four share-based compensation plans for our senior management, directors and employees, the BSAAR plan, the BSA plan, the AGA plan and the SO plan. In general, redeemable share warrants and share warrants no longer continue to vest following termination of the employment, office or service of the holder and all vested shares must be exercised within post-termination exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants.

As of December 31, 2019, share warrants, stock options and free shares were outstanding allowing for the purchase and/or free allocation of an aggregate of 573,182 ordinary shares.

Redeemable Share Warrants (BSAAR)

Redeemable share warrants have been granted to our directors 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:

- 5,901 BSAAR 2014-A, 17,822 BSAAR 2014-B and 18,711 BSAAR 2014-C were subscribed by members of the executive board during the 2014 and 2015 fiscal years;
- 3,118 BSAAR 2014-A, 6,237 BSAAR 2014-B, 6,237 BSAAR 2014-C were subscribed by Mr. Mouney during the 2014 and 2015 fiscal years; and
- 9,299 BSAAR 2014-A, 5,416 BSAAR 2014-B, 5,568 BSAAR 2014-C, 7,200 BSAAR 2016-A and 3,600 BSAAR 2016-B were subscribed by non-corporate officer employees.

As of December 31, 2019, 833 BSAAR 2014-A and 400 BSAAR-C have been exercised by non-corporate officer employees, and no BSAAR have been exercised by corporate officers. All of the BSAAR 2014 plans have lapsed.

The main terms of the BSAAR plans are 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, 2019	833	0	400	0	0
BSAAR cancelled or lapsed	14,367	23,238	23,879	0	0
BSAAR remaining as of December 31, 2019	0	0	0	7,200	3,600

(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, 2019, we have issued three share warrants plans as follows:

Plan title	BSA 2014-A	BSA 2014-B	BSA 2015-A	BSA 2015-B	BSA 2017-A	BSA 2017-B	BSA 2019
Meeting date	April 2, 2014	April 2, 2014	April 2, 2014	April 2, 2014	June 16, 2017	June 16, 2017	June 15, 2018
Dates of allocation	July 24, 2014	July 24, 2014	January 9, 2015	January 9, 2015	November 21, 2017	November 21, 2017	October 31, 2019
Exercise conditions(1)	1 warrant / 1.03 shares				1 warrant / 1 share		1 warrant / 1 share
Subscription periods	From August 1, 2014 to September 15, 2014	From January 2, 2015 to February 25, 2015	From January 20, 2015 to February 25, 2015	From July 1, 2015 to September 15, 2015	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	46,765	46,765	12,860	12,860	18,345	18,345	35,070
Start date for the exercise of the BSAs	November 1, 2014	March 1, 2015	June 1, 2015	December 1, 2015	July 1, 2018	July 16, 2018	July 1, 2019
BSA expiry date	September 30, 2018	February 28, 2019	May 31, 2019	November 30, 2019	June 30, 2022	July 15, 2022	May 31, 2024
BSA issuance price	€ 0.01	€ 0.01	€ 0.01	€ 0.01	€ 2.00	€ 2.00	€ 1.23
BSA exercise price per share	€ 23.50	€ 23.50	€ 35.95	€ 35.95	€ 19.97	€ 19.97	€ 12.32
Number of shares subscribed as of December 31, 2019	0	0	0	0	0	0	0
Warrants cancelled or lapsed	46,765	46,765	12,860	12,860	0	0	0
Warrants remaining as of December 31, 2019	0	0	0	0	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, 2019, Mr. Mouney served as both our chairman of our board and, through September 15, 2019, as our chief executive officer. Mr. Prigent served as our chief executive officer beginning September 16, 2019. 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).

During the years ended December 31, 2017, 2018 and 2019, the board of directors granted an aggregate of 41,196, 37,072 and 35,474 free shares, respectively, to all of our employees and senior management.

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, 2019, we granted an aggregate of 143,179 free shares 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	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(2)	€ 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	0
AGA D and S 2018	June 15, 2018	November 22, 2018	35,800	January 1, 2021	€ 20.02	0
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.

(2) Subject to meeting the conditions, the AGA 2016-1 could be definitively vested in whole or part on December 16, 2018, with a one year holding period, or on December 16, 2019 without a holding condition. As of December 31, 2019, 17,484 and 7,796 free shares were definitively vested under the AGA 2016-1 and AGA 2016-2, respectively.

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*). During the year ended December 31, 2019, Mr. Mouney served as both our chairman of our board and, through September 15, 2019, as our chief executive officer. Mr. Prigent served as our chief executive officer beginning September 16, 2019. We currently do not have any deputy executive officers. In addition, incentive stock options may not be granted to owners of shares possessing 10% or more of the share capital of our company.

In 2017, 2018 and 2019, the board of directors, using the authorizations granted to them by the extraordinary shareholders' meeting, decided to grant stock options to Mr. Mouney and certain senior managers, including Mr. Prigent, although he was not CEO at the time. 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 employees our company, 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.

In 2017, the board of directors granted an aggregate of 109,250 options as part of the plan SO 2017 which will expire December 31, 2027. In 2018, the board of directors granted an aggregate of 139,500 options as part of the SO 2018 and SO U.S. 2018 plans, each of which will expire December 31, 2028. In 2019, the board of directors granted an aggregate of 151,850 options as part of the SO 2019 and SO U.S. 2019 plans, each of which will expire September 17, 2029 and January 17, 2030.

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 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
Meeting date	June 21, 2016	June 21, 2016	June 16, 2017	June 16, 2017	June 15, 2018	June 15, 2018	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
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
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
SO expiry date	December 16, 2026	December 16, 2026	December 31, 2027	December 31, 2027	December 31, 2028	September 17, 2029	January 17, 2030
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
Number of SO exercised as of December 31, 2019	0	0	0	0	0	0	0
SO voided or lapsed	7,519	5,650	29,618	4,959	5,000	1,780	0
SO remaining as of December 31, 2019	34,398	15,308	43,212	31,461	134,500	136,720	13,350

(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.

All of our stock option plans (SO and SO US) and our AGA D free share plans are 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.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2016-1 SO US 2016-1 AGA D 2016-1	12/15/2018 and/or 12/15/2019	66 2/3 % of the instruments will be exercisable or definitively allocated, regardless of the variation of the stock market price, in the following events: (i) if, on the date of the Allocation Decision, one of the two ongoing or authorized clinical trials (RESOLVE-IT, Phase 2 in PBC) has revealed its first results and/or principal results and these results have been published; and (ii) if, on the date of the Allocation Decision, the authorization to launch at least one of the new clinical trials among the projected clinical trials has been obtained, either: • a clinical trial with elafibranor within a NASH subpopulation; or • a clinical trial with respect to fibrosis within the TGFTX4/repositioning program.
		Nature of external conditions
		33 1/3 % of the instruments will be exercisable or definitively allocated in proportion to the evolution of our 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] 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 2016-1	12/15/2018 and/or 12/15/2019	The free shares will be definitively allocated upon meeting the same internal performance conditions as the SO 2016-1, SO US 2016-1 and AGA D 2016-1 plans.
Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2016-2 SO US 2016-2 AGA D 2016-2	12/15/2019	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 in 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 two new clinical trials among the following are authorized by the EMA or the FDA, either: • Phase III clinical trials of or which aim to record a new product (TGFTX4) or a new indication for elafibranor (PBC); or • 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 our 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 2016-2	12/15/2019	The free shares will be definitively allocated upon meeting the same internal performance conditions as the SO 2016-2, SO US 2016-2 and AGA D 2016-2 plans.

Plans	Evaluation date for performance conditions	Nature of internal conditions
SO 2017-1 SO US 2017-1 AGA D 2017-1	12/31/2019	66 2/3 % of the instruments will be definitively allocated, regardless of the variation of the stock market price, in the following events: (i) if, on the date of the Allocation Decision, one of the two ongoing or authorized clinical trials (RESOLVE-IT, Phase 2 in PBC) has revealed its first results and/or principal results and these results have been published; and (ii) if, on the date of the Allocation Decision, the authorization to launch at least one of the clinical trials among the projected clinical trials has been obtained, either : • a clinical trial with elafibranor within a NASH subpopulation; or • a clinical trial with respect to fibrosis with NTZ.
		Nature of external conditions
		33 1/3 % of the instruments will be exercisable or definitively allocated in proportion to the evolution of our 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] 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 exercisable or definitively allocated.

Plans	Evaluation date for performance conditions	Nature of internal conditions
AGA S 2017-1	12/31/2019	The free shares will be definitively allocated upon meeting the same internal performance conditions as the SO 2017-1, SO US 2017-1 and AGA D 2017-1 plans.

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.

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
SAS Biotech Avenir represented by Florence Séjourné	Director	2010(3)	2022
Frédéric Desdouits	Director	2014(4)	2022
Catherine Larue	Director	2017	2022
Anne-Hélène Monsellato	Director	2017	2022
Philippe Moons	Director	2015(5)	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) 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.

(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.

(5) 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.

In 2019, the Board of Directors met 15 times, with an average participation rate of 93 % 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 % ;

Société Biotech Avenir (represented by Ms. Florence Séjourné) : 93 % ;

Mr. Frédéric Desdouits : 93 % ;

Ms. Catherine Larue : 67 % ;

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. Philippe Moons 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 is 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 2019, 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 and Mr. Jean-François Mouney currently serve on our nomination and compensation committee. Mr. Guille des Buttes is the chairperson of our remuneration and appointments 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 relatives 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 2019, the Nomination and Compensation Committee met five times, with an average participation rate of 100% of committee members.

Strategy and Alliances Committee. Mr. Jean-François Mouney, Mr. Xavier Guille des Buttes and Mr. Frédéric Desdouits 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 2019, the alliances committee met three times, with an average participation rate of 100% of committee members.

D. Employees

As of December 31, 2019, we had 194 employees. Of these employees, 127 were engaged in research and development and services related to research and development activities, 60 were engaged in administration and management, which includes finance, investor relations, information systems, human resources and legal, and 7 were engaged in marketing and commercial activities.

Of these 194 employees, 178 were employed by Genfit S.A. and 16 were employed by our U.S. subsidiary, Genfit Corp. Employees employed by Genfit Corp. were mainly based in our Cambridge, Massachusetts office.

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 May 1, 2020, 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 30, 2020, the date that is 60 days after May 1, 2020, and stock options and warrants that are currently exercisable or exercisable by June 30, 2020. Shares subject to options and warrants currently exercisable or exercisable by June 30, 2020 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 38,839,617 of our ordinary shares outstanding as of May 1, 2020.

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
5% Shareholders:		
Biotech Avenir SAS(1)	1,888,618[1]	4.86%
Directors and Senior Management:		
Jean-François Mouney(2)	1,907,839	4.91%
Pascal Prigent	4,000	*
Dean Hum, Ph.D(3)	7,750	*
Nathalie Huitorel(4)	10,752	*
Carol Addy	0	-
Jean-Christophe Marcoux(5)	3,564	*
Suneil Hosmane	0	-
Laurent Lannoo(6)	9,684	*
Xavier Guille Des Buttes(7)	6,342	*
Catherine Larue, Ph.D(8)	5,000	*
Anne-Hélène Monsellato(9)	5,000	*
Frédéric Desdouits(10)	19,561	*
Florence Séjourné	0	-
Philippe Moons(11)	5,310	*

Name of Beneficial Owner	Number of Ordinary Shares	Percentage
All directors and senior management as a group (14 persons)(12)	1,984,802	5.1%

* 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 1,899,884 ordinary shares, of which 1,888,618 shares are held directly by Biotech Avenir, 5,698 stock options that are exercisable within 60 days of May 1, 2020 and 2,257 free shares that may be acquired within 60 days of May 1, 2020.

(3) Consists of 11 ordinary shares, 5,698 stock options that are exercisable within 60 days of May 1, 2020 and 2,041 free shares that may be acquired within 60 days of May 1, 2020.

(4) Consists of 2,879 ordinary shares, 5,698 stock options that are exercisable within 60 days of May 1, 2020 and 2,175 free shares that may be acquired within 60 days of May 1, 2020.

(5) Consists of 554 ordinary shares, 2,707 stock options that are exercisable within 60 days of May 1, 2020 and 303 free shares that are exercisable within 60 days of May 1, 2020.

(6) Consists of 5,893 ordinary shares 2,848 stock options that are exercisable within 60 days of May 1, 2020 and 943 free shares that are exercisable within 60 days of May 1, 2020.

(7) Consists of 1,342 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of May 1, 2020.

(8) Consists of 5,000 BSA share warrants that are exercisable within 60 days of May 1, 2020.

(9) Consists of 5,000 BSA share warrants that are exercisable within 60 days of May 1, 2020.

(10) Consists of 111 ordinary shares and 19,450 BSA share warrants that are exercisable within 60 days of May 1, 2020.

(11) Consists of 310 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of May 1, 2020.

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

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2019 are as a result of dilution from our March 2019 global offering in which we issued and sold an aggregate of 7,647,500 new ordinary shares, comprising an initial public offering of 7,147,500 ordinary shares in the form of ADSs in the United States and a private placement of 500,000 ordinary shares in countries outside the United States, including France.

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, 2019, to the best of our knowledge, 3,768,324 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held by 77 shareholders of record in the United States. 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, 2019, 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 4.86% of our share capital and 8.87% of our voting rights. 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.

For the year ended December 31, 2019, we donated €45,000 to The NASH Education Program.

The registered office of The NASH Education Program is located at the same address as our principal executive offices, without charge to The NASH Education Program.

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. In 2019, we paid PCAS Group a total of €1.7 million (tax included).

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, 2019 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 alleges 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 seeks unspecified compensatory damages. We and the defendants intend to defend the matter vigorously.

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) are traded on Euronext Access in Paris under 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 included in this annual report, 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 are initial purchasers of the ADSs pursuant to the global offering and 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.

In 2011, France introduced a comprehensive set of tax rules applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor's net assets for the purpose of applying the former French wealth tax (replaced by the French real estate wealth tax (*impôt sur la fortune immobilière*) as from January 1, 2018), for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the former French wealth tax (replaced by the French real estate wealth tax (*impôt sur la fortune immobilière*) as from January 1, 2018) and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to securities (including ADSs) held in trusts. If ADSs are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of securities (including ADSs).

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

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 year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding 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-000467-20191218 issued on December 18, 2019, we are currently not included in such list.

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 year preceding 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% subject to 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 resident, established or incorporated in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC should be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds. A law aiming at fighting against tax fraud and adopted in October 2018 by the French Parliament expanded the list of non-cooperative States or territories as defined under Article 238-0 A of the FTC to include States and jurisdictions on the blacklist published by the Council of the European Union and as a consequence, expands this 75% withholding tax regime to certain States and jurisdictions included in the blacklist), subject to 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 resident, established or incorporated in in certain non-cooperative States or territories as defined in Article 238-0 A of the FTC) 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) 28% for fiscal years beginning on or after January 1st, 2020, 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) 28% for fiscal years beginning on or after January 1st, 2020, 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, will generally be subject to French withholding tax at a rate of 75%. The law aiming at fighting against tax fraud mentioned above expanded this 75% withholding tax regime to certain States and jurisdictions included in the blacklist of the European Union. 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 28% (to be decreased respectively to 26.5% and 25% in 2021 and 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-20-20-20-20120912 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 28% (to be decreased respectively to 26.5% and 25% in 2021 and 2022), or 75% if paid in certain non-cooperative States or territories (as defined in Article 238-0 A of the FTC), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid.

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

Form 5000 and Form 5001, together with instructions, will be provided by the 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 28% (to be decreased respectively to 26.5% and 25% in 2021 and 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 fortune*) 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. We have applied to list our ADSs 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. There can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. The Company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital, signed on August 31, 1994, as amended and currently in force, or the U.S.-France Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-France Tax Treaty is satisfactory for purposes of the qualified dividend 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 the global offering in our business. 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. We do not believe were characterized as a PFIC in our taxable year ended December 31, 2019; however, there can be no assurance that we will not be considered a PFIC for any future taxable year. 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.

We do not currently intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we were treated as a PFIC for any taxable year. 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. Prospective U.S. investors 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.

Certain Reporting Requirements With Respect to Payments of Offer Price. U.S. holders paying more than U.S. $100,000 for the ADSs generally may be required to file IRS Form 926 reporting the payment of the Offer Price for the ADSs to us. Substantial penalties may be imposed upon a U.S. holder that fails to comply. Each U.S. holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

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, 2019, expenses in U.S. dollars totaled $40.3 million based on the exchange rate in effect at December 31, 2019. 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 million for the year. For the year ended December 31, 2019, we realized a foreign exchange rate loss of €1.7 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 our clinical trials, we might need to manage an increasing number of transactions denominated in currencies other than the euro or indirectly exposed to currency risk, which will increase our overall exposure to this risk.

During 2019, 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.

Interest Rate Risk

We are exposed to interest rate risk related to our cash and cash equivalents. We had cash and cash equivalents of €276.7 million as of December 31, 2019, 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 €165.4 million as of December 31, 2019 in the form of convertible loans, which loans accrue interest at a fixed rate of 3.5% and for which the gross amount is €180 million. We also had outstanding at December 31, 2019 a total of €3.2 million in conditional advances from BPI France, €12.3 million of obligations under leases and €2.6 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 10 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 €55.7 million, €79.5 million and €65.1 million during the years ended December 31, 2017, 2018 and 2019, respectively, and had an accumulated deficit of €102.5 million, €158.9 million and €238.3 million as of December 31, 2017, 2018 and 2019, respectively. Net cash used in operating activities was €49.9 million , €56.1 million and €47.7 million for the years ended December 31, 2017, 2018 and 2019, 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, 2019, we had €276.7 million in cash and cash equivalents, compared to €207.2 million in cash and cash equivalents as of December 31, 2018 and compared to €273.8 million in cash and cash equivalents as of December 31, 2017. As of December 31, 2019, net cash was €93.1 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 €37.6 million and €109.1 million at December 31, 2018 and 2017 respectively (see the table below). Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents as of December 31, 2019 will be sufficient to fund our operations for at least the next 12 months.

Detail of calculation of net cash in € thousand	**As of December 31, 2017**	**As of December 31, 2018**	**As of December 31, 2019**
Cash and Cash equivalent	273,820	207,240	276,748
-Current convertible loans	-1,329	-1,312	-1,312
-Other current loans and borrowings	-1,834	-1,848	-3,226
-Non current convertible loans	-154,539	-159,176	-164,142
-Other non-current loans and borrowings	-6,978	-7,255	-14,939
Net cash	**109,140**	**37,649**	**93,129**

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.

Global Offering

In March 2019, we completed a global offering of an aggregate of 7,647,500 ordinary shares, including the full exercise of the underwriters' option to purchase 997,500 additional ordinary shares. The global offering consisted of an initial public offering of 7,147,500 ordinary shares in the form of American Depositary Shares, each representing one ordinary share, at an offering price of $20.32 per ADS, in the United States and a concurrent private placement in Europe and other countries outside of the United States, including France, of 500,000 ordinary shares at an offering price of €18.00 per ordinary share for aggregate gross proceeds to us of approximately $155.4 million (or €137.6 million based on the March 26, 2019 exchange rate of 0.88566 dollars to 1 euro). The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately €125.3 million. The offering commenced on March 26, 2019 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-229907, for our global offering was March 26, 2019.

SVB Leerink LLC and Barclays Capital Inc. acted as joint global coordinators for the global offering and joint bookrunners for the initial public offering of the ADSs. Roth Capital Partners, LLC and H.C. Wainwright & Co., LLC acted as co- managers for the initial public offering of the ADSs. Bryan, Garnier & Co. Limited and Natixis acted as joint bookrunners for the private placement of ordinary shares in countries outside the United States.

The net proceeds from our global offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering filed with the U.S. Securities and Exchange Commission on March 27, 2019.

None of the net proceeds of our global offering were paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

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, 2019, have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level, having implemented the remediation actions described further below.

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2018, our independent registered public accounting firm identified a control deficiency in our internal control over financial reporting that constituted a material weakness in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Our independent registered public accounting firm identified the material weakness attributable to our lack of expertise regarding complex and unusual IFRS accounting treatment for our convertible bonds and their associated deferred tax impacts. As such, our controls over financial reporting were not designed or operating effectively, and as a result there was an error in our previously issued financial statements for the year ended December 31, 2017 that required us to restate our financial statements for that year.

We have historically retained the services of an external consultant to assist us with complex and unusual IFRS accounting treatment, such as in the case of our convertible bonds. In an effort to remediate the material weakness identified with respect to our consolidated financial statements as of and for the year ended December 31, 2018, we have engaged additional personnel, both internal and external, with appropriate training, as well as to redesigned our supervision controls, some of which went into effect in 2019 (IFRS15 and IFRS16) including with respect to the documentation of assumptions used and the development of accounting positions, and reassessed the necessary qualifications for any external consultants. For the year ended December 31, 2019, no material weaknesses were identified.

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

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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

Except as described above as it relates to remediation of the material weakness identified in 2018, there has been no change in our internal control over financial reporting during the year ended December 31, 2019 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 2018 and 2019. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	Year Ended December 31,	
	2018	2019
	(in € thousands)	
Audit Fees	63	1,388
Audit-Related Fees	24	35
Tax Fees	-	-
Other Fees	-	-
Total	87	1,423

"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 2018 or 2019.

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-75 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				
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				
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				
4.8	Summary of Lease Agreement (English translation)	F-1	333-229907	10.5	02/27/19
4.9*#	Collaboration and License Agreement between the registrant and Terns Pharmaceuticals, Inc., dated June 24, 2019				
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				

* 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: May 27, 2020

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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, 2017, 2018 and 2019, 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, 2019, 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, 2017, 2018 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 4.7.2 to the consolidated financial statements, the Group changed its method of accounting for leases under IFRS 16 in 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
May 27, 2020

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

ASSETS (in € thousands)	Notes	As of 2017/12/31 (*)	2018/12/31 (*)	2019/12/31
Current assets				
Cash and cash equivalents	6.	273,820	207,240	276,748
Current trade and others receivables	9.	7,955	8,794	12,033
Other current financial assets	10.	31	—	—
Other current assets	11.	1,761	2,078	1,968
Inventories	-	4	4	4
Tax payable	-		—	—
Total - Current assets		283,572	218,116	290,753
Non-current assets				
Goodwill	-		—	—
Intangible assets	7.	636	796	920
Property, plant and equipment	8.	6,324	7,764	16,453
Non-current trade and other receivables	9.	1,921	1,489	—
Other non-current financial assets	10.	729	1,313	1,727
Other non-current assets	11.	—	—	—
Deferred tax assets	22.	—	—	—
Total - Non-current assets		9,611	11,362	19,099
Total - Assets		**293,183**	**229,478**	**309,853**

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	Notes	As of 2017/12/31	2018/12/31	2019/12/31
Current liabilities				
Current convertible loans	12.	1,329	1,312	1,312
Other current loans and borrowings	12.	1,834	1,848	3,226
Current trade and other payables	14.	23,580	35,974	36,917
Current deferred income and revenue	-	1	1	139
Current provisions	15.	361	112	2,061
Current employee benefits	16.	—	—	—
Other current tax liabilities	-	—	—	—
Total - Current liabilities		27,106	39,248	43,657
Non-current liabilities				
Non-current convertible loans	12.	154,539	159,176	164,142
Other non-current loans and borrowings	12.	6,978	7,255	14,939
Non-current trade and other payables	14.	—	—	450
Non-current deferred income and revenue	4.4.	2	1	—
Non-current provisions	15.	—	—	—
Non-current employee benefits	16.	936	1,085	1,408
Deferred tax liabilities	22.	2,165	1,773	1,193
Total - Non-current liabilities		164,620	169,291	182,132
Shareholders' equity				
Share capital	17.	7,792	7,796	9,715
Share premium	-	251,932	251,554	377,821
Retained earnings (accumulated deficit)	-	(102,531)	(158,897)	(238,340)
Currency translation adjustment	-	(8)	6	14
Net profit (loss)	-	(55,728)	(79,521)	(65,144)
Total shareholders' equity - Group share		101,457	20,939	84,065
Non-controlling interests	-	—	—	—
Total - Shareholders' equity		101,457	20,939	84,065
Total - Shareholders' equity & liabilities		**293,183**	**229,478**	**309,853**

* The Group applied IFRS 16 “Leases” from January 1, 2019 using the modified retrospective method, and therefore, the comparative information for 2017 and 2018 has not been restated. The impact of this application is presented in note 4.7.2 Application of the new IFRS 16 standard.

CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands of euros, except per share data)

(in € thousands, except earnings per share data)	Notes	Year ended 2017/12/31 (*)	2018/12/31 (*)	2019/12/31
Revenues and other income				
Revenue	2.2.	118	69	30,839
Other income	18.	6,737	7,425	10,122
Revenues and other income		6,856	7,494	40,961
Operating expenses and other operating income (expenses)				
Research and development expenses	19.	(54,189)	(67,024)	(66,170)
General and administrative expenses	19.	(9,421)	(9,076)	(17,265)
Marketing and market access expenses	19.	—	(717)	(13,708)
Other operating income (expenses)	19.	60	(162)	(1,649)
Operating income (loss)		(56,695)	(69,484)	(57,832)
Financial income	21.	642	728	5,221
Financial expenses	21.	(3,096)	(11,118)	(13,110)
Financial profit (loss)		(2,453)	(10,391)	(7,889)
Net profit (loss) before tax		(59,148)	(79,875)	(65,721)
Income tax benefit (expense)	22.	3,420	354	576
Net profit (loss)		**(55,728)**	**(79,521)**	**(65,144)**
Attributable to owners of the Company		(55,728)	(79,521)	(65,144)
Attributable to non-controlling interests		—	—	—
Basic and diluted earnings (loss) per share				
Basic and diluted earnings (loss) per share (€/share)	23.	(1.79)	(2.55)	(1.76)

* The Group applied IFRS16 ”leases” from January 1, 2019 using the modified retrospective method and therefore, the comparative information for 2017 and 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 2017/12/31 (*)	2018/12/31 (*)	2019/12/31
Net profit (loss)		**(55,728)**	**(79,521)**	**(65,144)**
Actuarial gains and losses net of tax	16.	(210)	(31)	(168)
Other comprehensive income (loss) that will never be reclassified to profit or loss		(210)	(31)	(168)
Exchange differences on translation of foreign operations		(29)	14	8
Other comprehensive income (loss) that are or may be reclassified to profit or loss		(29)	14	8
Gain on revaluation of properties		—	—	—
Net fair value gain on available-for-sale financial assets		—	—	—
Of which : changes in fair value for the period		—	—	—
Of which : unrealised gains or losses recognized in income for the period		—	—	—
Tax effect from the change in fair value of available-for-sale securities		—	—	—
Total other comprehensive income (loss)		**(55,967)**	**(79,537)**	**(65,304)**
Attributable to owners of the Company		(55,967)	(79,537)	(65,304)
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 2017 and 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 2017/12/31 (*)	Year ended 2018/12/31 (*)	Year ended 2019/12/31
Cash flows from operating activities			
+ Net profit (loss)	(55,728)	(79,521)	(65,144)
+ Non-controlling interests	—	—	—
Reconciliation of net loss to net cash used in operating activities			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets	1,226	1,819	3,263
+ Impairment and provision for litigation	186	(208)	357
+ Expenses related to share-based compensation	278	787	1,657
- Gain on disposal of property, plant and equipment	8	(2)	(19)
+ Net finance expenses (revenue)	2,296	10,971	11,437
+ Income tax expense (benefit)	(3,420)	(354)	(576)
+ Other non-cash items including Research Tax Credit litigation	17	0	1,702
Operating cash flows before change in working capital	(55,137)	(66,507)	(47,324)
Change in:			
Decrease (increase) in inventories	10	—	—
Decrease (increase) in trade receivables and other assets	(2,106)	(724)	(1,640)
(Decrease) increase in trade payables and other liabilities	7,364	11,056	1,284
Change in working capital	5,268	10,332	(356)
Income tax paid	13	93	—
Net cash flows used in operating activities	**(49,856)**	**(56,081)**	**(47,680)**
Cash flows from investing activities			
- Acquisition of property, plant and equipment	(2,800)	(2,938)	(2,030)
+ Proceeds / reimbursement from disposal of property, plant and equipment	15	3	2,517
- Acquisition of financial instruments	(163)	(1,050)	(160)
Net cash flows provided by (used in) investment activities	**(2,948)**	**(3,986)**	**327**
Cash flows from financing activities			
+ Proceeds from issue of share capital (net)	—	—	126,486
+ Proceeds from subscription / exercise of share warrants	37	37	43
+ Proceeds from new loans and borrowings net of issue costs	177,338	1,800	—
- Repayments of loans and borrowings	(1,655)	(2,000)	(1,884)
- Financial interests paid (including finance lease)	(1,372)	(6,351)	(7,785)
Net cash flows provided by (used in) financing activities	**174,348**	**(6,514)**	**116,860**
Increase (decrease) in cash and cash equivalents	**121,544**	**(66,580)**	**69,508**
Cash and cash equivalents at the beginning of the period	152,277	273,820	207,240
Cash and cash equivalents at the end of the period	**273,820**	**207,240**	**276,748**

* The Group applied IFRS16 ”leases” from January 1,2019 using the modified retrospective method, and therefore, the comparative information for 2017 and 2018 has not been restated. The impact of the application is presented in note 4.7

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, 2017	**31,166,437**	**7,792**	**237,305**	**(127)**	**(68,527)**	**21**	**(33,667)**	**142,797**	**—**	**142,797**
Net profit (loss)	—	—	—	—	—	—	(55,728)	(55,728)	—	(55,728)
Other comprehensive income (loss)	—	—	—	—	(210)	(29)	—	(239)	—	(239)
Total comprehensive income (loss)	—	—	—	—	**(210)**	**(29)**	**(55,728)**	**(55,967)**	**—**	**(55,967)**
Allocation of prior period profit (loss)	—	—	—	—	(33,667)	—	33,667	—	—	—
Capital increase	—	—	—	—	—	—	—	—	—	—
Equity component of OCEANE net of deferred taxes	—	—	14,312	—	—	—	—	14,312	—	14,312
Share-based compensation	—	—	278	—	—	—	—	278	—	278
Treasury shares										
Other movements	—	—	37	—	—	—	—	37	—	37
As of December 31, 2017	**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**

* The expenses incurred in 2018 and 2019 in relation to the Initial Public Offering are deducted from the share issue premium (see note 2.1 Initial Public Offering on the Nasdaq Global Select Market)

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 concentrates its research and development (R&D) efforts in the potential marketing of therapeutic and diagnostic solutions to combat certain metabolic, inflammatory, autoimmune and fibrotic diseases affecting in particular the liver (such as non-steatohepatitis alcoholic - NASH) and more generally gastroenterological diseases.

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").

2. MAJOR EVENTS IN THE PERIOD

2.1 Initial Public Offering on the Nasdaq Global Select Market

On March 29, 2019, Genfit completed a capital increase to a specified categories of investors, without preferential subscription rights, of an aggregate of

- 7,147,500 ordinary shares in the form of American Depositary Shares, each representing one ordinary share (“ADSs”), at a public offering price of $20.32 per ADS (the “ADS Offering”), and
- 500,000 ordinary shares in Europe (including France) and countries outside of the United States at the corresponding offering price of €18.00 per ordinary share (the “European Private Placement,” and together with the ADS Offering, the “Global Offering”).

The number of shares issued in the ADS Offering includes an additional 997,500 ADSs issued upon the full exercise by the underwriters for the Global Offering (the “Underwriters”) of their option to purchase additional ADSs (the “Underwriters’ Option”).

Aggregate gross proceeds of the Global Offering, before deducting underwriting discounts and commissions and offering expenses payable by the Company, were approximately US $155.4 million (or €137.6 million based on the March 26, 2019 exchange rate of 0.88566 dollars to 1 euro). All of the ADSs and ordinary shares in the Global Offering were offered by GENFIT (see the consolidated statements of changes in equity.)

The ADSs have been listed for trading on Nasdaq since March 27, 2019.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

2. BASIS OF PRESENTATION (Continued)

The expenses incurred and deducted from the issue premium are broken down as follows:

Expenses related to the global offering (in € thousands)	
Registration, filling, listing fees	(290)
Underwriting	(9,634)
Legal fees and expenses	(1,225)
Accounting fees and expenses	(1,045)
Printing expenses	(160)
TOTAL	(12,354)

A total of €12.3 million of expenses were incurred, of which € 1.2 million were incurred and recorded at December 31, 2018.

2.2. Licensing Agreements

LabCorp Agreement

On January 2, 2019, the Company signed a licensing agreement with Covance, LabCorp's drug development business. The licensing agreement will expand access to NIS4, a non-invasive IVD technology developed by Genfit to identify and monitor NASH patients, in the clinical research space. The primary focus of the licensing agreement will be to deploy NIS4 in the clinical research space through Covance's central laboratories to further validate the test's use for better identification and characterization of patients. Following commercial launch of NIS4 through Covance's central laboratories, the Company expects to recognize revenues under this agreement during the course of 2020.

Terns Pharmaceuticals Agreement

On June 24, 2019, the Company signed a of a licensing and collaboration agreement with Terns Pharmaceuticals, an international company based in the United States and China, dedicated to the development of new therapies for the treatment of liver diseases.

Pursuant to the agreement, Terns Pharmaceuticals obtained the exclusive rights to develop and market elafibranor in mainland China, Hong Kong, Macau and Taiwan ("Greater China") for both NASH and PBC.

The main terms of the agreement include:

- An exclusive license with the right to sublicense to develop, manufacture, distribute and market elafibranor for the treatment of patients suffering from NASH and PBC in Greater China;
- The Company's undertaking to transfer to Terns Pharmaceuticals its know-how and data regarding elafibranor;
- The Company's undertaking to provide, or have provided to Terns Pharmaceuticals the drug product it requires for its clinical trials.

As part of the deal, GENFIT and Terns Pharmaceuticals will also undertake joint R&D projects in liver disease, including the development of elafibranor in combination with Terns Pharmaceuticals' proprietary compounds.

2. BASIS OF PRESENTATION (Continued)

Under the terms of the licensing agreement, GENFIT has received or may receive:

- A $35 million upfront payment upon the signature of the agreement, received on July 3, 2019;
- Clinical and regulatory milestone payments;
- Commercial milestone payments;
- Mid-teen percentage royalties based on sales in the territory.

The potential clinical, regulatory and commercial milestone payments represent up to USD$193 million.

2.3. Extension of corporate headquarters

In May 2018, Genfit signed an agreement with the lessor of its corporate headquarters to extend in 2019 the current lease, that was at the time set to expire in 2022, for another ten years and to lease for ten years a new building to be built on the same premises. The new lease agreement is non-cancellable for a nine year period beginning in 2019.

Pursuant to the agreement, Genfit acted as agent of the lessor for the construction of the new building and was responsible for the cost of its construction. The agreement provides that the lessor must reimburse Genfit for costs of construction up to €2.5 million. All costs incurred above €2.5 million will be assumed by Genfit.

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 as adopted by the European Union at December 31, 2019.

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 IFRS.

These consolidated financial statements for the year ended December 31, 2019 were prepared under the responsibility of the Board of Directors that approved such statements on May 20, 2020.

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 condensed Consolidated Financial Statements are described below.

All financial information (unless indicated otherwise) is presented in thousands of euros (€).

3.1. Changes in accounting policies and new standards or amendments

The Group adopted IFRS 16 Leases on January 1, 2019. The new IFRIC 23 standard “Uncertainty over Tax Treatment”, came into effect on January 1, 2019, but they had no significant effect on Group financial statements.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

3. BASIS OF PRESENTATION (Continued)

Other required standards and interpretations, applicable from January 1, 2019, do not have any significant effect on the Group's financial statements for the year ended December 31, 2019. They concern, principally:

- Amendment to IFRS9: "Prepayment features with negative compensation"
- Amendment to IAS 28: "Long-term interests in Associates and Joint Ventures"
- Amendment to IAS 19 "Plan Amendment, Curtailment or Settlement"

New or amended policies or standards		Effective date	Potential impact on consolidated financial statements
IFRS 16 *Leases*	IFRS 16 aligns the accounting for operating leases with that of finance leases	Applicable for all reporting periods from January 1, 2019	The group adopted IFRS 16 using the modified retrospective method and elected to apply it to contracts that were previously identified as leases under IAS 17 and IFRIC 4. The Group used the exemptions provided for leases whose term is less than 12 months from the date of 1st application and those relating to assets of low value. See note 4.7 to the consolidated financial statement

3.2. Standards, interpretations and amendments issued but not yet effective

The Group has not identified any standards or amendments issued but not yet effective as of January 1, 2020 that may have a significant impact on the Group's consolidated financial statements.

However, following publication of the final decision of IFRS IC on December 16, 2019 relating to the duration of leases and its interaction with the amortization period for non-removable fixtures, the Group is in the process of identifying those agreements which may be impacted, collecting the necessary information and performing analyses in order to estimate the possible impacts of this decision.

These analyses mainly relate to the identification of agreements that may be impacted, the collection of relevant information, in particular among existing fixtures, the determination of estimates to define the execution period and the rental period.

As of December 31, 2019, the Group's analysis of the impact of the IFRS IC decision requires sufficient time and is still ongoing. Its implementation could result in an extension of the rental period initially assumed and lead to a revision of the lease debt and the right of use asset relating to the relevant leases.

However, the Group should not be significantly impacted given the absence of contracts with an automatic renewal / extension of rental period or contracts that may be terminated for an indefinite period, and for which the lease period is likely to be modified following completion of the analyses.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

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"), share-based payments (see Note 20, "Share-based compensation"), accruals related to clinical trials (see Note 19, "Operating expenses") and convertible loans (see Note 12, "Loans and Borrowings").

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:

Ratio : 1 US dollars (USD) = x euros (EUR)	Year ended 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31
Exchange rate at period end	0.83382	0.87336	0.89015
Average exchange rate for the period	0.88704	0.84758	0.89341

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

4.4 Revenues from ongoing activities under client agreements

The Group signed an agreement with Terns Pharmaceuticals on June 24, 2019. 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.

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.

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

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- 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.
- 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.
- 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.
- 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.

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, 2019. 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.

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.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

4.7.1 IFRS 16 and IAS 17

The Group has applied IFRS 16 in accordance with the modified retrospective method, under which the cumulative effect of the adoption of IFRS 16 is recorded as an adjustment to the balance of accumulated deficit as at January 1, 2019. As a result, comparative information presented for 2018 has not been restated and is therefore presented, as before, in accordance with the principles of IAS 17 and its interpretations. The resulting changes in accounting policies are explained in detail below.

Significant accounting policies of IAS 17

Finance leases

When substantially all of the risks and rewards of ownership are transferred from the lessor to the lessee, the leases are classified as finance leases, resulting in the initial recognition of an asset equal to the fair value of the relevant property or the present value of the minimum future payments due under the contract, whichever is lower. They are subsequently amortized or depreciated, as the case may be. The resulting financial liabilities are recorded in current and non current “other loans and borrowings”.

Operating leases

A lease agreement is qualified as an operating lease when substantially all of the risks and rewards of ownership are not transferred to the lessee. Payments under operating leases are recognized as an expense on a straight-line basis over the term of the lease. Benefits received from the lessor such as rent suspensions or variable payments are allocated on a straight-line basis over the term of the lease.

Significant accounting policies under IFRS 16

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.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 and has a significant impact on the amount of lease debt and the "right of use" asset in the accounts.

4.7.2 Application of the new IFRS 16 standard

IFRS 16 "Leases", adopted by the European Union on October 31, 2017, is mandatorily applicable for the reporting periods starting on or after January 1, 2019. It replaces IAS 17 "Leases" and its interpretations.

This new standard removes the concepts of finance lease and operating lease for the lessee and requires all leases to be recognized on the lessee's balance sheet in the form of a "right of use" asset with the corresponding entry for a financial debt. The Group's leases, formerly classified as operating leases in accordance with IAS 17, concern real estate assets, including the Group's corporate headquarters.

Contracts formerly classified as finance leases include, in particular, scientific equipment.

As part of the transition, the Group adopted the "modified retrospective" method and chose to apply some of the practical expedients offered by IFRS 16, namely:

- The exclusion of contracts of less than 12 months duration;
- Exclusion of low value contracts;
- Carryforward of contracts previously accounted for as finance lease contracts under IAS 17 "Leases".

The new standard is implemented as follows:

- The lease term for a contract corresponds to its non-cancellable period, extended, as the case may be, based on the Group's assessment of the reasonably certain nature of the exercise of contractual renewal or cancellation options;
- The discount rate applied is the incremental borrowing rate corresponding to the duration of the contract, in the absence of an implicit rate in the contract. To determine the incremental borrowing rate, the Group determined the remaining term of the contracts as from January 1, 2019. The weighted average incremental borrowing rate at January 1, 2019 was 1.26%. Duration is the average life of financial flows weighted by their discounted value.

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)

"Right of use" assets and lease liabilities were recognized in the Group's balance sheet as at January 1, 2019 for € 9,227 and € 8,947, respectively.

In accordance with IFRS 16, the Group has chosen to present the “right of use” assets in the same line item as property, plant and equipment as the assets of the same type.

As of December 31, 2018, the differences between the commitments related to operating leases presented in application of IAS 17 and the lease liability estimated in accordance with IFRS 16 can be explained as follows:

In € thousands	12/31/2018
Operating lease commitments as a lessee, as of 12/31/2018 as published	*4,791*
Differences related to extension options for which the exercise is reasonably certain	5,264
Differences in the amounts retained for the calculation of commitments and lease liability	(396)
Expenses not included in the lease liability but included in the commitments	(190)
Undiscounted lease liability estimated under IFRS 16 at 1/1/2019	*9,469*
Impact of discount	(522)
Lease liability estimated under IFRS 16 at 1/1/2019	*8,947*

The impact of the duration is entirely attributable to the Group's headquarters, where an agreement to extend the building led to a revision of the commitment period for Genfit and the lessor under this lease.

The lease expense that would have been recognized in 2019 if IAS 17 had applied would have amounted to € 1,480. Under IFRS 16, expenses recognized in 2019 amounted to € 1,241 in depreciation for right of use assets and € 128 in interest expense.

4.8. Impairment of tangible assets, intangible assets and 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 Company does not have any goodwill.

4.9. Financial instruments

IFRS 9 “Financial Instruments” replaces IAS39 “ Financial Instruments: Recognition and Measurement” starting from the 2018 financial year and takes into account three aspects of booking financial instruments:

- Classification and measurement;
- Impairment;
- Hedge accounting.

As was the case in the previous periods, application of IFRS 9 does not have an impact on the Group’s financial statements.

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.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. A valuation allowance for trade receivables is recognized if their recoverable amount is less than their carrying amount.

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 an available-for-sale 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 the characteristics of which are that some could be classified as liabilities and others as equity, the issuer must recognize the different components separately.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 having 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.

The liability component (after deduction of the portion of the expenses related to the transaction pro rata portion to the respective parts attributed to 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.

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

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.

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.

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.

Grants related to assets

Grants related to assets are intended to finance the purchase of long-term assets. They are presented in the statements of financial position as deferred income and recognized in the line item "Other income" in the statements of operations on a systematic basis over the useful life of the related asset.

Grants related to income

Grants related to income are intended to finance research programs.

They are presented in the statements of financial position as deferred income and recognized in the line item "Other income" in the statements of operations as and when costs related to the research programs are incurred.

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.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. If a program is unsuccessful, a predetermined 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.

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"). The CIR for fiscal years 2010, 2011, 2012 and 2014 was under audit by the tax authorities and a provision was made in the accounts. (see Note 24, "Litigation and contingent liabilities").

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.

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;
- donations to The NASH Epidemiology Institute endowment fund, in particular to fund the creation of patient registry;
- 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 in relation to the Research Tax Credit dispute (see note 24 to our financial consolidated statements)

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)

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.

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.);
- grants to the endowment fund, The NASH Epidemiology Institute™, earmarked in particular to finance the International NASH Day; and
- 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;
- facility-related costs;
- marketing, and market access firm fees;
- the cost of external employees seconded to the Company (market access..) and
- other service costs (recruitment, etc);

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 the share-based compensation is measured to reflect such conditions and there is no adjustment for differences between expected and actual outcomes.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 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 due to a growing portion of its operations being denominated in US dollars, and because the Group decided not to convert into euros the US dollar denominated cash it raised in March 2019 IPO. The Company expects to use cash held in US dollars to meet expenses denominated in this currency over the next few years.

In the future, and in particular with respect to its clinical trials and pre-marketing activities, the Group will manage an increasing 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; and
- the Group's foreign exchange risk policy.

During the 2017 fiscal year, the Group used specific hedging arrangements (e.g., purchase of U.S. dollars and of UCITS in U.S. dollars, as well as currency forwards in U.S. dollars). In 2018, the Group considered the implementation of appropriate certain hedging arrangements without ultimately using any such arrangements. During 2019, 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.

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)

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 2017, 2018 and 2019:

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**		
	2017/12/31	**2018/12/31**	**2019/12/31**
Cash and cash equivalents denominated in US dollars	3,611	1,188	153,438
Equivalent in euros, on the basis of the exchange rate described below	3,011	1,038	136,582
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	3,345	1,153	151,758
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	2,737	944	124,166

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**		
	2017/12/31	**2018/12/31**	**2019/12/31**
Expenses denominated in US dollars	5,993	9,613	40,355
Equivalent in euros, on the basis of the exchange rate described below	4,997	8,396	35,922
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	5,552	9,328	39,914
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	4,543	7,632	32,657

2019/12/31 : Equivalent in euros, on the basis of a 1 euro = 1.1234 US dollar ratio
2018/12/31 : Equivalent in euros, on the basis of a 1 euro = 1.145 US dollar ratio
2017/12/31 : Equivalent in euros, on the basis of a 1 euro = 1.1993 US dollar ratio

Cash, cash equivalents and financial assets (in € thousands or in US dollar thousands, as applicable)	**As of**		
	2017/12/31	**2018/12/31**	**2019/12/31**
At origin, denominated in EUR			
Cash and cash equivalents	270,210	206,199	139,863
Current and non current financial assets	729	1,303	1,614
Total	**270,939**	**207,502**	**141,477**
At origin, denominated in USD			
Cash and cash equivalents	3,611	1,041	136,884
Current and non current financial assets	31	10	113
Total	**3,642**	**1,051**	**136,997**
Total, in EUR			
Cash and cash equivalents	273,820	207,240	276,748
Current and non current financial assets	760	1,313	1,727
Total	**274,581**	**208,553**	**278,474**

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, 2019, 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, 2017, 2018, and 2019 the Group's financial liabilities totaled €164,680, €169,593 (net of the equity component of the convertible loan and debt issue costs), and €183,617 respectively. 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), 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.

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, 2017, 2018 and 2019, the Group had €274,581, €208,553, and €278,474 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, 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; and
- Negotiable medium-term notes, available with a quarterly maturity or by the way of early exit.

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)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Short-term deposits	244,279	201,522	263,147
Cash on hand and bank accounts	29,541	5,718	13,601
TOTAL	**273,820**	**207,240**	**276,748**

Short-term deposits	**As of**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
UCITS	38,052	29,189	3,096
TERM ACCOUNTS	138,967	124,316	215,018
NEGOTIABLE MEDIUM-TERM NOTES	4,150	—	—
INTEREST-BEARING CURRENT ACCOUNT	63,110	48,017	45,033
TOTAL	**244,279**	**201,522**	**263,147**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

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, 2017, 2018 and 2019:

Intangible assets—Variations (in thousands of euros)	As of January 1, 2017	Increase	Decrease	As of December 31, 2017
Gross				
Software	1,688	268	(56)	1,900
Patents	21	—	—	21
TOTAL – Gross	**1,709**	**268**	**(56)**	**1,921**
Accumulated depreciation and impairment				
Software	(1,020)	(298)	54	(1,264)
Patents	(21)	—	—	(21)
TOTAL - Accumulated depreciation and impairment	**(1,042)**	**(298)**	**54**	**(1,285)**
TOTAL – Net	**668**	**(29)**	**(2)**	**636**

Intangible assets—Variations (in thousands of euros)	As of January 1, 2018	Increase	Decrease	As of December 31, 2018
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**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

7. INTANGIBLE ASSETS (continued)

Intangible assets – Variations (in € thousands)	As of 2018/12/31	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**

8. PROPERTY, PLANT AND EQUIPMENT

The following tables show the variations in tangible assets for the years ended December 31, 2017,2018 and 2019:

Property, plant & equipment—Variations (in thousands of euros)	As of January 1, 2017	Increase	Decrease	Reclassification	As of December 31, 2017
Gross					
Buildings on non-freehold land	—	11	—	—	11
Scientific equipment	6,078	3,546	(49)	—	9,576
Fittings	988	138	—	—	1,126
Vehicles	82	61	(44)	—	99
Computer equipment	1,475	211	(12)	281	1,954
Furniture	317	40	—	—	357
In progress	—	281		(281)	—
TOTAL - Gross	**8,940**	**4,287**	**(105)**	—	**13,123**
Accumulated depreciation and impairment					
Scientific equipment	(4,438)	(673)	48	—	(5,063)
Fittings	(657)	(65)	—	—	(722)
Vehicles	(29)	(17)	22	—	(24)
Computer equipment	(530)	(184)	11	—	(703)
Furniture	(276)	(9)	—	—	(285)
In progress	—	—	—	—	—
TOTAL - Depreciation and impairment	**(5,930)**	**(949)**	**81**	—	**(6,798)**
TOTAL - Net	**3,010**	**3,338**	**(24)**	—	**6,324**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

8. **PROPERTY, PLANT AND EQUIPMENT (continued)**

Property, plant and equipment—Variations (in thousands of euros)	As of January 1, 2018	Increase	Decrease	Reclassification	As of December 31, 2018
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	—	805	—	(804)	—
TOTAL - Gross	**13,123**	**2,939**	**(288)**	—	**15,774**
Accumulated depreciation and impairment					
Buildings on non-freehold land	—	(1)	—	—	(1)
Scientific equipment	(5,063)	(1,142)	218	—	(5,988)
Fittings	(722)	(91)	43	—	(769)
Vehicles	(24)	(21)	0	—	(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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

8. PROPERTY, PLANT AND EQUIPMENT (continued)

Property, plant and equipment - Variations (in € thousands)	As of 2018/12/31	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**

Assets related to contracts that were classified as finance leases under IAS 17 are scientific equipment. As mentioned above, these contracts are accounted for in the same manner under IFRS 16. Their net carrying value as of December 31, 2017, 2018 and 2019 amounted to €1,895, €1,889, and €1,413 respectively.

In May 2018, Genfit signed an agreement with the lessor of its corporate headquarters to extend in 2019 the current lease, that was set to expire in 2022, for another ten years and to lease for ten years a new building to be built on the same premises. The new lease agreement is non-cancellable for a nine year period beginning in 2019.

Pursuant to the agreement, Genfit acted as agent of the lessor for the construction of the new building and is responsible for the cost of its construction. The agreement provides that the lessor must reimburse Genfit for costs of construction up to €2.5 million. All costs incurred above €2.5 million will be assumed by Genfit.

As of December 31, 2018, the costs incurred to date by Genfit for the construction were €1.4 million and classified as property, plant and equipment in progress. In 2019, Genfit incurred additional costs of €1.3 million. The extension of the corporate headquarters was delivered on April 30, 2019 and the lessor reimbursed Genfit for €2.5 million for the construction costs incurred. The resulting difference of €0.3 million euros is classified as leasehold improvements and will be amortized over 10 years.

On January 1, 2019, upon adoption of IFRS 16, the right of use asset and lease 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 the new building were recognized for an amount of €2.2 million.

8. PROPERTY, PLANT AND EQUIPMENT (continued)

GENFIT CORP signed a new lease agreement, starting from July 1, 2019, in order to accompany the growth of its activities and workforce.

In accordance with IFRS 16, the Group has chosen not to present the “right of use” separately from other assets and added them to assets of the same type as the underlying leased assets.

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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(amounts in thousands of euros, except for numbers of shares and per share amounts)

9. TRADE AND OTHER RECEIVABLES

Trade and other receivables consisted of the following:

Trade and other receivables - Total	**As of December 31,**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Trade receivables, net	61	25	207
Research tax credit	8,466	8,785	9,585
Social security costs receivables	3	10	5
VAT receivables	994	1,103	1,814
Grants receivables	13	(0)	3
Other receivables	340	361	420
TOTAL	**9,876**	**10,284**	**12,033**

Trade and other receivables - Current	**As of December 31,**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Trade receivables, net	61	25	207
Research tax credit	6,545	7,295	9,585
Social security costs receivables	3	10	5
VAT receivables	994	1,103	1,814
Grants receivables	13	(1)	3
Other receivables	340	361	420
TOTAL	**7,955**	**8,794**	**12,033**

Trade and other receivables - Non-current	**As of December 31,**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Trade receivables, net	—	—	—
Research tax credit	1,921	1,489	—
Social security costs receivables	—	—	—
VAT receivables	—	—	—
Grants receivables	—	—	—
Other receivables	—	—	—
TOTAL	**1,921**	**1,489**	**—**

Research tax credit

The research tax credit due for 2018 was received on November 18, 2019.

The research tax credit receivable of €9,585 as of December 31, 2019 includes:

- a partial payment of the assessment (€333) due to an ongoing tax audit
- the balance of the amount due for the 2014 fiscal year (€1,140)
- the balance of the amount due for the 2016 fiscal year (€447), the two amounts are used as partial compensation with the assessment notices and the tax notice related to the 2014 CIR, as described in Note 24, "Litigation and contingent liabilities";
- the amount received following the favorable decision of the Montreuil court (€432) and (€29) having been deducted and
- in addition to the amount related to the dispute with the French tax authorities discussed in note 24 “Litigation and contingent liabilities” should be added to the amount of the 2019 research tax credit of €8.125 million.

A provision of €1,892 was recognized at the closing, including an allocation of €1,785 during the first half of 2019 and appears as a liability in the consolidated statement of financial position in relation to the Research Tax Credit dispute (see note 19 herein).

Other receivables

- The line item “other receivables” primarily consists of credit notes from suppliers for €408, €235 and €174 respectively as of December 31, 2019, as of December 31,2018 and as of December 31,2017.

(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	**As of**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Financial investments	—	—	—
Loans	219	259	307
Loan related security deposit	—	—	—
Deposits and guarantees	274	284	396
Liquidity contract	267	770	1,023
TOTAL	**760**	**1,313**	**1,727**

Financial assets - Current	**As of**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Financial investments	—	—	—
Loans	—	—	—
Loan related security deposit	0	—	—
Deposits and guarantees	31	—	—
Liquidity contract	—	—	—
TOTAL	**31**	**—**	**—**

Financial assets - Non current	**As of**		
(in € thousands)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Financial investments	—	—	—
Loans	219	259	307
Loan related security deposit	(0)	—	(0)
Deposits and guarantees	243	284	396
Liquidity contract	267	770	1,023
TOTAL	**729**	**1,313**	**1,727**

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, 2019, the liquidity account had a cash balance of €1,023.

As of December 31, 2018, the liquidity account had a cash balance of €770

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, CMC-CIC Market Solutions holds on behalf of Genfit 27,911 shares, recorded as a deduction from equity. During the period, Genfit made an additional contribution of €1.0 million to the liquidity agreement with CMC-CIC Market Solution.

11. OTHER ASSETS

Other assets of €1,761, €2,078 and €1,968 at December 31, 2017, 2018 and 2019, 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, 2017, 2018 and 2019, the Group recorded a liability of €155,868, €160,489 and €165,454 respectively, related to the OCEANEs net of the equity portion and debt issue costs. Of this amount, €1,329, €1,312 and €1,312 respectively, was classified as current and €154,539, €159,176 and €164,142 respectively, was classified as non-current.

The conversion of all of the convertible bonds would result in a dilution of 15.6% (expressed as a percentage of share capital at December 31, 2019).

(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	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Refundable and conditional advances	3,407	3,229	3,229
Bank loans	3,488	3,964	2,645
Development loans with participation feature		—	—
Renewable credit facility	—	—	—
Obligations under leases	1,890	1,900	12,281
Accrued interests	3	3	1
Other financial loans and borrowings	24	7	7
Bank overdrafts	—	—	—
TOTAL	**8,812**	**9,104**	**18,165**

Other loans and borrowings - Current	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Refundable and conditional advances	178	—	—
Bank loans	1,209	1,319	1,105
Development loans with participation feature	—	—	—
Renewable credit facility	—	—	—
Obligations under leases	420	520	2,112
Accrued interests	3	3	1
Other financial loans and borrowings	24	7	7
Bank overdrafts	—	—	—
TOTAL	**1,834**	**1,848**	**3,226**

Other loans and borrowings - Non current	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Refundable and conditional advances	3,229	3,229	3,229
Bank loans	2,279	2,645	1,540
Development loans with participation feature	—	—	—
Renewable credit facility	—	—	—
Obligations under leases	1,469	1,381	10,169
Accrued interests	—	—	—
Other financial loans and borrowings	—	—	—
Bank overdrafts	—	—	—
TOTAL	**6,978**	**7,255**	**14,939**

12. LOANS AND BORROWINGS (continued)

The line item “obligations and leases” is impacted by the adoption of IFRS 16. See Note 4.7 “Leases”.

12.2.1. Refundable and conditional advances

General overview

From 2006 to 2010, the Company received conditional advances from BPI France. Advances are subject to no or low interest rates and are intended to finance research programs described in Note 3.19.1, "Government grants". The following table summarizes advances outstanding at December 31, 2019, 2018 and 2017

Refundable and conditional advances - general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value 12/31/2019
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 of euros)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value as of December 31, 2018
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**

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (continued)

Refundable and conditional advances—general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value as of December 31, 2017
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						
BPI FRANCE—ADVANCE N°1—OLNORME II—1	11/24/2010	250	200	(134)	(2)	64
BPI FRANCE—ADVANCE N°2—OLNORME II—2	11/24/2010	250	200	(134)	(2)	64
BPI FRANCE—ADVANCE N°3—OLNORME II—3	11/24/2010	200	160	(108)	(2)	51
Research of pharmaceutical entities in plant extracts for the treatment of inflammatory diseases						
TOTAL						**3,407**

Receipts and repayments of refundable and conditional advances

During the years ended December 31, 2017 and 2018, the Group repaid €166 and €183, respectively, of refundable and conditional advances.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (continued)

Main terms of the contracts

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.
BPI FRANCE ADVANCE N°1— OLNORME II—1	These non-interest bearing advances are repayable in full (at 100% of their nominal amount) in the event of technical and/or commercial success. The balance of these advances (in an amount of €66) were reimbursed during 2018.
BPI FRANCE ADVANCE N°2— OLNORME II—2	These non-interest bearing advances are repayable in full (at 100% of their nominal amount) in the event of technical and/or commercial success. The balance of these advances (in an amount of €66) were reimbursed during 2018.
BPI FRANCE ADVANCE N°3— OLNORME II—3	These non-interest bearing advances are repayable in full (at 100% of their nominal amount) in the event of technical and/or commercial success. The balance of these advances (in an amount of €52) were reimbursed during 2018.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (continued)

12.2.2. Bank loans

Bank loans are primarily used to finance research and laboratory equipment. Bank loans consisted of the following as of December 31, 2017:

Bank loans (in € thousands)	Loan date	Facility size	Interest rate	Available as of December 31, 2017	Installments	Outstanding as of December 31, 2017
CIC 5	July 2017	1,000	0.69%	500	60 monthly	451
CDN 4	June 2017	600	0.36%	—	48 monthly	525
BNP 4	April 2017	800	0.87%	800	60 monthly	—
CIC 4	December 2016	264.6	0.69%	—	60 monthly	217
BNP 3	October 2016	1,050	0.80%	—	20 quarterly	945
NEUFLIZE 2	June 2016	500	1.10%	—	12 quarterly	252
BNP 2	June 2016	500	0.80%	—	20 quarterly	377
CDN 3	April 2016	500	0.72%	—	60 monthly	335
CIC 3	March 2015	500	0.85%	—	16 quarterly	158
BNP	December 2014	500	2.00%	—	20 quarterly	205
Other						23
TOTAL						**3,488**

Bank loans consisted of the following as of December 31, 2018:

Bank loans (in € thousands)	Loan date	Facility size	Interest rate	Available As of 2018/12/31	Installments	Outstanding As of 2018/12/31
CDN 5	November 2018	500	0.46%	—	48 monthly	490
CIC 5	July 2017	1000	0.69%	0	60 monthly	753
CDN 4	June 2017	600	0.36%	0	48 monthly	376
BNP 4	April 2017	800	0.87%	0	60 monthly	695
CIC 4	December 2016	265	0.69%	—	60 monthly	164
BNP 3	October 2016	1050	0.80%	0	20 quarterly	735
NEUFLIZE 2	June 2016	500	1.10%	0	12 quarterly	84
BNP 2	June 2016	500	0.80%	0	20 quarterly	277
CDN 3	April 2016	500	0.72%	—	60 monthly	236
CIC 3	March 2015	500	0.85%	0	16 quarterly	32
BNP	December 2014	500	2.00%	0	20 quarterly	103
Other						19
TOTAL						**3,964**

(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	0.46%	—	48 monthly	365
CIC 5	July 2017	1000	0.69%	0	60 monthly	554
CDN 4	June 2017	600	0.36%	0	48 monthly	226
BNP 4	April 2017	800	0.87%	0	60 monthly	537
CIC 4	December 2016	265	0.69%	—	60 monthly	111
BNP 3	October 2016	1050	0.80%	0	20 quarterly	525
NEUFLIZE 2	June 2016	500	1.10%	0	12 quarterly	0
BNP 2	June 2016	500	0.80%	0	20 quarterly	177
CDN 3	April 2016	500	0.72%	—	60 monthly	135
CIC 3	March 2015	500	0.85%	0	16 quarterly	0
BNP	December 2014	500	2.00%	0	20 quarterly	0
Other						14
TOTAL						**2,645**

12.3. Development agreements with participation feature

In June 2010, BPI France granted the Company a development agreement with participation feature amounting to €2.3 million over a 7-year period with a fixed interest rate of 4.46%. No repayment of principal was scheduled during the first two years.

The loan agreement has a provision applicable during the reimbursement period which provides for additional remuneration to BPI France depending on whether the Company had industrial income. This additional remuneration amounts to 0.2294% of sales. However, this loan was repaid in its entirety in June 2017.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

12. LOANS AND BORROWINGS (continued)

12.4. Maturities of financial liabilities

Maturity of financial liabilities (in € thousands)	As of 2019/12/31	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	165,454	1,312	—	164,142	—	—	—
Bank loans	2,645	1,105	942	544	54	—	—
Development loans with participation feature	—	—	—	—	—	—	—
Renewable credit facility	—	—	—	—	—	—	—
Leases	12,281	2,112	2,118	1,575	1,151	1,103	4,223
Accrued interests	1	1	—	—	—	—	—
Other financial loans and borrowings	7	7	—	—	—	—	—
Bank overdrafts	—	—	—	—	—	—	—
TOTAL - Other loans and borrowings	**180,390**	**4,539**	**3,060**	**166,260**	**1,205**	1,103	**4,223**
TOTAL	**183,619**	**4,539**	**3,060**	**166,260**	**1,205**	**1,103**	**7,452**

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 3 years.

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, 2017, 2018 and 2019:

	As of December 31, 2017						
	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							
Loans	219	—	219	—	—	219	—
Deposits and guarantees	274	—	274	—	—	274	—
Trade receivables	61	—	61	—	—	61	—
Cash and cash equivalents	273,820	273,820	—	—	273,820	—	—
TOTAL—Assets	**274,375**	**273,820**	**555**	**—**	**273,820**	**555**	**—**
Liabilities							
Conditional advances	3,407	—	—	3,407	—	—	3,407
Convertible loans	155,868	—	—	155,868	—	155,868	—
Bank loans	3,488	—	—	3,488	—	3,488	—
Obligations under finance leases	1,890	—	—	1,890	—	1,890	—
Accrued interests	3	—	—	3	—	3	—
Other financial loans and borrowings	24	—	—	24	—	24	—
Trade payables	19,053	—	—	19,053	—	19,053	—
Other payables	34	—	—	34	—	34	—
TOTAL—Liabilities	**183,766**	**—**	**—**	**183,766**	**—**	**180,359**	**3,407**

(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, 2018						
	Carrying value				Fair value		
(in € thousands)	As per statement of financial position	Assets at fair value through profit and loss	Loans and receivables	Debt at amortized cost	Level 1	Level 2	Level 3
Assets							
Financial investments	—	—			—		
Loans	259		259			259	
Loan related security deposit	—		—			—	
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	
Participating development loan	—			—		—	
Renewable credit facility	—			—		—	
Obligations under finance leases	1,900			1,900		1,900	
Accrued interests	3			3		3	
Other financial loans and borrowings	7			7		7	
Bank overdrafts	—			—		—	
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)	As per statement of financial position	Assets at fair value through profit and loss	Loans and receivables	Debt at amortized cost	Level 1	Level 2	Level 3
Assets							
Financial investments	—	—			—		
Loans	307		307			307	
Loan related security deposit	—		—			—	
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	
Participating development loan	—			—		—	
Renewable credit facility	—			—		—	
Obligations under finance leases	12,281			12,281		12,281	
Accrued interests	1			1		1	
Other financial loans and borrowings	7			7		7	
Bank overdrafts	—			—		—	
Trade payables	32,753			32,753		32,753	
Other payables	527			527		527	
TOTAL - Liabilities	**216,898**	—	—	**216,898**	—	**213,669**	**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	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Trade payables	19,053	32,649	32,753
Social security costs payables	4,217	2,949	3,581
Employee profit sharing	17	17	17
VAT payables	19	1	2
Taxes payables	241	286	487
Other payables	34	71	527
TOTAL	23,580	35,974	37,368

Trade and other payables - Current	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Trade payables	19,053	32,649	32,753
Social security costs payables	4,217	2,949	3,581
Employee profit sharing	17	17	17
VAT payables	19	1	2
Taxes payables	241	286	487
Other payables	34	71	76
TOTAL	23,580	35,974	36,917

Trade and other payables - Non current	As of		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Trade payables	—	—	—
Social security costs payables	—	—	—
Employee profit sharing	—	—	—
VAT payables	—	—	—
Taxes payables	—	—	—
Other payables	—	—	450
TOTAL	—	—	450

15. PROVISIONS

At December 31, 2017, 2018 and 2019, this line item amounted to €361, €112, and €2,061 respectively.

The accruals recorded are mainly related to the research tax credit. See Note 24, "Litigation and contingent liabilities".

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, 2017, 2018 and 2019 amounted to €543, €765, and €927 respectively.

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)

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. At December 31, 2017, 2018 and 2019 pension provisions recorded were €936, €1,085 and €1,408, respectively.

As part of the measurement of the retirement indemnity to employees, the following assumptions were used for all categories of employees:

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)	**2017/12/31**	**2018/12/31**	**2019/12/31**
Salary growth rate - in 2020	5.8%	5.80%	5.80%
Salary growth rate - beyond	3.0%	3.00%	3.00%
Discount rate	1.5%	1.53%	0.75%

The discount rates are based on the market yield at December 31, 2017, 2018 and 2019 on high quality corporate bonds.

16. EMPLOYEE BENEFITS (Continued)

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)	
Defined benefit obligation as of January 1, 2017	**849**
Current service cost	76
Interest cost on benefit obligation	13
Actuarial losses on obligation	210
Past service costs	(211)
Defined benefit obligation as of December 31, 2017	**936**
Current service cost	104
Interest cost on benefit obligation	14
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
Actuarial losses / (gains) on obligation	168
Past service costs	—
Defined benefit obligation as of December 31, 2019	**1,408**

The actuarial differences are mainly explained by the changes in personnel observed against the hypothesis used in the actuarial calculation.

Sensitivity of the Group's retirement and post-employment benefits to a variation of the discount rate :

	Retirement and post-employment benefits	
in thousands of euros	Changes in assumptions/discount rate	Impact/present value of the undertaking
	+0.25%	-51
	-0.25%	53

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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, 2019, 2,311,439 shares have been held for more than two years and entitle their holders to double voting rights (5.95% of the issued share capital).

Changes in share capital in 2017

On October 16, 2017, the Company issued bonds convertible or exchangeable into new or existing shares (OCEANEs) due October 16, 2022 for a nominal amount of €180 million. This transaction is recorded as a liability component and an equity component; the latter is measured at €14,312 net of deferred taxes (see Note 12.2, "Breakdown of other loans and borrowings").

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.

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. 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.

At December 31, 2019, the total number of shares comprising the share capital, taking into account the above, was 38,858,617 shares.

18. OTHER INCOME

Other income consisted of the following:

Other income	Year ended		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
CIR tax credit	6,545	7,295	8,125
Other operating income (including CICE tax credit)-	171	130	1,992
Government grants and subsidies	21	—	5
TOTAL	**6,737**	**7,425**	**10,122**

During 2019, the Group recognized in “Other operating income” €1,985 for exchange gains on trade receivables linked to services denominated in US dollars (€38 were recognized as financial income in 2018).

During the 2017 and 2018 fiscal years, the Group recognized in other operating income €170 and €122, respectively, relating to the CICE (Crédit d'impôt pour la compétitivité et l'emploi), which is a tax credit implemented to enhance the competitiveness of businesses through the promotion of certain activities and employment. In 2017 and 2018, the tax credit was equal to 7% and 6%, respectively, of all wages paid to employees during the year in respect of salaries that do not exceed 2.5 times the French minimum wage.

During the year ended December 31, 2019 we had foreign exchange gains related to trade receivables linked to services denominated in U.S dollars, which amount to €1,985 which is recorded as other operating income.

The CICE was discontinued on January 1, 2019.

19. OPERATING EXPENSE

Year Ended December 31, 2017

Operating expenses and other operating income (expenses) (in thousands of euros)	Year ended 2017/12/31	Raw materials& consumables used	Contracted research & development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes)	Depreciation, amortization & impairment charges	Gain / (loss) on disposal of plant & property, equipment
Research and development expenses	(54,189)	(2,117)	(35,088)	(7,915)	(7,973)	(1,095)	—
General and administrative expenses	(9,421)	(112)	(7)	(5,491)	(3,374)	(437)	—
Other operating income (expenses)	60	—	—	—	68	—	(8)
TOTAL	**(63,550)**	**(2,229)**	**(35,095)**	**(13,406)**	**(11,280)**	**(1,532)**	**(8)**

(amounts in thousands of euros, except for numbers of shares and per share amounts)

19. OPERATING EXPENSE (Continued)

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)	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
TOTAL	**(76,979)**	**(1,855)**	**(47,662)**	**(13,625)**	**(12,403)**	**(1,435)**	**2**

		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)	—
Other operating income (expenses)	(1,649)	—	—	—	(1,668)	—	19
TOTAL	**(98,793)**	**(2,202)**	**(41,568)**	**(20,984)**	**(28,807)**	**(5,251)**	**19**

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)

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. In 2019, the CRO (Clinical Research Organization) commissioned as part of the RESOLVE- IT trial updated its investigator cost estimation model by refining 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 to a reduction in the amount recognized for invoices not received related to these specific costs in an amount of €6,994 compared to the previous model.

The subcontracting costs in 2019 are mainly due to the start of new satellite studies in the RESOLVE-IT Phase 3 study, the work required to prepare the marketing authorization dossier for elafibranor in NASH, and the increase in the production volume of the active ingredient necessary for the realization of the various clinical trials. The impact of the changes in estimation of investigator costs for the RESOLVE-IT study led to a stabilization in R&D expenses in 2019.

The increase in employee-related costs results mainly from the increase in headcount (194 at December 31, 2019 versus 148 as of December 2018), the change in employee profiles and the associated increase in compensation, and the bonuses that were awarded to employees in 2019 for their involvement in the development of the Group.

The change in other expenses in 2019 is related in particular to the costs related to the preparation of commercialization of elafibranor in NASH and NIS4, costs related to the purchase of two civil liability insurance policies in connection with the listing of shares on the NASDAQ, fees of financial advisors and statutory auditors, and intellectual property expenses.

In 2017, the donation to The NASH Education Program (€1,808) was classified as a research & development expense because the 2017 donation was primarily related to the creation of a NASH patient registry in particular to increase understanding of the prevalence and natural history of NASH/

NAFLD, and the development of co-morbidities historically linked to NASH/NAFLD, which information is to be used as part of the efforts to collect RWE (Real World Evidence) data to better address the needs of the patients, which information could be utilized by the Company in its research & development efforts.

The increase in contracted research and development activities conducted by third parties in the 2018 period was primarily the result of the progression of the research and development pipeline; and mainly operational outsourcing costs related to the Phase 3 RESOLVE-IT clinical trial of elafibranor for the treatment of NASH and, to a lesser extent, those related to the Phase 2 trial of elafibranor in PBC and the launch of the Phase 2 trial in NTZ.

The increase in employee expenses in 2018 is mainly due to the evolution of employee profiles (specialized and more experienced), the increase in compensation, and the increase in the number of employees.

Other operating expenses include costs related to facilities and their maintenance, intellectual property costs, and expenses related to the preparation of marketing of elafibranor in NASH. In 2018, the Company's donation to The Nash Education Program endowment fund (€959) was dedicated mainly to the organization of the first international NASH Day. In this context, in 2018, the Company has classified this charge as general and administrative expenses.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

19. OPERATING EXPENSE (Continued)

19.1. Employee expenses

Employee expenses and number of employees were as follows:

Employee expenses	Year ended		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
Wages and salaries	(9,267)	(9,012)	(14,018)
Social security costs	(3,996)	(3,722)	(5,171)
Changes in pension provision	135	(104)	(138)
Individual training entitlement	—	—	—
Share-based compensation	(278)	(787)	(1,657)
TOTAL	**(13,406)**	**(13,625)**	**(20,984)**

	Year ended		
Number of employees at year-end - detail	2017/12/31	2018/12/31	2019/12/31
Average number of employees	123	135	175
Average age of employees	38 years 4 months	38 years 11 months	37 years 1 month
Number of employees			
Research and development	77	84	108
Services related to research and development	15	16	19
Administration and management	33	48	60
Marketing and commercial	—	—	7
TOTAL	**125**	**148**	**194**
Number of employees			
Senior staff	92	115	144
Staff	29	30	45
Others (apprentices)	4	3	5
TOTAL	**125**	**148**	**194**
Number of employees			
Male	45	57	78
Female	80	91	116
TOTAL	**125**	**148**	**194**

20. SHARE-BASED COMPENSATION

Share-based compensation is granted by the Group to employees, executive officers, board members and consultants.

Share-based compensation granted to employees and executive officers in 2014 through 2019 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").

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)

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 2017, 2018 and 2019.

New plans were put in place in 2019 under the terms and conditions discussed below.

The expense recognized pursuant to IFRS 2 was €1,645 in 2019, €787 in 2018 and €278 in 2017.

The Group has 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 .

	Year ended			Total expense	Total expense
Share-based compensation - Annual expense	**2017/12/31**	**2018/12/31**	**2019/12/31**	**calculated**	**remaining**
BSA 2014-A	—	—	—	**945**	—
Of which : expense related to non-executive officers	—	—	—	365	—
Of which : expense related to consultants	—	—	—	581	—
BSA 2014-B	—	—	—	**1,045**	—
Of which : expense related to non-executive officers	—	—	—	365	—
Of which : expense related to consultants	—	—	—	680	—
BSAAR 2014-A	—	—	—	**43**	—
Of which : expense related to non-executive officers	—	—	—	9	—
Of which : expense related to consultants	—	—	—	34	—
BSAAR 2014-B	—	—	—	**191**	**0**
Of which : expense related to non-executive officers	—	—	—	35	0
Of which : expense related to consultants	—	—	—	156	—
BSAAR 2014-C	—	—	—	**189**	**0**
Of which : expense related to non-executive officers	—	—	—	35	—
Of which : expense related to consultants	—	—	—	154	0

	Year ended			Total expense	Total expense
Share-based compensation - Annual expense	**2017/12/31**	**2018/12/31**	**2019/12/31**	**calculated**	**remaining**
BSA 2015-A	—	—	—	**335**	—
Of which : expense related to non-executive officers	—	—	—	178	—
Of which : expense related to consultants	—	—	—	157	—
BSA 2015-B	—	—	—	**315**	—
Of which : expense related to non-executive officers	—	—	—	178	—
Of which : expense related to consultants	—	—	—	138	—

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 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31	Total expense calculated	Total expense remaining
BSAAR 2016-A	—	—	—	—	—
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	—	—	—
BSAAR 2016-B	—	—	—	—	—
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	—	—	—
AGA D 2016-1	**38**	**127**	**—**	**166**	**0**
Of which : expense related to executive officers	7	25	—	32	0
Of which : expense related to employees	31	101	—	133	0
AGA D 2016-2	**17**	**17**	**39**	**74**	**—**
Of which : expense related to executive officers	3	3	8	14	—
Of which : expense related to employees	14	14	31	59	—
AGA S 2016-1	**44**	**151**	**—**	**197**	**—**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	44	151	—	197	—
AGA S 2016-2	**22**	**22**	**44**	**88**	**—**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	22	22	44	88	—
SO 2016-1	**83**	**83**	**213**	**383**	**—**
Of which : expense related to executive officers	13	13	36	63	—
Of which : expense related to employees	70	70	176	319	—
SO 2016-2	**38**	**38**	**93**	**170**	**—**
Of which : expense related to executive officers	6	6	16	28	—
Of which : expense related to employees	32	32	77	142	—
SO US 2016-1	**12**	**12**	**(24)**	**—**	**—**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	12	12	(24)	—	—
SO US 2016-2	**5**	**5**	**(11)**	**—**	**—**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	5	5	(11)	—	—

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 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31	Total expense calculated	Total expense remaining
BSA 2017-A	**6**	**63**	**—**	**69**	**—**
Of which : expense related to non-executive officers	4	43	—	47	—
Of which : expense related to employees	2	20	—	22	—
BSA 2017-B	**3**	**66**	**—**	**70**	**0**
Of which : expense related to non-executive officers	2	46	—	48	0
Of which : expense related to employees	1	21	—	22	0
AGA D 2017-1	**1**	**17**	**199**	**217**	**—**
Of which : expense related to executive officers	0	2	28	30	—
Of which : expense related to employees	1	15	171	187	—
AGA D 2017-2	**2**	**29**	**56**	**131**	**44**
Of which : expense related to executive officers	0	3	8	18	6
Of which : expense related to employees	2	26	48	113	37
AGA S 2017-1	**—**	**—**	**209**	**209**	**—**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	209	209	—
AGA S 2017-2	**2**	**24**	**45**	**104**	**34**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	2	24	45	104	34
SO 2017-1	**2**	**28**	**27**	**61**	**4**
Of which : expense related to executive officers	0	5	5	11	1
Of which : expense related to employees	2	23	22	50	4
SO 2017-2	**3**	**48**	**2**	**81**	**28**
Of which : expense related to executive officers	1	8	0	15	5
Of which : expense related to employees	3	39	2	66	23
SO US 2017-1	**0**	**3**	**(4)**	**—**	**0**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	0	3	(4)	—	0
SO US 2017-2	**0**	**5**	**(6)**	**—**	**0**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	0	5	(6)	—	0

(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 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31	Total expense calculated	Total expense remaining
AGA D 2018	—	**10**	**135**	**277**	**132**
Of which : expense related to executive officers	—	2	21	43	21
Of which : expense related to employees	—	9	114	234	111
AGA S 2018	—	**12**	**148**	**305**	**145**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	12	148	305	145
SO 2018	—	**24**	**285**	**849**	**539**
Of which : expense related to executive officers	—	3	40	118	75
Of which : expense related to employees	—	21	245	730	464
SO US 2018	—	**3**	**25**	**76**	**48**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	3	25	76	48

Share-based compensation - Annual expense	Year ended 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31	Total expense calculated	Total expense remaining
BSA 2019	—	—	**7**	**26**	**20**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	7	26	20
AGA D 2019	—	—	**35**	**242**	**207**
Of which : expense related to executive officers	—	—	5	38	33
Of which : expense related to employees	—	—	29	204	175
AGA S 2019	—	—	**41**	**288**	**246**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	41	288	246
SO 2019	—	—	**86**	**599**	**513**
Of which : expense related to executive officers	—	—	10	68	58
Of which : expense related to employees	—	—	76	531	455
SO US 2019	—	—	**1**	**43**	**42**
Of which : expense related to executive officers	—	—	—	—	—
Of which : expense related to employees	—	—	1	43	42

Share-based compensation - Annual expense	Year ended 2017/12/31	Year ended 2018/12/31	Year ended 2019/12/31	Total expense calculated	Total expense remaining
TOTAL	**278**	**787**	**1,645**	**7,787**	**2,004**

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-base 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.).

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)

20.2. Redeemable warrants (*bons de souscription et/ou d'acquisition d'actions remboursables* or BSAAR)

Share-Based compensation Redeemable share subscription warrants (BSAAR)	**2 016** **BSAAR 2016-A and B**	**2 014** **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	0	61,484
Total number of BSAAR exercised	0	1,233
Total number of BSAAR remaining	10,800	0
Issue Price	€23.5	€23.5
Exercise period	From 01/01/2018 to 27/07/2020	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

The exercise of the BSAAR 2016-A is subject to the following performance condition: the Group will have, at the date it receives the exercise notice accompanied by the payment of the exercise price, the financial means to carry out its research and development programs, and at a minimum its development program for elafibranor in NASH until at least the end of 2018.

The exercise of the BSAAR 2016-B is subject to the following performance condition: the Group will have published, on the date it receives the exercise notice accompanied by the exercise price, the main results of the RESOLVE-IT clinical trial for which it is the sponsor.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

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
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 11/22/2018 to 12/31/2020	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	40.16%				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 terms and conditions of the 2016 to 2018 allocations to the Chairman and CEO are provided in the Universal Registration Document or the financial statements for the relevant periods.

(1) : Chief executive officer

The final allocation of free shares is subject to continued employment with the Group and performance conditions. These performance conditions are described in item 6 B

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	2 019				2 018		2 017		2 016	
Stock-options (SO)	SO		SO US 1	SO US 2	SO 2018	SO US 2018	SO 1 et 2 2017	SO US 2017	SO 1 et 2 2016	SO US 2016
	Officers(1)	Employees	Employees	Employees	Employees and Offices	Employees	Employees and Offices	Employees	Employees and Offices	Employees
Date of the Shareholders meeting	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	07/18/2019			11/27/2019	11/07/2018		11/21/2017			
Date of the CEO decision	07/18/2019			11/27/2019	11/07/2018		12/06/2017			
Total number of SO subscribed	15,130	92,750	30,620	13,350	122,000	17,500	96,250	13,000	62,875	10,500
Total number of SO voided	0	1,780	0	0	2,000	3,000	21,577	13,000	13,169	10,500
Total number of SO definitively vested	0	0	0	0	0	0	0	0	49,706	0
Total number of SO remaining	15,130	90,970	30,620	13,350	120,000	14,500	74,673	0	0	0
Excercise price	€13.99		€16.9	€14.31	€16.00	€21.65	€17.91	€22.54	€15.79	€21.12
Vesting period	From 07/18/2019 to 09/16/2022			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	
Exercise period	From 09/17/2022 to 09/17/2029			From 01/17/2023 to 01/17/2030	From 01/01/2022 to 12/31/2028		From 01/01/2021to 12/31/2027		From 12/16/2019 to 12/16/2026	
Fair value	€4.59		€3.67	€3.23	€9.32	€6.9	€9.32		€10.3	€8.52
Valuation method used	Monte Carlo									
Price of the share at the time of allocation	€17.06			€14.5	€22.12		€21.95		€20.79	
Expected dividends	0%			0%	0%		0%		0%	
Expected volatility	40.16%			40.0%	44.07%		53.7%		63.0%	
Risk-free interest rate	0.0%			0.0%	0.0%		0.0%		0.0%	
Turnover rate	0.00%			0.00%	15.00%		15.00%		15.00%	

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 3-years period prior to the grant date, adjusted for extreme variations, if any. See note 4.22 share based compensation.

Definitive vesting is subject to continued employment with the Group and performance conditions. These performance conditions are described in item 6 B

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20. SHARE-BASED COMPENSATION (Continued)

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.

20.5.1. Performance conditions of the 2019 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 the Company's 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 at least a new licensing agreement, on one or another of Genfit's products in one or several territories, is entered into by the Company.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

20.SHARE-BASED COMPENSATION (Continued)

		Nature of external conditions 33 1/3 % of the instruments will be exercisable or definitively vested, in proportion to the variation of the Company's 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; (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
SO US 2019-2	01/09/2023	**Nature of internal conditions** 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; (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 the Company's 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; (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.
AGA S 2019	07/31/2022	**Nature of internal conditions** The free shares will definitively vest upon the same internal performance conditions as the SO 2019, SO US 2019 and AGA D 2019 plans

(amounts in thousands of euros, except for numbers of shares and per share amounts)

21. FINANCIAL INCOME AND EXPENSES

Financial income and expenses	Year ended		
(in € thousands)	2017/12/31	2018/12/31	2019/12/31
	(*)	(*)	
Financial income			
Interest income	389	202	2,626
Foreign exchange gain	59	101	2,272
Other financial income	195	425	324
TOTAL - Financial income	**642**	**728**	**5,221**
Financial expenses			
Interest expenses	(2,309)	(10,955)	(11,289)
Interest expenses for leases	(10)	(21)	(148)
Foreign exchange losses	(764)	(127)	(1,657)
Other financial expenses	(13)	(14)	(17)
TOTAL - Financial expenses	**(3,096)**	**(11,118)**	**(13,110)**
FINANCIAL GAIN (LOSS)	**(2,453)**	**(10,391)**	**(7,889)**

- * The Group applied IFRS 16 “Leases” from January 1, 2019 using the modified retrospective method, and therefore, the comparative information for 2017 and 2018 has not been restated. The impact of this application is presented in note 4.7.2 Application of the new IFRS 16 standard.

Financial expenses for loans and borrowings are due to the interest on the OCEANEs, mainly due to interest payments at a rate of 3.5% and the discounting of the bond debt at an effective interest rate of 7.2%. The discounting 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.

The increase in financial income is due to the increase in interest on term accounts. GENFIT has decided to keep some of its cash in US dollars. See note 6.6 “Cash and cash equivalents”.

22. INCOME TAX

22.1. Losses available for offsetting against future taxable income

At December 31, 2017, 2018 and 2019, the tax loss carry forwards for the Company amounted to €226,708, €305,530 and €384,471, 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, 2017 and 2018 related to:

Tax loss carry forwards: €226,708 and €305,530, respectively;

- Temporary differences:
  - related to the OCEANE: a net deferred tax liability for €2,165 and €1,773 as of December 31, 2017 and 2018, respectively and
  - related to post-employment benefits: €936 and €1,085, respectively, or an impact on deferred tax assets of €262 and €304, respectively.

The Group's main sources of deferred tax assets and liabilities as of December 31, 2019 related to:

- Tax losses carry forwards: €384,471 (compared to €305,530 as of December 31, 2018);
- Temporary differences related to:
  - the OCEANE: a deferred tax liability of €3,182 and an asset of €1,989, i.e., a net deferred tax liability of €1,193; and
  - post-employment benefits: a deferred tax liability of €352 offset by an asset of the same amount;

The Company offsets its deferred tax assets and liabilities (€1,988 and €3,182, respectively), as permitted by IAS 12, resulting in a net deferred tax liability of €1,193.

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.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

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		
	2017	2018/12/31	2019/12/31
Earnings per share	(*)	(*)	
Profit (loss) for the period (in € thousands)	**(55,728)**	**(79,521)**	**(65,144)**
Weighted average number of ordinary shares for the period	31,166,437	31,167,203	36,987,982
Profit (loss) per share (in €)	**(1.79)**	**(2.55)**	**(1.76)**
Weighted average number of ordinary shares used in the above calculation	31,166,437	31,167,203	36,987,982

- * The Group applied IFRS 16 “Leases” from January 1, 2019 using the modified retrospective method, and therefore, the comparative information for 2017 and 2018 has not been restated. The impact of this application is presented in note 4.7.2 Application of the new IFRS 16 standard.

24. LITIGATION AND CONTINGENT LIABILITIES

Dispute over research tax credit calculation

Context

In 2014, the Company was under a tax audit at the end of which the French tax authorities questioned part of the Research Tax Credit (CIR) received by the Company for the 2010 fiscal year. The tax audit was extended to the CIR for the 2011 and 2012 fiscal years.

This tax audit was also extended to the 2014 CIR as part of a documentary audit the purpose of which was to apply the rules described below.

Subject matter of the dispute

The dispute with the French tax authorities pertained mainly to collaborative research alliances with partners in the pharmaceutical industry. The tax authorities contended that, in these alliances, the Company was acting as a sub-contractor, which should reduce the basis on which the CIR was computed by deducting amounts billed by the Company to the other party. The Company maintained that the contracts governing the collaborative research alliances included reciprocal provisions concerning intellectual property, the shared governance of the research programs, risk sharing, conditions governing the termination of the agreements and the terms of compensation, which demonstrated that they were not sub-contracting agreements.

On April 5, 2018, the Administrative Court of Montreuil partially accepted the Company's claims on the CIR for 2010, 2011 and 2012, in particular, on the qualification of collaborative research. On June 28, 2018, the Administrative Court of Montreuil accepted the Company's claim on the CIR for 2014. On September 11, 2018, following the judgment, the Company was repaid €432.

On July 25, 2018, and then on October 28, 2018, the Company was informed that the Ministry of Action and Public Accounts, appealed the aforementioned judgments.

On June 18, 2019, the Court of Appeals of Montreuil delivered its judgment on the first judgment and gave the Company the right to take into account the depreciation of certain assets eligible for the CIR but reversed the decision of the Administrative Court as it relates to the collaboration research for the CIRs received in connection with the 2010, 2011 and 2012 fiscal years. The Company will have to reduce the basis of its CIR claims by the amounts invoiced to its partners.

Provision

The Company has decided not to appeal the Court of Appeals decision, and therefore has recognized a provision totaling €1,892, which includes adjustments to the 2014 CIR, and for which it did not seek to continue before the court of appeals during a hearing in March 2020. The provision replaces in full the potential debts mentioned in the 2018 annual financial statements.

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 approximately thirteen Company employees.

Jean-François Mouney, the Chairman of the Company, is also the Chairman of Biotech Avenir SAS.

At December 31, 2019, 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 2017, 2018 or 2019, 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.

The transactions carried out in 2017, 2018 and 2019 between the Group and The NASH Education Program ™ (now The NASH Epidemiology Institute ™) and the Group's obligations with respect to The NASH Epidemiology Institute ™ are described in Note 27, "Commitments".

Frédéric Desdouits

Mr. Frédéric Desdouits, member of the Genfit 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 since Mr. Frédéric Desdouits became PCAS Group's CEO, has become a related party as defined by IAS 24.9 since March 2019. In 2019, we paid PCAS Group a total of €1.7 million (tax included).

In January 2020, the Company signed a Memorandum of Understanding with PCAS settings out the conditions under which the PCAS Group will:

- set up a second manufacturing source for the active ingredient used in the composition of elafibranor, as part of initiatives to secure Genfit's supply chain;
- carry out technology transfers between the current manufacturing unit and the second source; 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 for elafibranor.

(amounts in thousands of euros, except for numbers of shares and per share amounts)

26. COMPENSATION OF CORPORATE OFFICERS

By resolution of the General Shareholders Meeting on June 16, 2017, the shareholders adopted the change in mode of administration and management of the Company and elected to change from a historical two-tiered board structure (Executive Board and Supervisory Board) to a single board (Board of Directors).

As a result, the table below provides details of the compensation paid to the Chairman and CEO, as well as that paid to the members of the Executive Board during the first half of 2017 (prior to the change in mode of governance) and for the financial years in which the relevant amounts were recognized in the statements of operations.

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 2017, 2018 and during the period from January 1, 2019 to September 16, 2019, and the compensation paid to the Chief Executive Officer 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 and Chief Executive Officer	**Year ended**		
in 2017 and 2018 and during the period from January 1, 2019 to September 16, 2019	**2017/12/31**	**2018/12/31**	**2019/12/31** (1)
Short-term employee benefits (gross + employer's social contributions, paid)	1,476	1,569	1,338
Post-employment pension & medical benefits	199	—	—
Attendance fees		—	—
Share-based payment transactions	51	104	109
Director fees Genfit Corp (net)	37	30	22
TOTAL	**1,763**	**1,703**	**1,469**

Compensation paid to the Chief Executive Officer	**Year ended**		
in 2018 and during the period from September 16, 2019 to December 31, 2019	**2017/12/31**	**2018/12/31**	**2019/12/31**
Short-term employee benefits (gross + employer's social contributions, paid)	—	—	140
Post-employment pension & medical benefits	—	—	—
Attendance fees	—	—	—
Share-based payment transactions	—	—	—
Director fees Genfit Corp (net)	—	—	—
TOTAL	**—**	**—**	**140**

(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. The balance, i.e. a gross sum of €187,631 related to the work in 2019 was to be paid subject to the approval by the shareholders of the General Meeting to approve the accounts for the financial year ended on December 31, 2019. It is therefore not shown in this table but was provisioned in the accounts for the year ended December 31, 2019. However, in May 2020, the Chairman of the Board of Directors decided to forgo this amount; as a result, as noted by the Board of Directors, the balance of €187,631 will not be paid.

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 table above in the "Other compensation" 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, 2019 would amount to €341.

(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:

	Amounts due*	Amounts paid*	Amounts due*	Amounts paid*	Amounts due*	Amounts paid*
	During the year ended December 31,					
Attendance fees and other forms of remuneration payable to each of the non executive officer (in euros)	**2017(4)**		**2018**		**2019**	
Jean-François MOUNEY(1)						
Attendance fees	—	—	—	—	14,791	633
Other remuneration (except his compensation as CEO between January 1, and September 16, 2019)(5)	—	—	—	—	88,874	88,874
Total	—	—	—	—	103,665	89,507
Xavier GUILLE DES BUTTES						
Attendance fees	30,218	24,688	53,330	41,311	68,016	67,580
Other remuneration	—	—	—	—	—	—
Total	30,218	24,688	53,330	41,311	68,016	67,580
Charles WOLER(2)						
Attendance fees	5,925	5,925	—	—	—	—
Other remuneration	—	—	—	—	—	—
Total	5,925	5,925	—	—	—	—
Frédéric DESDOUITS						
Attendance fees	13,627	11,258	21,174	17,113	33,136	30,302
Other remuneration	—	—	—	—	—	—
Total	13,627	11,258	21,174	17,113	33,136	30,302
BIOTECH AVENIR						
Represented by Florence Séjourné						
Attendance fees	—	—	—	—	—	—
Other remuneration	—	—	—	—	—	—
Total	—	—	—	—	—	—
Philippe MOONS						
Attendance fees	18,763	14,023	29,704	22,345	36,188	41,202
Other remuneration	—	—	—	—	—	—
Total	18,763	14,023	29,704	22,345	36,188	41,202
Anne-Hélène MONSELLATO(3)						
Attendance fees	14,813	10,468	37,075	24,307	44,472	53,410
Other remuneration	—	—	—	—	—	—
Total	14,813	10,468	37,075	24,307	44,472	53,410
Catherine LARUE(3)						
Attendance fees	11,258	8,098	21,256	17,985	33,136	28,122
Other remuneration	—	—	—	—	—	—
Total	11,258	8,098	21,256	17,985	33,136	28,122
TOTAL	94,602	74,458	162,539	123,061	318,613	310,123

(amounts in thousands of euros, except for numbers of shares and per share amounts)

26. COMPENSATION OF CORPORATE OFFICERS (continued)

	2017(4)	2018	2018
IFRS 2 valuation of share warrants granted during the financial year	94,875	—	—

* After applying a required 21% withholding

(1) Jean-François MOUNEY joined the Board of Directors on June 16, 2017 as Chairman.

(2) Since the Shareholders' Meeting on June 16, 2017, Charles WOLER is no longer a board member.

(3) Anne-Hélène MONSELLATO and Catherine LARUE were appointed to the Board of Directors by the shareholders at the June 16, 2017 Shareholders' Meeting.

(4) The remuneration received by Xavier GUILLE DES BUTTES, Frédéric DESDOUITS, Biotech Avenir and Philippe MOONS until June 16, 2017 was in their capacities as members of the Supervisory Board.

(5) 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.

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 period starting in March 2019, the insurance premium including the IPO insurance policy premium for the implementation of this insurance coverage amounted to €3,146 and is being amortized over the coverage period.

27. COMMITMENTS

Subcontracting agreements

The Group enters into contracts in the normal course of business 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.

In 2019, the Company signed a Memorandum of Understanding –(MoU) with one of its CMOs to be followed by an implementation contract with the CMO to set up a second supply and manufacture source of elafibranor.

The costs related to the transfer of technology required for the establishment of the second source of supply and manufacturing, as well as the costs of manufacturing the registration lots are borne by the CMO and serve as a basis for calculating the penalties that would be payable by the Group in certain cases of early termination of the MoU or its implementation contract. The amount of these penalties could reach a maximum of €1,360.

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€542 at December 31, 2019 and €455 at December 31, 2018 and €455 at December 31,2017.

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.

27. COMMITMENTS (continued)

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.

Other liabilities

Pursuant to an agreement with effect from July 1, 2016, the Company decided to finance the creation by Pinnacle Clinical Research of a registry of NAFLD/NASH patients, which diseases are targeted by certain of the Company's drug and biomarker candidates. This donation, for a maximum amount of USD $1,582 is being paid over the course of the creation of the registry on the basis of reporting periods.

The Company's goal in supporting the creation of this registry was to contribute to the improvement of scientific and medical knowledge around NAFLD and NASH. As a result, the Company decided on December 22, 2016, with effect from December 31, 2016, to assign the benefit and obligations of this agreement to its endowment fund, The NASH Education Program ™ . The NASH Education Program ™ was created on November 3, 2016 with Genfit as its sole founding member to educate the medical community and patients on the lessons that can be learned from these patients, in accordance with its objectives.

In 2017, 2018 and 2019, the Company granted to The NASH Education Program ™ endowment fund a donation of €1,808 and €959 and €45, respectively, so that The NASH Education Program ™ could honor its obligations under the transfer of registry donation and carry out the other planned disease awareness activities to patients and doctors and the organization of the first International NASH Day, which took place in June 2018. In 2019, the organization of this event was transferred to a patients' organization.

28. EVENTS AFTER THE REPORTING PERIOD

In May 2020, the Company published the top-line results of the interim analysis of the RESOLVE-IT Phase 3 trial of elafibranor in NASH. Elafibranor did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis or on the key secondary endpoints. GENFIT continues to review the data and will be conducting additional analyses. The Company will share its conclusions with regulatory authorities and with their guidance, determine a final decision regarding the continuation of the RESOLVE-IT trial. In parallel, we continue as planned with our NIS4 and Phase 3 PBC programs, which are independent of our NASH program with elafibranor.

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 alleges 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 seeks unspecified compensatory damages. We and the defendants intend to defend the matter vigorously.

The financial impact of this class action complaint cannot be quantified at this time.

28. EVENTS AFTER THE REPORTING PERIOD (Continued)

A new coronavirus strain, COVID-19, was identified in Wuhan, China in December 2019. Since then and particularly since the closing date, the COVID-19 coronavirus has spread to several countries, including the United States and several European countries, including countries in which the Company has clinical trials in progress, in countries where it plans to conduct clinical trials and in 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. In March 2020, the Company published a press release outlining the main impacts of this unprecedented spread of COVID-19 on its activities:

- RESOLVE-IT Phase 3 trial of elafibranor in NASH with fibrosis continues ; Working with our contract research organization, we have implemented appropriate measures to ensure the safety of patients who are already participating in the study: virtual clinic visits, local laboratory assessment, home delivery of study drug, and halting the screening of new patients.
- All phase 1 trials – which include pharmacokinetic, food effect and bioequivalence studies – have been put on hold. These studies are necessary to support the elafibranor NDA submission for NASH.
- Enrollment of patients in the PK/PD trial in pediatric patients with NASH as well as the Phase 2 study addressing liver fat have also been paused.
- The initiation of the Phase 2 combination study, as well as that of the Phase 3 study in patients with PBC, have been put on hold.
- NIS4 continues to be deployed in the clinical research field through our commercial partner Labcorp/Covance. There may be some limits in test utilization due to delays potentially experienced by some NIS4 clients as the result of the current COVID-19 situation. GENFIT teams are progressing the in-vitro diagnostic (IVD) aspect of the program in parallel.
- Although the COVID-19 pandemic is rapidly evolving, and our plans may change accordingly, at this stage we do not anticipate any supply disruption for any of our current or planned studies.
- All supporting activities pertaining to continuation of ongoing studies or the initiation of new studies will continue in order to minimize potential delays when the pandemic crisis subsides.

The financial impact of COVID-19 cannot be quantified at this time.

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GENFIT SA
Corporation with a Board of Directors and a share capital of € 9,707,855.25
Registered office: Parc Eurasanté, 885 Avenue Eugène Avinée, 59120 LOOS
424 341 907 R.C.S. LILLE Métropole

ARTICLES OF ASSOCIATION

As of March 29, 2019

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 nine million seven hundred and seven thousand eight hundred and fifty-five Euros and twenty five cents (€ 9,707,855.25). It is divided into thirty eight million eight hundred and thirty-one thousand four hundred and twenty one (38,831,421) 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, authorise 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 favour, 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 authorised 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 authorised 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 regularised 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 organises 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 authorisation 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 authorisation 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 authorisation. If he/she is a member of the Board of Directors, he/she shall not take part in the vote on the authorisation sought.

The President of the Board of the Directors gives notice to the Auditors of all authorised 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 authorised 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 summarising 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 summarises 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 authorised 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 authorised 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, 2019, 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, 2019, the Company's outstanding share capital consisted of a total of 38,858,617 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.

	FRANCE	DELAWARE
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.
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.

	FRANCE	DELAWARE
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.
Shareholder Action by Written Consent	Under French law, shareholders' action by written consent is not permitted in a *société anonyme*.	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.

	FRANCE	DELAWARE
Preemptive Rights	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.
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.

FRANCE	DELAWARE

	FRANCE	DELAWARE
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.
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.

	FRANCE	DELAWARE
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.
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.

	FRANCE	DELAWARE
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.
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 4.3

Summary of 2019 BSA Plans

Share warrants or BSA (*bons de souscription d'actions*) are purchased by the holders and entitle each of them to subscribe for new 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 list of the beneficiaries, the grant dates, the purchase price, the exercise price, the number of BSA granted and the terms and conditions of the BSA, including the number shares underlying each BSA and their exercise period.

Grants. Our 2019 BSA were granted to scientific consultants of our Company. A total of 35,070 BSA have been granted under one (1) plan in 2019 (the BSA 2019 plan), which has terms and conditions as set out below.

Underlying shares. The securities to which our BSA give right are new ordinary shares of our Company. Each BSA 2019 gives right to one (1) ordinary share.

The number of ordinary shares to which each BSA gives right can be adjusted, upwards or downwards, as a result of certain corporate transactions, such as rights issues.

Standard terms. Our BSA are exercisable by tranches of a minimum of 2,000 BSA, or a multiple thereof, with an exception for any outstanding balance of unexercised BSA under 2,000.

The BSA 2019 have been issued at a price of €1.23 and at an exercise price of €12.32 per BSA.

Exercise period. The exercise period of the 2019 BSA plan is:

	Exercise period
BSA 2019	July 1, 2019 to May 31, 2024

Exhibit 4.5

Summary of 2019 Free Shares (AGA) Plans

Free shares or AGA (*actions gratuites*) are shares of our Company that are granted to the beneficiary for free. They vest (i.e. the grant becomes definitive) after a minimum vesting period of one (1) year and can be subject to a lock-up period of at least one (1) further year. The sum of the vesting period and the lock-up period cannot be less than two (2) years (three (3) years for older plans) and, if there is no lock-up period, the vesting period must be of at least two (2) years (three (3) years for older plans). The total number of free shares granted (whether or not they are vested) cannot exceed 10% of our share capital.

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors determines (and formerly our executive board (*directoire*) determined) the list of the beneficiaries, the grant dates, the number of AGA granted and the terms and conditions of the AGA, including their vesting schedule and, if any, lock-up period.

Grants. Our AGA were granted to our Chief Executive Officer and Chairman of our board of directors and employees of our Company. A total of 36,788 AGA have been granted and a total of 36,626 AGA have been accepted by the beneficiaries under two (2) plans in 2019. We have different AGA plans for senior managers and executive officers (AGA D) and for other employees (AGA S). In 2019, we had one (1) AGA D plan (AGA D 2019) and one (1) AGA S plan (AGA S 2019), with different terms and conditions as set out below.

Underlying shares. Our AGA are new ordinary shares of our Company that are issued upon vesting of the AGA.

Until they are vested, the number of AGA to which each beneficiary has right can be adjusted, upwards or downwards, as a result of certain corporate transactions, such as rights issues.

Standard terms. Our AGA will be definitively granted following a 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 the realization of performance conditions that are assessed by our board of directors.

The terms and conditions of our AGA in respect of each of our plans are as follows:

	Performance condition(s)	Assessment date(s) of presence and performance conditions and end of vesting period	Lock-up period end date
AGA D 2019	(i) Internal performance (1) (ii) External performance (2)	September 16, 2022	September 17, 2022
AGA S 2019	Internal performance (1)	September 16, 2022	September 17, 2022

(1) Based on the achievement of milestones in our development.
(2) Based on the evolution of the share price of our ordinary shares.

Exhibit 4.7

Summary of the 2019 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 (and formerly our executive board (*directoire*) determined) the list of the beneficiaries, the grant dates, the exercise price, the 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.

Grants. Our stock options were granted to our Chief Executive Officer and Chairman of the Board of Directors, executive officers and employees of our Company. A total of 151,850 stock options have been granted and accepted by the beneficiaries under three (3) plans in 2019, with different terms and conditions as set out below. We have one (1) stock option plan for French beneficiaries (SO 2019) and two (2) stock plans for U.S. beneficiaries, that were designed to benefit from the "Incentive Stock Options" status (SO US 2019 and SO US 2019-2).

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 2019	(i) Internal performance (1)	September 16, 2022	September 17, 2022	€ 13.99
SO US 2019	(ii) External performance (2)	September 16, 2022	September 17, 2022	€ 16.90
SO US 2019-2		January 16, 2023	January 17, 2023	€ 14.31

(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.

Certain information has been excluded from this agreement (indicated by "[***]") because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 4.9

COLLABORATION AND LICENSE AGREEMENT

This **Collaboration and License Agreement** (the "**Agreement**") is entered into as of June 24, 2019 (the "**Effective Date**") by and between **Genfit SA,** a corporation organized and existing under the laws of France and having a place of business at Parc Eurasanté, 885 avenue Eugène Avinée, 59120 Loos, France ("**Genfit**"), and **Terns Pharmaceutical, Inc.**, an exempted company organized and existing under the laws of the Cayman Islands and having a place of business at P. O. Box 613, Harbor Center, George Town, Grand Cayman KY1-1107, Cayman Islands ("**Terns**"). Genfit and Terns are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

Whereas, Genfit is currently conducting research and development of elafibranor, a proprietary dual PPARα/δ agonist;

Whereas, Terns is a pharmaceutical company with experience in developing pharmaceutical products in, among other regions, Greater China;

Whereas, Terns desires to obtain from Genfit an exclusive license to Develop, Manufacture and Commercialize the Licensed Products in the Terns Territory (with each capitalized term as respectively defined below), and Genfit is willing to grant such license to Terns, all under the terms and conditions hereof.

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Accounting Standards**" means U.S. generally accepted accounting principles ("**GAAP**") or, to the extent that Terns adopts International Financial Reporting Standards ("**IFRS**"), then "Accounting Standards" means IFRS, in either case consistently applied.

1.2 "**Act**" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§262 et seq., as such may be amended from time to time.

1.3 "**Adverse Risk**" means any risk [***] on the Development, procurement or maintenance of Regulatory Approval, Manufacture or Commercialization of Licensed Products.

1.4 "**Affiliate**" means, with respect to a particular Party, a Person that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party. Notwithstanding the above, in no event shall [***] or any of its affiliates be deemed an Affiliate of Terns.

1.5 "**Anti-Corruption Laws**" means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, to the extent applicable, the *Corruption of Foreign Public Officials Act (CFPOA)*, the *US Foreign Corrupt Practices Act (FCPA)*, the *UK Bribery Act 2010*, *the French Law of December 9, 2017 on Transparency, the Fight Against Corruption and the Modernization of the Economy* (*Loi Sapin II*), and similar laws governing corruption and bribery, whether public, commercial or both, to the extent applicable.

1.6 "**API**" means active pharmaceutical ingredient.

1.7 "**Business Day**" means a day other than Saturday, Sunday or any day that banks in Shanghai, China; Paris, France; or New York City, New York, are required or permitted to be closed.

1.8 "**Calendar Quarter**" means each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30, or December 31.

1.9 "**Change of Control**" means with respect to either Party: (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement (other than to an Affiliate of such Party); (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person, or group of Persons, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

1.10 "**Clinical Trial**" means a Phase 1 Clinical Trial, a Phase 2 Clinical Trial, a Phase 3 Clinical Trial or a Phase 4 Clinical Trial.

1.11 "**CMC Information**" means Information related to the chemistry, manufacturing and controls of the Licensed Products, as specified by the FDA, NMPA and other applicable Regulatory Authorities.

1.12 "**Commercialization**" means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, medical education and medical liaison activities, marketing, pricing, reimbursement, sale, and distribution of Licensed Products, including strategic marketing, sales force detailing, advertising, market Licensed Product support, all customer support, Licensed Product distribution and invoicing and sales activities; *provided, however*, "**Commercialization**" shall exclude any activities relating to the Manufacture of Licensed Product. "**Commercialize**" and "**Commercializing**" shall have the correlative meanings.

1.13 "**Commercially Reasonable Efforts**" means, with respect to either Party's obligations under this Agreement, the carrying out of such obligations with a level of efforts and resources consistent with [***] for the active and diligent commercialization of a similarly situated branded pharmaceutical product as the Licensed Product at a similar stage of commercialization, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, the profitability of the product in light of pricing and reimbursement issues, and all other relevant factors [***].

1.14 "**Common Technical Document**" or "**CTD**" means a set of specifications for application dossier adopted by the ICH for organizing applications of pharmaceuticals for human use to regulatory authorities.

1.15 "**Competing Product**" means any product or compound, other than a Licensed Compound or Licensed Product, that [***] as its [***].

1.16 "**Confidential Information**" of a Party means any and all Information of such Party or its Affiliates that is disclosed to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by a Party or its Affiliates pursuant to the confidentiality agreement between the Parties dated [***], as amended (the "**Confidentiality Agreement**") shall be deemed to be Confidential Information of such Party disclosed hereunder; *provided, however,* that any use or disclosure of any such Information that is authorized under Article 12 shall not be restricted by, or be deemed a violation of, the Confidentiality Agreement. For clarity, Genfit Licensed Know-How shall be deemed Confidential Information of Genfit.

1.17 "**Control**" means, with respect to any material, Information, Patent or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license, or otherwise, to grant a license, sublicense, or other right to or under, such material, Information, Patent, or intellectual property right without violating the terms of any existing agreement or other arrangement with any Third Party; provided that, with respect to any material, Information, Patent or other intellectual property right obtained by Genfit after the Effective Date from a Third Party, Genfit shall be deemed to Control such material, Information, Patent or other intellectual property right only if it possesses the right to grant such license, sublicense, or other right thereto without being obligated to pay any royalties or other consideration therefor, unless Terns agrees in advance of any grant of rights thereto to pay such royalties or other consideration.

1.18 "**Cover**" means, with respect to a Patent and a Licensed Product, that the Manufacture, use, offer for sale, sale or import of such Licensed Product by an unlicensed Third Party would infringe a Valid Claim in such Patent; provided, however, that in determining whether a claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then currently being prosecuted. "**Covered**" and "**Covering**" shall have the correlative meanings.

1.19 "**CTA**" means a Clinical Trial Application which provides comprehensive information about the investigational medicinal product(s) and planned trial, enabling Regulatory Authorities to assess the acceptability of conducting the applicable study.

1.20 "**Data**" means all data, including CMC Information, non-clinical data, preclinical data and clinical data, generated by or on behalf of a Party or its Affiliates or their respective Sublicensees (in the case of Terns) or licensees, including Genfit Partners (in the case of Genfit), pursuant to activities conducted under this Agreement. For clarity, Data does not include any patentable Inventions.

1.21 "**Development**" means all activities conducted after the Effective Date relating to preclinical and clinical trials, toxicology testing, statistical analysis, publication and presentation of study results with respect to Licensed Products, and the reporting, preparation and submission of regulatory applications (including any CMC Information) for obtaining, registering and maintaining Regulatory Approval of Licensed Products; *provided, however*, "**Development**" shall exclude any activities relating to the Manufacture of Licensed Product. "**Develop**" and "**Developing**" shall have the correlative meanings.

1.22 "**Divest**" means, for purposes of Section 15.5, the sale or transfer of rights to the Competing Program to a Third Party where neither the assigning Party nor its assignee have the right to engage, and neither the assigning Party nor its assignee in fact engage, in any management, governance or decision-making activities in connection with such Competing Program. "**Divestiture**" shall have the correlative meaning.

1.23 "**EMA**" means the European Medicines Agency or any successor entity.

1.24 "**FDA**" means the U.S. Food and Drug Administration or any successor entity.

1.25 "**Field**" means the treatment of patients for (a) NASH, (b) PBC, (c) any Indication for which Genfit is Developing or Commercializing a Licensed Product in the Genfit Territory, and (d) any additional Indications approved by the JSC pursuant to Section 3.2(a)(ii).

1.26 "**First Commercial Sale**" means with respect to a Region, the first sale of a Licensed Product in such Region to a Third Party by or on behalf of Terns, its Affiliates or Sublicensees after Regulatory Approval has been obtained in such Region.

1.27 "**Fiscal Year**" means Terns' fiscal year that starts on January 1 and ends on December 31.

1.28 "**GCP**" or "**Good Clinical Practices**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the NMPA or other Regulatory Authority applicable to the Terns Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.29 "**Genfit Additional Products**" means any Competing Products that Genfit or any of its Affiliates Controls as of the Effective Date or during the Term or Develops, Manufactures or Commercializes during the Term.

1.30 "**Genfit Additional Product Opportunity**" means the rights to Develop, Manufacture, or Commercialize any Genfit Additional Product in the Terns Territory.

1.31 "**Generic Product**" means, with respect to a Licensed Product in a Region, any pharmaceutical product that: (a) is marketed for sale in such Region by a Third Party other than pursuant to any rights granted by Terns or its Affiliates; (b) contains the same API (or one which is substantially the same or bioequivalent, such as a solvate, hydrate, salt, stereoisomer, metabolite, pro-drug or polymorph thereof) as such Licensed Product; and (c) was granted pursuant to an MAA that relies on data held by a Regulatory Authority in relation to a Licensed Product.

1.32 "**Genfit Licensed Know-How**" means any and all Information (including Data and Regulatory Materials) that (a)(i) is Controlled by Genfit or its Affiliates as of the Effective Date or (ii) becomes Controlled by Genfit or its Affiliates during the Term, and (b)(i) is necessary for the Development, Manufacture, or Commercialization of the Licensed Compound or any Licensed Products in the Field in the Terns Territory, or (ii) is or was generated, developed, conceived, reduced to practice (constructively or actually) or used by or on behalf of Genfit or its Affiliates in the Development, Manufacture, or Commercialization of the Licensed Compound or any Licensed Products, including Genfit's interest in Genfit Inventions and Joint Inventions.

1.33 "**Genfit Licensed Patents**" means any and all Patents that (a)(i) are Controlled by Genfit or its Affiliates as of the Effective Date or (ii) become Controlled by Genfit or its Affiliates during the Term, and (b) Cover the Licensed Compound or any Licensed Products in the Terns Territory. Genfit Licensed Patents include the Patents listed in **Exhibit A** and Genfit's interest in any Joint Patents that may be filed during the Term.

1.34 "**Genfit Product-Specific Licensed Patents**" means any Genfit Licensed Patents specifically claiming the composition of matter of, or the method of making or using, the Licensed Compound and/or any Licensed Products. The Parties acknowledge and agree that the Patents Listed in **Exhibit A** are Genfit Product-Specific Licensed Patents.

1.35 "**Genfit Technology**" means the Genfit Licensed Know-How and Genfit Licensed Patents.

1.36 "**Genfit Territory**" means the world except for the Terns Territory.

1.37 "**GLP**" or "**Good Laboratory Practices**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by NMPA or other Regulatory Authority applicable to the Terns Territory, as may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.38 "**GMP**" means the good manufacturing practices required by the FDA and set forth in the FDCA or FDA regulations (including without limitation 21 CFR 210 and 211), policies, guidances or guidelines, or any applicable equivalent within a regulatory jurisdiction, including, without limitation, any applicable current good manufacturing practices requirements and pharmaceutical industry standards for the manufacture and testing of investigational pharmaceutical materials in force from time-to-time in the European Union (including, without limitation, Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice), the relevant national implementations of these rules and any relevant national and European Commission and Committee on Proprietary Medicinal Products guidance and, in particular, Annex 13 of the Guide to Good Manufacturing Practice entitled "Manufacture of investigational medicinal products", as updated and amended from time-to-time, in each case in effect at any time during the term of this Agreement, for the manufacture, handling and testing of investigational pharmaceutical products; (b) the corresponding requirements of each applicable Regulatory Agency or other governmental authority, and (c) any other guidances, procedures, practices, arrangements, additions or clarifications, as the Parties may agree in writing from time-to-time.

1.39 "**Government Official**" means (a) any official or employee of any Governmental Authority, or any department, agency, or instrumentality thereof (including without limitation commercial entities owned or controlled, directly or indirectly, by a Governmental Authority), (b) any political party or official thereof, or any candidate for political office, or (c) any official or employee of any public international organization.

1.40 "**Governmental Authority**" means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.41 "**ICH**" means International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.42 "**Indication**" means a class of human disease or condition for which a separate MAA (including any extensions or supplements) is required to be filed with a Regulatory Authority. For clarity, if an MAA is approved for a Licensed Product in a particular Indication and patient population, a label expansion for such Licensed Product to include such Indication in a different patient population shall not be considered a separate Indication.

1.43 "**Information**" means any Data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, copyrights, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC Information, stability data and other study data and procedures.

1.44 "**Initiation**" means, with respect to a Clinical Trial, the first visit in the first patient in such Clinical Trial.

1.45 "**Inventions**" means any inventions and/or discoveries, including processes, manufacture, composition of matter, Information, methods, assays, designs, protocols, and formulas, and improvements or modifications thereof, patentable or otherwise, that are generated, developed, conceived or reduced to practice (constructively or actually) by or on behalf of a Party or its Affiliates or their respective Sublicensees (in the case of Terns) or licensees, including Genfit Partners (in the case of Genfit) (a) pursuant to activities conducted under this Agreement, or (b) in connection with the Development, Manufacture, and Commercialization of Licensed Product, in each case of (a) and (b), including all rights, title and interest in and to the intellectual property rights therein and thereto; *provided, however,* that Inventions shall exclude Data.

1.46 "**Investigator Sponsored Clinical Study**" means a clinical study of a Licensed Compound or Licensed Product in the Field that is sponsored and conducted by a physician, physician group or other Third Party not acting on behalf of a Party, its Affiliates, Sublicensees or Genfit Partners and who does not have a license from a Party, its Affiliates, Sublicensees or Genfit Partners to Commercialize such Licensed Compound or Licensed Product, pursuant to an IND owned by such Third Party, and with respect to which a Party, its Affiliates, Sublicensees or Genfit Partners only provides clinical supplies of the Licensed Compound and Licensed Product (and not funding or any other support) for such clinical study.

1.47 "**Joint Patents**" means any Patents that claim Joint Inventions.

1.48 "**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, municipal, city or other political subdivision, domestic or foreign.

1.49 "**Licensed Compound**" means elafibranor, having the chemical structure set forth on **Exhibit B**.

1.50 "**Licensed Product**" means any pharmaceutical product in any form suitable for oral administration to adults or children that contains the Licensed Compound as the sole API for the treatment of patients in the Field.

1.51 "**Manufacture**" and "**Manufacturing**" mean activities directed to manufacturing, processing, filling, finishing, packaging, labeling, quality control, quality assurance testing and release, post-marketing validation testing, inventory control and management, storing and transporting any Licensed Product, including oversight and management of vendors therefor.

1.52 "**Manufacturing Cost**" means, with respect to a particular drug product supplied by Genfit pursuant to Section 7.1: (a) if Genfit or its Affiliate Manufactures the applicable drug product, the actual manufacturing cost of such drug product (as determined in accordance with U.S. GAAP consistently applied with its other products); or (b) if a Third Party Manufactures such drug product, the actual transfer price paid by Genfit or its Affiliate to such Third Party for the Manufacture of such drug product without mark-up; in each case of (a) and (b), excluding [***], [***], and similar charges, for such drug product.

1.53 "**Marketing Authorization Application**" or "**MAA**" means a New Drug Application ("**NDA**") or any other application to the appropriate Regulatory Authority for approval to market a Licensed Product, but excluding pricing approvals.

1.54 "**NASH**" means nonalcoholic steatohepatitis.

1.55 "**Net Sales**" means the gross amounts billed or invoiced by Terns, its Affiliates and their respective Sublicensees for sales of Licensed Products to Third Parties, less the following deductions to the extent reasonable, customary, and actually allowed and taken with respect to such sales:

(a) trade, cash or quantity discounts not already reflected in the amount invoiced, to the extent related to the gross amount billed or invoiced;

(b) price reductions, rebates and [***] (including those paid or credited to [***] or otherwise) (provided that, such [***] shall not be in excess, in the aggregate of [***] with respect to any given [***]);

(c) shipping costs, including freight, insurance and other transportation charges or costs incurred in shipping of Licensed Products to Third Parties (provided that, such shipping costs shall not be in excess of [***] with respect to any given [***]);

(d) sales, use, excise, value-added or similar taxes, customs duties and other governmental fees, charges and surcharges imposed on the sale of Licensed Products;

(e) amounts repaid or credited by reason of [***];

(f) amounts paid or credited for [***]; and

(g) any receivables that have been included in gross sales and are deemed to be uncollectible according to Accounting Standards (any such bad debt deductions shall be applied to Net Sales in the period in which such receivables are written off) (provided that, the amount of such receivables shall not be in excess of [***] with respect to any given [***]).

Notwithstanding the foregoing, amounts received or invoiced by Terns, its Affiliates, or their respective Sublicensees for the sale of Licensed Product among Terns, its Affiliates or their respective Sublicensees shall not be included in the computation of Net Sales hereunder unless the purchasing entity is the end-user. For purposes of determining Net Sales, the Licensed Product shall be deemed to be sold when billed or invoiced. Net Sales shall be accounted for in accordance with standard Terns practices for operation by Terns, its Affiliates or their respective Sublicensees,

as practiced in the Terns Territory, but in any event in accordance with Accounting Standards consistently applied in the Terns Territory. For clarity, a particular item may only be deducted once in the calculation of Net Sales. Notwithstanding anything to the contrary in the foregoing, to the extent any amounts deducted pursuant to subsections (d) or (g) above are subsequently recovered by Terns, its Affiliates, or their respective Sublicensees during the Term, such recovered amounts shall be deemed "Net Sales" for the subsequent Calendar Quarter; provided that, if no royalties are owed by Terns for such subsequent Calendar Quarter pursuant to Section 8.4, Terns shall promptly refund such recovered amounts to Genfit.

The transfer of any Licensed Product to an Affiliate, Sublicensee, or other Third Party (x) in connection with the research, development or testing of a Licensed Product (including, without limitation, the conduct of Clinical Trials), (y) for purposes of distribution as promotional samples, or (z) at nominal cost for indigent or similar public support or compassionate use programs, will not, in any case, be considered a Net Sale of a Licensed Product under this Agreement.

With respect to any transfer of any Licensed Product in the Terns Territory for any substantive consideration other than monetary consideration on arm's length terms, for the purposes of calculating the Net Sales under this Agreement, such Licensed Product shall be deemed to be sold exclusively for money at the average Net Sales price charged to Third Parties for cash sales in the Terns Territory during the applicable reporting period (or if there were only de minimus cash sales in the Terns Territory, at the fair market value as determined by comparable markets).

Terns, its Affiliates, and their respective Sublicensees shall sell the Licensed Product as a standalone product and will not sell the Licensed Product as a part of a bundle with other products or offer packaged arrangements to customers that include the Licensed Product, except with Genfit's prior written consent.

1.56 "**NMPA**" means the National Medical Products Administration of the People's Republic of China, formerly known as the China National Drug Administration, or any successor agency or authority thereto.

1.57 "**Patents**" means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificate, patent term additions, patent term extensions or the equivalent thereof.

1.58 "**PBC**" means primary biliary cholangitis.

1.59 "**Person**" means an individual, corporation, partnership, limited liability company, limited partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

1.60 "**Phase 1 Clinical Trial**" means any human clinical trial of a Licensed Compound conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique) that would satisfy the requirements of 21 C.F.R. § 312.21(a) or its non-United States equivalents.

1.61 "**Phase 2 Clinical Trial**" means any human clinical trial of a Licensed Compound conducted mainly to test the effectiveness of chemical or biologic agents or other types of interventions for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular Indication or Indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-United States equivalents. A "Phase 2/3 Clinical Trial" shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

1.62 "**Phase 3 Clinical Trial**" means any human clinical trial of a Licensed Compound designed to: (i) establish that such Product is safe and efficacious for its intended use; (ii) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (iii) support regulatory approval of such Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-United States equivalents. A "Phase 2/3 Clinical Trial" shall be deemed to be a Phase 3 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

1.63 "**Phase 4 Clinical Trial**" means a human clinical trial of a Licensed Compound that is (a) designed to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval for such Licensed Compound or (b) conducted after the first Regulatory Approval of such product in the same disease state for which the Licensed Compound received Regulatory Approval.

1.64 "**PPAR**" means peroxisome proliferator-activated receptor.

1.65 "**Proper Conduct Practices**" means, Terns, its Affiliates and Sublicensees, and each of their Representatives not, directly or indirectly, (a) making, offering, authorizing, providing or paying anything of value in any form, whether in money, property, services or otherwise to any Government Official, or other Person charged with similar public or quasi-public duties, or to any customer, supplier, or any other Person, or to any employee thereof, or failing to disclose fully any such payments in violation of the laws of any relevant jurisdiction to (i) obtain favorable treatment in obtaining or retaining business for it or any of its Affiliates, (ii) pay for favorable treatment for business secured, (iii) obtain special concessions or for special concessions already obtained, for or in respect of it or any of its Affiliates, in each case which would have been in violation of any applicable Law, (iv) influence an act or decision of the recipient (including a decision not to act) in connection with the Person's or its Affiliate's business, (v) induce the recipient to use his or her influence to affect any government act or decision in connection with the Person's or its Affiliate's business or (vi) induce the recipient to violate his or her duty of loyalty to his or her organization, or as a reward for having done so; (b) engaging in any transactions, establishing or maintaining any fund or assets in which it or any of its Affiliates shall have proprietary rights that have not been recorded in the books and records of it or any of its Affiliates; (c) making any unlawful payment to any agent, employee, officer or director of any Person with which it or any of its Affiliates does business for the purpose of influencing such

agent, employee, officer or director to do business with it or any of its Affiliates; (d) violating any provision of applicable Anti-Corruption Laws; (e) making any payment in the nature of bribery, fraud, or any other unlawful payment under the applicable Laws of any jurisdiction where it or any of its Affiliates conducts business or is registered; or, (f) if such Person or any of its Representatives is a Government Official, improperly using his or her position as a Government Official to influence the award of business or regulatory approvals to or for the benefit of such Person, its Representatives or any of their business operations, or failing to recuse himself or herself from any participation as a Government Official in decisions relating to such Person, its Representatives or any of their business operations.

1.66 "**Regulatory Approval**" means any and all approvals (including marketing authorization approvals, supplements, amendments, pre- and post-approvals, and pricing and reimbursement approvals), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the Manufacture, distribution, marketing, importation, exportation, use or commercial sale of a Licensed Product in a given country or regulatory jurisdiction.

1.67 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.68 "**Regulatory Materials**" means regulatory applications (including MAA), submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize Licensed Products in a particular country or jurisdiction.

1.69 "**Representatives**" means, as to any Person, such Person's Affiliates and its and their successors, controlling Persons, directors, officers and employees.

1.70 "**Sublicensee**" means a Third Party that has received a license or other right under the Genfit Technology in accordance with Section 2.1(c), but shall not include (i) any Third Party wholesaler or distributor engaged for the sale of Licensed Product (even if such wholesaler or distributor is granted a right or license to sell Licensed Product) provided that such wholesaler or distributor does not make any royalty, milestone, profit share or other payment to Licensee or its Affiliate based on such wholesaler's or distributor's sale of Licensed Product; or (ii) any Third Party contract research organization or manufacturer providing services to Licensee or its Affiliate (even if such contract research organization or manufacturer is granted a right or license to make Licensed Compound or Licensed Product). For clarity, the gross invoiced price for sale of Licensed Product to any wholesaler, distributor, contract research organization or manufacturer described above shall be included in Net Sales.

1.71 "**Terns Patents**" means any Patents that claim Terns Inventions.

1.72 "**Terns Territory**" means, collectively, mainland China, Taiwan, Hong Kong and Macau (each a "**Region**").

1.73 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.74 "**U.S. Dollar**" means a U.S. dollar, and "**US$**" shall be interpreted accordingly.

1.75 "**U.S.**" or "**USA**" means the United States of America, including all possessions and territories thereof.

1.76 "**Valid Claim**" means a claim (including a process, use, or composition of matter claim) of (a) an issued and unexpired patent that has not (i) irretrievably lapsed or been revoked, dedicated to the public or disclaimed or (ii) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and unappealable or unappealed within the time allowed for appeal, or (b) a pending patent application that has been prosecuted in good faith pending for no more than [***] years since its priority date and has not been abandoned or finally disallowed without the possibility of appeal.

1.77 "**Year**" means any period of twelve (12) consecutive months.

1.78 **Additional Definitions**: The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	**Section**
Accused Party	9.5
Agreement	Preamble
Alliance Manager	3.1
API Manufacturing Technology Transfer Agreement	7.2(b)(ii)
Claims	11.1
Clinical Drug Product Manufacturing Technology Transfer Agreement	7.1(b)
Clinical Supply Agreement	7.1(a)
Commercial Drug Product Manufacturing Technology Transfer Agreement	7.2(a)(ii)
Commercialization Plan	6.2(a)
Competing Program	15.5(b)
Confidentiality Agreement	1.16
Data Working Group	3.5(b)
Development Plan	4.2
Effective Date	Preamble
Enforcing Party	9.4(c)
Executive Officer	14.1
First Supplemental Development Plan	4.2
GAAP	1.1
Genfit	Preamble
Genfit API Supplier	7.2(b)(i)
Genfit Indemnitees	11.2

Defined Terms	**Section**
Genfit Inventions	9.1(c)(i)
Genfit Partner	2.2
ICC	14.2
IFRS	1.1
Indemnified Party	11.3
Indemnifying Party	11.3
Infringement	9.4(a)
Infringement Action	9.5
Initial Development Plan	4.2
Joint Inventions	9.1(c)(iii)
Joint Steering Committee	3.2(a)
Losses	11.1
NDA	1.53
Party	Preamble
Pharmacovigilance Agreement	5.8
Product Materials	4.6
Remedial Action	5.9
ROFN	2.5(b)
ROFN Exercise Period	2.5(b)
ROFN Exercise Notice	2.5(b)
ROFN Negotiation Period	2.5(b)
ROFN Offer Notice	2.5(b)
Royalty Term	8.4(b)
SEC	12.3(c)
Step-In Rights	9.2(d)
Tax Withholding	8.9(b)
Term	13.1
Terns	Preamble
Terns Housemarks	9.6(b)
Terns Indemnitees	11.1
Terns Inventions	9.1(c)(ii)
Terns Product Mark	9.6(a)
Terns Sublicense Agreement	2.1(c)
Third Party Drug Product Supply Agreement	7.2(a)(i)
Third Party API Supply Agreement	7.2(b)(i)
VAT	8.9(d)
Working Group	3.5(a)

ARTICLE 2
LICENSE

2.1 License to Terns.

(a) License Grant. Subject to the terms and conditions of this Agreement, Genfit hereby grants Terns an exclusive (even as to Genfit except as provided in Section 2.1(b) below) license, with the right to sublicense (solely as provided in Section 2.1(c)), under the Genfit Technology, to Develop, Manufacture and have Manufactured (solely in accordance with Section 7.2), distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise Commercialize Licensed Products in the Field in the Terns Territory. For clarity, no rights shall be granted to Terns under this Section 2.1(a), with respect to the Development, Manufacture or Commercialization of any product containing the Licensed Compound together with one or more APIs other than the Licensed Compound, which shall be exclusively subject to the joint research and development collaboration projects to be entered into between the Parties as set forth in Section 2.7. As consideration for the foregoing license and access to and transfers of know-how under this Agreement, Terns will make certain payments to Genfit as set out in, and subject to the terms and conditions of, Article 8.

(b) Genfit Retained Rights. Notwithstanding the exclusive rights granted to Terns in Section 2.1(a), Genfit and its Affiliates shall retain the following:

(i) the right to practice the Genfit Technology within the scope of the license granted to Terns under Section 2.1(a) in order to perform, or have performed by a Third Party contractor, Genfit's obligations under this Agreement;

(ii) the right to Manufacture or have Manufactured Licensed Products anywhere in the world for sale and use in the Field in the Genfit Territory; and

(iii) the right to practice and license the Genfit Technology outside the scope of the license granted to Terns under Section 2.1(a), provided that in no event shall Genfit Develop or Commercialize the Licensed Compound or any Licensed Products in the Terns Territory without Terns' prior written consent, whether within or outside the Field.

(c) Sublicense Rights. Terns shall not have the right to grant sublicenses of the license granted in Section 2.1(a) without Genfit's express prior written consent, except that Terns may grant such sublicense without Genfit's consent (i) to its Affiliates and (ii) to a Third Party solely with respect to the right to distribute, market, promote, sell, have sold, offer for sale, import, label, package and otherwise Commercialize Licensed Products in the Field in the Terns Territory, provided that (A) such Third Party is not debarred or disqualified under the Act or comparable applicable Laws outside the U.S., and (B) Terns retains a material involvement with respect to the marketing and promotion of the applicable Licensed Product. Terns shall, within thirty (30) days after granting any such sublicense, notify Genfit of the grant of such sublicense and provide Genfit with a true and complete copy of the sublicense agreement (which may have financial information and other confidential information redacted, provided that such redacted information is not reasonably necessary for Genfit to assess compliance of the sublicense agreement with this Section 2.1(c)) (each, a "**Terns Sublicense Agreement**"). Each Terns

Sublicense Agreement shall be consistent with the terms and conditions of this Agreement, and Terns shall be solely responsible for all of its Sublicensees' activities and any and all failures by its Sublicensees to comply with the applicable terms of this Agreement. Without limiting the foregoing, each Terns Sublicense Agreement shall include the following additional terms and conditions:

(i) the Sublicensee shall be bound by non-use and non-disclosure obligations no less stringent than those set forth in this Agreement;

(ii) the Sublicensee shall not have any right to grant further sublicenses to the Genfit Technology (excluding sublicenses to Third Party contractors, including distributors and wholesalers);

(iii) the Sublicensee shall not have any right to prosecute or maintain or enforce any Genfit Licensed Patents; and

(iv) the Sublicensee shall assign or license to Terns all Data and Inventions generated by such Sublicensee, and shall grant Terns all of the rights necessary for Terns to fulfill its obligations under Sections 9.1(a) and 9.1(c).

2.2 Genfit Partner. Genfit has the right, in its sole discretion, to enter into one or more agreements with Third Parties and grant such Third Parties the right to Develop, Manufacture and/or Commercialize Licensed Products in one or more countries in the Genfit Territory (each such Third Party, a "**Genfit Partner**"); provided that (a) Genfit shall remain solely responsible for any Genfit Partner's activities, (b) the grant of such rights to such Genfit Partner shall not affect Genfit's obligations under the Agreement, and (c) the Genfit Partner shall be required to promptly provide to Genfit any Product Materials generated by or on behalf of such Genfit Partner, and such Genfit Partner shall consent in writing to the provision of such Product Materials by Genfit to Terns as set forth in Section 4.6. So long as such Genfit Partner(s) is not actively developing, manufacturing or commercializing a Competing Product or any product containing the Licensed Compound in the Terns Territory, (i) Genfit shall have the right (but not the obligation) to fulfill any of its obligations under this Agreement through Genfit Partner(s), excluding Genfit's obligations under Article 3, and (ii) Genfit shall have the right to disclose to Genfit Partner(s) all Information solely regarding Licensed Products (which, for clarity, shall exclude any Information relating to any combination including one or more Licensed Products), including all Regulatory Materials relating thereto, disclosed by Terns to Genfit under this Agreement, for use by Genfit Partner(s) in their Development, Manufacture and Commercialization of Licensed Products in the Genfit Territory; *provided, however,* that (A) all such Information disclosed to Genfit Partner(s) by Genfit shall be deemed the Confidential Information of Terns, and (B) any Genfit Partner(s) that receive such information shall be obligated to abide by restrictions on disclosure and use substantially similar to the provisions set forth in Section 12.1.

2.3 Negative Covenant. Terns covenants that it will not, and will not permit any of its Affiliates or Sublicensees to, use or practice any Genfit Technology outside the scope of the license granted to it under Section 2.1(a). The foregoing shall not be construed to limit Terns' ability to conduct non-clinical or clinical studies with respect to the Licensed Compound and/or any Licensed Products in the Terns Territory; provided that, Terns shall not conduct any non-clinical or clinical studies with any new formulations of Licensed Product, without the prior written consent of Genfit.

2.4 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

2.5 Exclusivity.

(a) Exclusivity Covenant of Terns. During the Term, Terns shall not, directly or indirectly, either by itself or with or through any of its Affiliates or any Third Party (including via any arrangement or series of arranges with a Third Party), Develop, Manufacture or Commercialize any Competing Product in the Terns Territory.

(b) Terns' Right of First Negotiation. Genfit hereby grants to Terns a right of first negotiation (the "**ROFN**") with respect to any and all Genfit Additional Products as described in this Section 2.5(b). If, at any time during the Term, Genfit desires to pursue any Genfit Additional Product Opportunity in the Terns Territory (i) by itself or with or through any of its Affiliates, or (ii) with, through or in collaboration with a Third Party, whether through license, assignment, joint venture or otherwise, Genfit shall promptly provide Terns with written notice of its desire with respect to such Genfit Additional Product Opportunity, together with any data generated by, or on behalf of, Genfit with respect to such Genfit Additional Product Opportunity as would be reasonably useful for Terns to determine its interest in such Genfit Additional Product Opportunity (the "**ROFN Offer Notice**"). Within [***] following Terns' receipt of such ROFN Offer Notice (the "**ROFN Exercise Period**"), Terns may exercise its ROFN by providing Genfit with written notice of its intent thereto (the "**ROFN Exercise Notice**"). Upon Genfit's receipt of such ROFN Exercise Notice, Terns shall have the right to exclusively negotiate in good faith with Genfit for a period of [***] from date of the ROFN Exercise Notice (the "**ROFN Negotiation Period**") the terms of a license for such Genfit Additional Product Opportunity in the Terns Territory. If (A) Terns does not provide Genfit with a ROFN Exercise Notice within the ROFN Exercise Period, or if (B) Terns provides Genfit with a ROFN Exercise Notice within the ROFN Exercise Period but the Parties fail to reach a definitive agreement on the terms of a license with respect to such Genfit Additional Product Opportunity during the ROFN Negotiation Period, the ROFN will expire and Terns shall have no further rights with respect to such Genfit Additional Product Opportunity; provided that, in the case of clause (B) above, for a period of [***] following such ROFN expiration, Genfit shall not enter into a definitive agreement with a Third Party with respect to such Genfit Additional Product Opportunity on terms that are more favorable to such Third Party than those offered to Terns during such ROFN Negotiation Period. For clarity, except for any ROFN that has expired pursuant to the terms and conditions above, Terns shall retain its ROFN with respect to any other Genfit Additional Product Opportunity in the Terns Territory.

2.6 Transfer of Genfit Licensed Know-How. Genfit shall provide Terns with complete and accurate copies of the Genfit Licensed Know-How to the extent expressly provided for in **Exhibit C** and in accordance with the timeline specified therein. The JSC shall establish a reasonable process and schedule for the transfer of additional Genfit Licensed Know-How as required for the filing of an MAA in the Terns Territory and any other Genfit Licensed Know-How that subsequently comes into existence and becomes Controlled by Genfit or its Affiliates during the Term. Genfit shall reasonably cooperate with Terns in providing Terns with copies of such Genfit Licensed Know-How in accordance with the process and schedule agreed upon through the JSC; provided that Genfit shall not be obligated to share with or transfer to Terns under this Section 2.6 any CMC Information (which, for clarity, will be transferred under Sections 7.1 and 7.2).

2.7 Future R&D Collaboration. No later than [***], each Party shall submit to the other Party its proposals for potential future collaborations between the Parties regarding joint research and development projects with a focus on, among other things, China development activities, including without limitation, Development of Licensed Compounds in combination with proprietary compounds of Terns in the Field, with a total budget of [***], to be [***]. Each such proposal shall specify the Licensed Product or other compounds, the Development activities and the Indication(s) to be pursued thereunder, as well as a summary timeline and budget in connection therewith. Within [***] of the receipt by each Party of such proposals from the other Party, the JSC shall promptly confer and discuss in good faith the proper budget for each proposal and the Parties shall determine whether they agree to pursue any such proposal, taking in account factors such as scientific feasibility, project design, cost, revenue sharing and intellectual property rights. If, within [***] of the meeting of the JSC, the Parties do not agree on any such proposals to pursue, or if the aggregate budget for all agreed-upon proposals is [***], the following selection procedure shall apply: [***]. Upon the Parties' agreement to pursue or acceptance of any such proposal, the Parties will negotiate in good faith for a period of [***] the terms of such collaboration and enter into a separate R&D collaboration agreement therefor based on the terms set forth in such proposal.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Within thirty (30) days after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development, manufacturing, and commercialization issues, to act as its alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress and results of Terns' Development, Manufacturing, and Commercialization of Licensed Products. The Alliance Managers shall also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties with respect to Licensed Products. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

3.2 Joint Steering Committees.

(a) Formation; Purpose. Within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") for the overall coordination and oversight of the Parties' activities under this Agreement. The role of the JSC shall be:

(i) to review, discuss and coordinate the overall strategy for the Development, Manufacturing, and Commercialization of Licensed Products in the Terns Territory, including related regulatory activities;

(ii) to discuss and approve the inclusion of additional Indications within the Field for the Development and Commercialization of Licensed Products in the Terns Territory, including approval of the relevant Development Plan for such Indications;

(iii) to review, discuss and approve any proposed amendments or revisions to the Development Plan, including the First Supplemental Development Plan and those with respect to clinical Development activities set forth in Section 4.3(b);

(iv) to review and discuss (but not approve) the Commercialization Plan and any proposed amendments or revisions to such plan, and review and discuss (but not approve) the Commercialization of Licensed Products in the Terns Territory;

(i) to coordinate the Commercialization of Licensed Products in the Terns Territory and Genfit Territory to ensure consistent global marketing of Licensed Products;

(v) to review and discuss whether to pursue either Party's proposals for Development collaboration, and the scope and allocation of rights and obligations relating thereto, as set forth in Section 2.7; and

(ii) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

(b) Members. The JSC shall be comprised of an equal number of representatives from each Party. Each Party's representatives shall be an officer or employee of such Party or its Affiliate having sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. Each Party shall initially appoint [***] representatives to the JSC. The JSC may change its size from time to time by unanimous consent of its representatives, and each Party may replace its representatives at any time upon written notice to the other Party. Each Party shall appoint one (1) of its representatives on the JSC to act as the co-chairperson. The role of the co-chairpersons shall be to convene and preside at the JSC meetings and to ensure the circulation of meeting agendas at least [***] in advance of JSC meetings and the preparation of meeting minutes and any pre-read materials in accordance with Section 3.2(c), but the co-chairpersons shall have no additional powers or rights beyond those held by other JSC representatives. Employees or consultants of either Party that are not representatives of the Parties on the JSC may attend meetings of the JSC, provided that such attendees shall not vote or otherwise participate in the decision-making process of the JSC and are subject to obligations of confidentiality substantially similar to the provisions set forth in Section 12.1.

(c) Meetings. The JSC shall meet at least [***] per [***] during the Term, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special JSC meeting (by videoconference or teleconference) by at least [***] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JSC no later than [***] prior to the special meeting with materials reasonably adequate to enable an informed decision. The JSC may meet in person, by videoconference or by teleconference. All JSC meetings shall be conducted in English, and all communications, reports and records by and between the Parties under this Agreement shall be in English. The co-chairpersons shall alternate responsibility for preparing reasonably detailed written minutes of the JSC meetings that reflect, without limitation, all material decisions made at such meetings. The co-chairpersons (or their designees) shall send draft meeting minutes to each representative of the JSC for review and approval within [***] after the JSC meeting. Such minutes shall be deemed approved unless [***] JSC representatives object to the accuracy of such minutes within [***] of receipt.

(d) Decision Making. The JSC shall strive to seek consensus in its actions and decision making process and all decisions by the JSC shall be made by consensus, with each Party having collectively one (1) vote in all decisions. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter (to the extent that such matter requires the agreement of the Parties hereunder) within [***] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, then, [***] shall have the final decision making authority with respect to such matter within the JSC's authority; *provided, however,* that [***] shall have the right to veto any decision by [***] relating to any of the following matters (any such determination by [***] shall be in writing and provided to [***]): (a) [***] and (b) [***], in each case (whether under (a) or (b)) [***].

3.3 Limitation of JSC Authority. The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement.

3.4 Discontinuation of the JSC. The activities to be performed by the JSC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agree to disband the JSC; or (b) Genfit provides written notice to Terns of its intention to disband and no longer participate in the JSC. Thereafter, the JSC shall have no further obligations under this Agreement and each Party shall designate a contact person for the exchange of information relevant to activities that would have been performed by the JSC under this Agreement and decisions of the JSC shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

3.5 Working Groups.

(a) From time to time, the JSC may establish and delegate duties of the JSC to sub-committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities; provided that in any case neither Party shall be required by the Working Group to assume any responsibility, financial or otherwise, beyond those agreed to in writing by such Party, in particular pursuant to each Party's respective obligations under this Agreement. Each such Working Group shall be constituted and shall operate as the JSC determines; provided that each Working Group shall have equal representation from each Party, unless otherwise mutually agreed. Working Groups may be established on an ad hoc basis for purposes of a specific project or on such other basis as the JSC may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. In no event shall the authority of the Working Group exceed that of the JSC. All decisions of a Working Group shall be by consensus. Any disagreement between the members of a Working Group shall be referred to the JSC for resolution.

(b) Without limiting Section 3.5(a), within [***] after the Effective Date, the Parties shall establish a Working Group to for the overall coordination and oversight of the Parties' activities under Section 4.6 (the "**Data Working Group**"). The Data Working Group shall meet at least [***] per [***] during the Term or as frequently as appropriate to effect an expeditious and orderly transfer of Product Materials as set forth in Section 4.6.

ARTICLE 4
DEVELOPMENT

4.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Terns shall be solely responsible for the Development of Licensed Products in the Field in the Terns Territory, at its own cost and expense (except as otherwise expressly set forth herein), including (except as set forth in Section 4.6) all non-clinical and clinical studies and collection of CMC Information, as necessary to obtain Regulatory Approval for Licensed Products in any Region in the Terns Territory. Terns shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for Licensed Products in the Field in each Region in the Terns Territory, provided that Terns shall not be liable for any delays in any Development activities that are caused by Genfit's failure to provide to Terns Product Materials that are necessary for the performance of such Development activities, except to the extent Genfit's failure to provide such Product Materials is caused by Terns' action or inaction. Without limiting the generality of the foregoing, Terns shall use Commercially Reasonable Efforts to conduct its Development activities under and in accordance with the Development Plan, as well as Manufacturing activities related to such Development, as set forth in the Initial Development Plan.

4.2 Development Plan. Without limiting the generality of the other provisions in this Article 4, an initial, mutually agreed Development Plan is attached hereto as **Exhibit D** (the "**Initial Development Plan**"). Within [***] after the Effective Date, Terns (in conjunction with assistance from Genfit) will prepare and submit to the JSC a detailed plan containing the strategy, activities, study designs, timeline, study material needs (API and drug product) and budget for research and Development of the Licensed Compound and Licensed Products in the Field in the Terns Territory (the "**First Supplemental Development Plan**," and together with the Initial Development Plan and any subsequent updates pursuant to this Section 4.2, the "**Development Plan**"). The First Supplemental Development Plan shall include among other things, all material non-clinical and clinical studies, CMC Information collection activities and regulatory activities with respect to the Licensed Compound and Licensed Products to be conducted by or on behalf of Terns or its Affiliates or their respective Sublicensees in the Terns Territory. From time to time during the Term (but at least [***] per [***]), Terns shall prepare amendments and updates, as appropriate, to the then-current Development Plan, and shall submit such amendments and updates to the JSC in accordance with Section 4.3. For clarity, if there are no amendments or updates to the then-current Development Plan that are applicable in a [***], Terns' sole responsibility under this Section 4.2 during such [***] shall be to inform Genfit that the then-current Development Plan is up to date. Notwithstanding the above, following [***] in the Terns Territory, no amendment or update to the Development Plan shall be required for Investigator Sponsored Clinical Studies for such Licensed Product in the Terns Territory, *provided* that Terns shall provide to Genfit a reasonably detailed description of each such study [***], and shall consider in good faith any comments provided by Genfit with respect to such study before such commencement. Terns shall be solely responsible for all decisions regarding the day-to-day conduct of Development within the Terns Territory.

4.3 Other Development Activities.

(a) Pre-Clinical Development. Terns shall have the right to conduct any pre-clinical studies to generate and obtain Data that is reasonably useful for the Development of any Licensed Product in the Terns Territory, provided that Terns shall promptly amend the Development Plan to include such pre-clinical studies and submit such amendment to the JSC for review.

(b) Clinical Development. If Terns wishes to conduct any Clinical Trials for the Development of (i) any Licensed Product for any Indication in the Field other than an Indication included in the First Supplemental Development Plan, or (ii) any new dosage strength formulations of Licensed Product, in each case of (i) or (ii) in the Field in the Terns Territory, Terns may propose an amendment to the Development Plan to include such Clinical Trials and submit such amendment to the JSC for review and approval. If and upon receipt of such proposal, the JSC shall promptly (but in any event [***]) review and decide on whether to approve such proposal. Upon the JSC's approval of such amendment, such Clinical Trials shall be included in the amended Development Plan and Terns may conduct such Clinical Trials at its own cost. Terns shall ensure that any Clinical Trials conducted in the Terns Territory, whether by itself or through a subcontractor pursuant to Section 4.7, are conducted only at medical facilities that are qualified and registered with the NMPA or any other applicable Regulatory Authority. For clarity, Terns shall not conduct any Clinical Trials of any Licensed Product outside of the Field without Genfit's prior written approval.

(c) Cooperation. Genfit shall provide such technical assistance and cooperation to Terns as Terns may reasonably request, at Terns' sole cost and expense, as necessary or reasonably useful for Terns to Develop or Commercialize Licensed Products in the Field in the Terns Territory.

4.4 Development Records. Terns shall maintain complete, current and accurate records of all activities (and all Data and other Information resulting from such activities) conducted with respect to Licensed Products by Terns, its Affiliates and their respective Sublicensees in the Terns Territory. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Terns shall document all non-clinical studies and Clinical Trials for Licensed Products in formal written study records according to applicable Laws, including applicable national and international guidelines such as ICH, GCP and GLP, and shall provide the other Party English translations thereof (to the extent prepared and originated in a language other than English). Genfit shall have the right to review and copy such records at reasonable times and to obtain access to the original to the extent necessary or useful for regulatory or patent purposes in accordance with this Agreement.

4.5 Development Reports. Terns shall keep Genfit reasonably informed as to the progress and results of Terns', its Affiliates' and their respective Sublicensees' Development activities (including prompt reporting of available clinical Data). Without limiting the foregoing, at each regularly scheduled JSC meeting, Terns shall provide Genfit with a reasonably detailed written report summarizing its Development activities performed since the last JSC meeting and the results thereof, as reasonably sufficient to enable Genfit to determine Terns' compliance with

its diligence obligations under Section 4.1. At such JSC meeting, the Parties shall discuss the status, progress and results of Terns', its Affiliates' and their respective Sublicensees' Development activities. Terns shall promptly respond to Genfit's reasonable questions or requests for additional information relating to such Development activities. In addition, within [***] after the end of each Fiscal Year, Terns shall provide Genfit with a detailed written annual report regarding the progress of its Development activities and any results therefrom.

4.6 Data Exchange. In addition to Genfit's obligation with respect to the transfer of Genfit Licensed Know-How set forth under Section 2.6 and each Party's adverse event and safety Data reporting obligations pursuant to Section 5.8, but subject to the remainder of this Section 4.6, each Party shall, at its sole cost and expense, promptly provide the other Party with copies of any Data and Regulatory Materials related to the Licensed Compound or Licensed Products generated by or on behalf of such Party or its Affiliates or Sublicensees in the performance of Development activities hereunder that would be reasonably necessary for the Development, Manufacture and Commercialization of Licensed Compound or Licensed Products in the Field in the other Party's respective territory (the "**Product Materials**"), in accordance with the principles and timelines set forth in **Schedule 4.6**. The JSC may establish reasonable policies to effectuate the exchange of additional Product Materials between the Parties. For clarity, Genfit shall not be obligated under this Section 4.6 to share with Terns or provide Terns access to CMC Information or any other Information related to the Manufacture of Licensed Products (which, for clarity, will be transferred under Sections 7.2(a) and 7.2(b)).

4.7 Subcontractors. Terns shall have the right to engage subcontractors to conduct any activities necessary for Development or Manufacturing (subject to the terms of Article 7) of Licensed Products, including but not limited to non-clinical studies, Clinical Trials, CMC activities, and regulatory services for Licensed Products, under this Agreement, provided that such subcontractors (a) are bound by written obligations of confidentiality, non-use and compliance with applicable Laws, including Proper Conduct Practices, consistent with this Agreement and have agreed in writing to assign to Terns all Data, Information, inventions or other intellectual property generated by such subcontractor in the course of performing such subcontracted work, (b) are capable of producing Data (including non-clinical Data, clinical Data and CMC Information, as applicable) acceptable to the NMPA, the FDA and the EMA (and other applicable Regulatory Authorities in the Terns Territory, the United States or the European Union) and (c) as applicable, with respect to matters covered by Article 7, meet the specifications and requirements thereunder. Terns shall remain responsible for any obligations that have been delegated or subcontracted to any subcontractor, and shall be responsible for the performance of its subcontractors.

ARTICLE 5
REGULATORY MATTERS

5.1 Regulatory Responsibilities.

(a) Subject to the terms and conditions of this Agreement, Terns will be responsible, at its sole cost and expense, for the conduct of all regulatory activities required to obtain and maintain Regulatory Approval of Licensed Products in the Field in the Terns Territory, including the preparation and submission of all Regulatory Materials and all communications and interactions with Regulatory Authorities, as necessary to obtain Regulatory Approval for Licensed Products in any Region in the Terns Territory. Terns shall be responsible for filing each CTA in the Terns Territory for each Licensed Product, provided that, if required under applicable Laws, Terns (or its Affiliate) and Genfit will file such CTA(s), and will hold such CTA(s) as co-sponsors. Terns shall be responsible for filing each MAA in the Terns Territory for each Licensed Product in Terns' name, if permitted by applicable Laws. Notwithstanding the above, if applicable Laws require Terns to file an MAA in Genfit's name, then (i) Genfit shall initially be the holder of the Regulatory Approval for each Licensed Product in the Terns Territory, and Genfit hereby designates Terns as Genfit's regulatory agent and exclusive general distributor for the Licensed Product in the Terns Territory, and (ii) as soon as permitted by applicable Laws, Genfit shall promptly assist and cooperate with Terns and transfer and assign all Regulatory Approvals and Regulatory Materials (including any CTAs filed as set forth above) for each Licensed Product in the Terns Territory to Terns to allow Terns to be the holder of the Regulatory Approval for each Licensed Product in the Terns Territory. The Development Plan shall include the regulatory strategy for obtaining Regulatory Approval of Licensed Products in the Terns Territory. Terns shall use Commercially Reasonable Efforts to carry out its regulatory obligations for Licensed Products pursuant to such strategy.

(b) Genfit shall provide all reasonable assistance and cooperation to Terns as Terns may reasonably request, at Terns' sole cost and expense, during the Term of this Agreement, with respect to the satisfaction of its obligations under Section 5.1(a), including (i) in connection with the preparation of Regulatory Materials, (ii) (A) making available competent personnel to attend regulatory meetings or join such meetings by teleconference and (B) providing documentation within Genfit's possession and control, in each case as requested by Regulatory Authorities at Terns' cost, and (iii) providing Terns with additional Regulatory Materials in the Genfit Territory as requested by Regulatory Authorities in the Terns Territory within a reasonable timeframe commensurate with the volume of Terns' reasonable request. In the event that Genfit believes that such requests are not reasonable or are otherwise burdensome to Genfit, then such matter shall be promptly submitted to the JSC for review and discussion. Without limiting the foregoing, Genfit shall provide Terns with [***] of the CTD for any formulation of Licensed Product for which Genfit has prepared a CTD for Regulatory Filings in the Field in the Genfit Territory, in a manner sufficient for filing in the U.S. within [***] after completion of all such [***] of the CTD. Terns shall be responsible for publishing and submitting the CTD (including [***]) to the Regulatory Authority in the Terns Territory. Any such transfer of CMC Information as set forth in this Section 5.1 is conditioned on Terns establishing appropriate firewalls or equivalent means designed to ensure that such CMC Information is protected from unauthorized disclosure and is used only for legal and regulatory compliance purposes and not for any other purpose. In furtherance of the foregoing, Terns shall ensure that any CMC Information provided

by or on behalf of Genfit pursuant to this Section 5.1 shall only be disclosed to those identified personnel of Terns (or a designated agreed Third Party) who (x) have a need to know the same to comply with the above obligations, and (y) have been fully informed of and acknowledge the highly sensitive and proprietary nature of such information and the need to maintain its secrecy and avoid inappropriate usage or disclosure, by using the firewall or equivalent means. Notwithstanding anything to the contrary herein, Genfit's obligations under this Section 5.1(b), including to provide Terns with [***] of the CTD and such other information or assistance specified in this Section 5.1(b), shall apply solely to the extent Genfit is Manufacturing and supplying Terns with Licensed Products.

5.2 Regulatory Information Sharing. Terns shall (a) provide Genfit with the English translations (to the extent originated by Terns in Chinese), along with the original documents (in the electronic format in which it has been prepared by Terns) of draft package inserts, CTA and CTD, for Genfit's review and comment, in connection with obtaining or maintaining any MAA approval for Licensed Products in the Field in the Terns Territory, prior to the submission of such documents to the Regulatory Authority in the Terns Territory; and (b) shall keep Genfit informed of any material verbal or written communication or question relating to Licensed Products received by Terns from the Regulatory Authority in the Terns Territory. Except as required by applicable Law, Terns, its Affiliates and Sublicensees shall not submit any Regulatory Materials to, or communicate with, any Regulatory Authority in the Genfit Territory regarding any Licensed Products. If such submission or communication is required by applicable Law, Terns shall, if legally permitted, promptly notify Genfit in writing of such requirement and the content of such submission or communication.

5.3 Meetings with Regulatory Authorities. Terns shall lead all interactions with Regulatory Authorities in the Terns Territory with respect to Licensed Products. Terns shall keep Genfit reasonably informed of any material regulatory developments related to Licensed Products in the Field in the Terns Territory. At each regularly scheduled JSC meeting, Terns shall provide Genfit with a list and schedule of any in-person meeting or teleconference with the applicable Regulatory Authorities (or related advisory committees) in the Terns Territory planned for the next Calendar Quarter that relates to any Licensed Product in the Field. In addition, Terns shall notify Genfit as soon as reasonably possible (but in no event later than [***] if possible) after Terns becomes aware of any additional such meetings or teleconferences that become scheduled for such Calendar Quarter. Genfit shall provide all assistance and documentation reasonably requested by Terns to prepare for any such meeting or teleconference, including making available competent personnel to attend any such meeting or teleconference at Terns' reasonable request. To the extent permitted by applicable Laws and by the Regulatory Authorities (as reasonably determined by Terns), Genfit shall have the right to participate (whether directly or through a representative) in all such meetings and teleconferences [***].

5.4 Regulatory Costs. Unless otherwise provided in this Agreement, Terns shall be responsible for the costs and expenses incurred in connection with the preparation and filing of any and all Regulatory Materials and the maintenance of any and all Regulatory Approvals (including MAA approvals) for Licensed Products in the Field in the Terns Territory.

5.5 Right of Reference to Regulatory Materials. Each Party hereby grants to the other Party the right of reference to all Regulatory Materials pertaining to Licensed Products submitted by or on behalf of such Party. The receiving Party may use such right of reference solely for the purpose of seeking, obtaining and maintaining Regulatory Approval of Licensed Products in its respective territory. Each Party shall support the other Party, as reasonably requested by such other Party and at such other Party's expense, in obtaining Regulatory Approvals in such other Party's territory, including providing necessary documents or other materials required by applicable Laws to obtain Regulatory Approval in such territory, all in accordance with the terms and conditions of this Agreement.

5.6 No Harmful Actions. If either Party believes that the other Party is taking or intends to take any action with respect to any Licensed Product that could reasonably be expected to have an Adverse Risk, whether in the Genfit Territory or in the Terns Territory, such Party may bring the matter to the attention of the JSC and the Parties shall discuss in good faith to promptly resolve such concern.

5.7 Notification of [***] Action. Each Party shall immediately notify the other Party (including by providing notice to the other Party's Alliance Manager) of any information it receives regarding any [***] action, inspection or communication by or from any Third Party, including without limitation a Regulatory Authority, which may affect the Development, Manufacture, Commercialization or regulatory status of any Licensed Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.8 Adverse Event Reporting and Safety Data Exchange. No later than [***] before the Initiation of a Clinical Trial with respect to the Development of any Licensed Product in the Terns Territory, the Parties shall define and finalize the actions that the Parties shall employ with respect to such Licensed Product to protect patients and promote their well-being in a written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") for the Development of the Licensed Product globally. Further, no later than [***] before the anticipated launch date of any Licensed Product in the Terns Territory, the Parties shall enter into a separate Pharmacovigilance Agreement for the Commercialization of the Licensed Product. Each of the Pharmacovigilance Agreements shall include mutually acceptable guidelines and procedures for the receipt, investigation, recording, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of the Licensed Product, and other routine pharmacovigilance reporting requirements. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory reporting safety reporting requirement, in which case local reporting requirement shall prevail. The Pharmacovigilance Agreement shall provide for an adverse event database for the Licensed Products in the Field in the Terns Territory to be maintained by Terns [***], and a global safety database for the Licensed Products to be maintained by Genfit [***]. As between the Parties, Terns shall be responsible for preparing all adverse event reports and responses to safety issues and requests of Regulatory Authorities relating to Licensed Products in the Field in the Terns Territory, and Terns shall be responsible for filing such reports and responses with Regulatory Authorities in the Terns Territory. As between the Parties, Terns shall also be

responsible for reporting any quality complaints, adverse events and safety data related to Licensed Products in the Field in the Terns Territory to Genfit for inclusion in the global safety database. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted Sublicensees to comply with such obligations.

5.9 Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action taken by virtue of applicable Laws (a "**Remedial Action**"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Terns shall, and shall ensure that its Affiliates and Sublicensees will, maintain adequate records to permit the Parties to trace the packaging, labeling, distribution, sale and use (to the extent possible) of the Licensed Product in the Terns Territory. Terns shall have sole discretion with respect to any matters relating to any Remedial Action in the Terns Territory, including the decision to commence such Remedial Action and the control over such Remedial Action in its territory, at its cost and expense; *provided, however,* if Genfit determines in good faith that any Remedial Action with respect to any Licensed Product in the Terns Territory should be commenced or is required by applicable Laws or Regulatory Authority, (a) Genfit shall discuss such Remedial Action with Terns and (b) Terns shall carry out such Remedial Action upon Genfit's request. Notwithstanding anything to the contrary in clause (b) above, if Terns in good faith disagrees that such Remedial Action should be commenced or is required by applicable Laws or Regulatory Authority, such Remedial Action shall be conducted [***]. Each Party shall provide the other Party, [***] with such assistance in connection with a Remedial Action as may be reasonably requested by such other Party.

ARTICLE 6
COMMERCIALIZATION

6.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Terns shall have the sole right and responsibility for and have operational control over all aspects of the Commercialization of Licensed Products in the Field in the Terns Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Licensed Products; (c) marketing, advertising and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Licensed Products in the Field in the Terns Territory. Terns shall bear all of the costs and expenses incurred in connection with such Commercialization activities. Terns shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Terns Territory and to actively market and sell the Licensed Products in the Terns Territory and to expand annual Net Sales of the Licensed Products in the Terns Territory. Without limiting the generality of the foregoing, Terns shall use Commercially Reasonable Efforts to conduct its Commercialization activities under and in accordance with the Commercialization Plan.

6.2 Commercialization Plan.

(a) General. Terns shall Commercialize Licensed Products in the Field in the Terns Territory pursuant to a commercialization plan (the "**Commercialization Plan**"). The Commercialization Plan shall include (i) a detailed description of all key strategic decisions (including messaging, branding, marketing, advertising, sales force positioning, number of representatives and details, pricing strategy, etc.), implementation tactics and pre-launch and post-launch activities; (ii) a reasonably detailed description and timeline of Terns', its Affiliates' and their respective Sublicensees' Commercialization activities for Licensed Products in the Terns Territory for the next Fiscal Year, including medical marketing activities, sales forecasts and projections, pricing, reimbursement, market research, sales training, distribution channels, customer service and sales force matters related to the launch and sale of Licensed Products in the Terns Territory, and (iii) a strategic plan for Commercialization of Licensed Products in the Terns Territory for the following [***] Fiscal Years. In the event that Terns' Commercialization Plan requires the use of Genfit internal resources to conduct additional activities, the extent of such need shall be clearly specified in the Commercialization Plan and will require the prior written approval of Genfit.

(b) Initial Plan and Amendments. Within a reasonable time (but no less than [***]) prior to the anticipated Regulatory Approval of each Licensed Product in the Terns Territory, Terns shall prepare and present to the JSC an initial Commercialization Plan for review and discussion (but not approval) by the JSC. From time to time (but at least on an annual basis) during the Term, Terns shall prepare updates and amendments, as appropriate, to the then-current Commercialization Plan, and shall submit all updates and amendments to the Commercialization Plan to the JSC for review and discussion (but not approval). Notwithstanding anything to the contrary contained in this Agreement, the Commercialization Plan, and any updates and amendments thereto, shall not require the approval of the JSC or Genfit.

6.3 Data Exchange. Terns shall keep Genfit reasonably informed of Terns', its Affiliates' and their respective Sublicensees' Commercialization activities with respect to the Licensed Products in the Field in the Terns Territory. Genfit shall provide to Terns, upon Terns' request, and no more than [***] each [***], [***] copies of any materials prepared by or on behalf of Genfit that are necessary or reasonably useful in connection with Terns' Commercialization of Licensed Products in the Field in the Terns Territory (including relevant training materials, global brand and global market research, in each case, with respect to Licensed Products), and, to the extent elected by Terns, Terns shall have the right to use such materials in connection with the Commercialization of Licensed Products in the Field in the Terns Territory in accordance with the Agreement.

6.4 No Diversion. Each Party hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and Sublicensees (in the case of Terns) or licensees, including Genfit Partners (in the case of Genfit) will not, directly or indirectly, promote, market, distribute, import, sell or have sold the Licensed Products, including via internet or mail order, in the other Party's territory. With respect to any country in the other Party's territory, a Party shall not, and shall ensure that its Affiliates and their respective Sublicensees (in the case of Terns) or licensees, including Genfit Partners (in the case of Genfit) will not: (a) establish or maintain any branch, warehouse or distribution facility for Licensed Products in such countries, (b) knowingly engage in any advertising or promotional activities relating to Licensed Products that are directed primarily to customers or other purchaser or users of Licensed Products located in such countries,

(c) actively solicit orders for Licensed Products from any prospective purchaser located in such countries, or (d) knowingly sell or distribute Licensed Products to any person in such Party's territory who intends to sell or has in the past sold Licensed Products in such countries. If either Party receives any order for any Licensed Product from a prospective purchaser reasonably believed to be located in a country in the other Party's territory, such Party shall immediately refer that order to the other Party and such Party shall not accept any such orders. Each Party shall not deliver or tender (or cause to be delivered or tendered) Licensed Products into a country in the other Party's territory. Each Party shall not, and shall ensure that its Affiliates and their respective Sublicensees (in the case of Terns) or licensees, including Genfit Partners (in the case of Genfit) will not, knowingly restrict or impede in any manner the other Party's exercise of its retained exclusive rights in the other Party's territory.

6.5 Field Restrictions. Terns hereby covenants that it shall not, and shall cause its Affiliates and Sublicensees not to, promote or encourage the use of Licensed Products in the Terns Territory for any use outside the Field. Genfit acknowledges and understands that Terns cannot control the ultimate use of Licensed Products it sells.

ARTICLE 7
MANUFACTURE AND SUPPLY

7.1 Clinical Supply.

(a) Clinical Drug Product Supply. Genfit will supply Terns' clinical requirements of the applicable drug product for clinical use in the Terns Territory, [***] under a separate agreement ("**Clinical Supply Agreement**") to be entered into between the Parties within [***] following the Effective Date. The Clinical Supply Agreement shall contain commercially reasonable terms as may be agreed upon in good faith by the Parties.

(b) Clinical Drug Product Manufacturing Technology Transfer. Upon Terns' request, the Parties shall enter into a manufacturing technology transfer agreement for the [***] of the applicable drug product ("**Clinical Drug Product Manufacturing Technology Transfer Agreement**"). Under such Clinical Drug Product Manufacturing Technology Transfer Agreement, Genfit shall transfer to Terns such documents and information, and provide such technical assistance and support, necessary or reasonably useful for Terns to Manufacture, or have Manufactured by a Third Party contractor engaged by Terns that is reasonably acceptable to Genfit, the [***] of the applicable drug product, to the extent Controlled by Genfit as of such date; *provided* that (i) Terns shall notify Genfit of any such Third Party contractor and only engage with such Third Party contractor after receiving the prior written consent of Genfit, not to be unreasonably withheld, conditioned or delayed, and (ii) any such Third Party contractor shall (A) be bound by written obligations of confidentiality, non-use and compliance with applicable Laws (including Proper Conduct Practices, GMP and any regulations required by the NMPA, the FDA and the EMA), consistent with this Agreement and have agreed in writing to assign to Terns all Data, Information, inventions or other intellectual property generated by such subcontractor in the course of performing such subcontracted work, and (B) upon reasonable prior written notice given by Genfit to Terns, shall permit Genfit or its representatives to audit, during such subcontractor's normal business hours and without additional charge, the performance of Manufacturing activities hereunder, the facilities used and relevant processes, systems, books, documents and records, in order to determine Terns' compliance with this Agreement. Terns shall pay Genfit's reasonable external costs incurred in connection with providing such information or assistance pursuant to this Section 7.1(b).

7.2 Commercial Supply.

(a) Commercial Drug Product.

(i) Third Party Manufacture and Supply. Genfit shall not be responsible for supplying drug product to Terns for commercial use. Genfit shall permit Terns to negotiate and enter into with Genfit's Third Party supplier of the applicable drug product a separate agreement for the commercial supply of such drug product for commercial use in the Terns Territory ("**Third Party Drug Product Supply Agreement**"), and Genfit shall use Commercially Reasonable Efforts to facilitate the negotiations of such Third Party Drug Product Supply Agreement.

(ii) Manufacturing Technology Transfer. Upon Terns' request, the Parties shall enter into a manufacturing technology transfer agreement for the applicable drug product ("**Commercial Drug Product Manufacturing Technology Transfer Agreement**"). Under such Commercial Drug Product Manufacturing Technology Transfer Agreement, Genfit shall transfer to Terns such documents and information, and provide such technical assistance and support, necessary or reasonably useful for Terns to Manufacture, or have Manufactured by a Third Party contractor engaged by Terns that is reasonably acceptable to Genfit, the commercial formulation of the applicable drug product, to the extent Controlled by Genfit as of such date; *provided* that (i) Terns shall notify Genfit of any such Third Party contractor and only engage with such Third Party contractor after receiving the prior written consent of Genfit, not to be unreasonably withheld, conditioned or delayed, and (ii) any such Third Party contractor shall (A) be bound by written obligations of confidentiality, non-use and compliance with applicable Laws (including Proper Conduct Practices, GMP and any regulations required by the NMPA, the FDA and the EMA), consistent with this Agreement and have agreed in writing to assign to Terns all Data, Information, inventions or other intellectual property generated by such subcontractor in the course of performing such subcontracted work, and (B) upon reasonable prior written notice given by Genfit to Terns, shall permit Genfit or its representatives to audit, during such subcontractor's normal business hours and without additional charge, the performance of Manufacturing activities hereunder, the facilities used and relevant processes, systems, books, documents and records, in order to determine Terns' compliance with this Agreement. Terns shall [***] incurred in connection with providing such information or assistance pursuant to this Section 7.2(a)(ii).

(b) API.

(i) Third Party Manufacture and Supply. Genfit shall not be responsible for supplying API to Terns for commercial use. Genfit shall permit Terns to negotiate and enter into with Genfit's Third Party supplier of the applicable API ("**Genfit API Supplier**") a separate agreement for the commercial supply of such API for commercial use in the Terns Territory ("**Third Party API Supply Agreement**"), and Genfit shall use Commercially Reasonable Efforts to facilitate the negotiations of such Third Party API Supply Agreement.

(ii) Manufacturing Technology Transfer. Upon the [***] of the [***] of a Licensed Product in the Terns Territory, Terns may (but is not obligated to) request in writing from Genfit to enter into a manufacturing technology transfer agreement for the applicable API ("**API Manufacturing Technology Transfer Agreement**"). Under such API Manufacturing Technology Transfer Agreement, Genfit shall transfer or have transferred to Terns such documents

and information, and provide such technical assistance and support, necessary or reasonably useful for Terns to Manufacture, or have Manufactured by a Third Party contractor engaged by Terns that is reasonably acceptable to Genfit, the applicable API, to the extent Controlled by Genfit as of such date; *provided* that (A) Terns shall notify Genfit of any such Third Party contractor and only engage with such Third Party contractor after receiving the prior written consent of Genfit, not to be unreasonably withheld, conditioned or delayed, (B) such Third Party contractor shall be bound by written obligations of confidentiality, non-use and compliance with applicable Laws (including Proper Conduct Practices, GMP and any regulations required by the NMPA, the FDA and the EMA), consistent with this Agreement and have agreed in writing to assign to Terns all Data, Information, inventions or other intellectual property generated by such subcontractor in the course of performing such subcontracted work, and (C) upon reasonable prior written notice given by Genfit to Terns, Terns shall cause such Third Party contractor to (x) provide a sample of [***] the applicable API, promptly following the Manufacture thereof, to Genfit for testing purposes, and (y) permit Genfit or its representatives to audit, during such Third Party contractor's normal business hours and without additional charge, the performance of Manufacturing activities hereunder, the facilities used and relevant processes, systems, books, documents and records, in order to determine Terns' compliance with this Agreement. Terns shall pay any reasonable external costs incurred by Genfit in connection with providing such information or assistance pursuant to this Section 7.2(b) and the API Manufacturing Technology Transfer Agreement.

7.3 **Distribution**. Terns will be solely responsible for the distribution of Licensed Products in the Field in the Terns Territory.

7.4 **Brand Security and Anti-Counterfeiting**. The Parties will establish contacts for communication regarding brand security issues, and each Party shall reasonably cooperate with the other Party with respect thereto. Practices around these incidents will comply with Genfit's then-current standards, where such standards define product security features, warehouse/cargo protection requirements, and response and communication process for such incidents.

ARTICLE 8
COMPENSATION

8.1 **Upfront Payment**. Within ten (10) Business Days after the Effective Date, Terns shall pay to Genfit a one-time, non-refundable, non-creditable financial milestone payment of thirty-five million U.S. Dollars (US$35,000,000).

8.2 **Development Milestone Payments**. Terns shall pay to Genfit the one-time, non-refundable, non-creditable payments set forth in the table below within [***] of the first achievement by a Licensed Product of the applicable milestone event, whether by or on behalf of Terns, its Affiliate, or their Sublicensees. For clarity, each Development milestone payment shall be payable only once with respect to NASH or PBC regardless of the number of times achieved by one or more Licensed Products.

Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

8.3 Commercial Milestone Payments. Terns shall pay to Genfit the additional one-time, non-refundable, non-creditable payments set forth in the table below within [***] after the first achievement by the aggregate Net Sales of Licensed Products in a Fiscal Year of the applicable sales milestone event. For clarity, the milestone payments in this Section 8.3 shall be additive such that if multiple milestone events specified below are achieved in the same Fiscal Year, then the milestone payments for all such milestone events shall be payable within [***] after the end of such Fiscal Year. For clarity, each of the following milestone payments shall be payable only once regardless of the number of times such milestone is achieved.

Commercial Milestone Event	Milestone Payment
The aggregate Net Sales of Licensed Products in the Terns Territory in a Fiscal Year first reaches [***]	[***]
The aggregate Net Sales of Licensed Products in the Terns Territory in a Fiscal Year first reaches [***]	[***]
The aggregate Net Sales of Licensed Products in the Terns Territory in a Fiscal Year first reaches [***]	[***]

8.4 Royalties on Net Sales.

(a) Royalty Rate. Subject to the terms and conditions of this Section 8.4, within [***] after the end of each Calendar Quarter during the Royalty Term, Terns shall pay to Genfit non-creditable, non-refundable royalties of [***] percent ([***]%) of all Net Sales in the Terns Territory during such Calendar Quarter.

(b) Royalty Term. Royalties payable under Section 8.4(a) shall be paid by Terns (on a Licensed Product-by-Licensed Product and Region-by-Region basis) from the period beginning on the date of the First Commercial Sale of each Licensed Product in a Region in the Terns Territory and continuing until the later of: (i) ten (10) years from the date of First Commercial Sale of such Licensed Product in such Region, and (ii) expiration of the last Valid Claim of a Genfit Licensed Patent or Joint Patent Covering such Licensed Product in such Region (the "**Royalty Term**"). For clarity, if a Valid Claim of a Genfit Licensed Patent or Joint Patent Covers the Manufacture of such Licensed Product in such Region, then regardless of whether such Licensed Product is actually Manufactured in such Region, such Licensed Product shall be deemed to be Covered by a Valid Claim of a Genfit Licensed Patent or Joint Patent in such Region.

(c) Royalty Reduction for No Valid Claim. Starting from the first Calendar Quarter that a Licensed Product is not Covered by a Valid Claim of a Genfit Licensed Patent or Joint Patent in a Region where such Licensed Product is sold, the applicable royalty rate set forth in Section 8.4(a) with respect to Net Sales of such Licensed Product and such Region shall be reduced by [***] percent ([***]%).

(d) Anti-Stacking. In the event that Terns, based on the reasonable opinion of Terns' outside patent counsel in consultation with Genfit's patent counsel, determines that rights to intellectual property owned or controlled by a Third Party are required in order to make, use, or sell a Licensed Product in a Region, Terns shall have the right to negotiate and acquire such rights through a license or otherwise and shall have the right to deduct from the royalty payments due to Genfit under this Agreement with respect to Net Sales of such Licensed Product in such Region in a particular Calendar Quarter, an amount equal to [***] percent ([***]%) of the royalties paid by Terns to such Third Party pursuant to such license for such rights on account of the sale of such Licensed Product in such Region during such Calendar Quarter; provided that such reduction shall not reduce the royalties due to Genfit for the Net Sales of such Licensed Product in such Region in a particular Calendar Quarter below [***] percent ([***]%) of the royalties that would otherwise have been due to Genfit under Section 8.4(a).

(e) Royalty Floor. Notwithstanding the operation of Sections 8.4(c) and 8.4(d), in no event shall the royalty rate payable pursuant to Section 8.4(a) fall below [***] percent ([***]%).

8.5 Royalty Payments; Reports. Royalties under Section 8.4 shall be calculated and reported for each Calendar Quarter during the Royalty Term and shall be paid within [***] after the end of the applicable Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of a Licensed Product occurs. Each payment of royalties shall be accompanied by a report of Net Sales of Licensed Products by Terns, its Affiliates and their respective Sublicensees in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including: (a) the amount of gross sales and Net Sales of Licensed Products in the Terns Territory on a Licensed Product-by-Licensed Product and Region-by-Region basis, (b) an itemized calculation showing the deductions from gross sales (by major category as set forth in the definition of Net Sales) to determine Net Sales, and (c) a calculation of the amount of royalties due to Genfit in U.S. Dollars, including the application of any exchange rate used.

8.6 Payment Method; Foreign Exchange. All payments owed by Terns under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Genfit. For clarity, all payments by Terns to Genfit pursuant to Sections 8.1, 8.2, 8.3 and 8.4 shall be in U.S. Dollars. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars of any amounts payable in U.S. Dollars by Terns to Genfit under this Agreement shall be determined and calculated using the average rate of exchange based on [***] for the Calendar Quarter in which the applicable payment is due.

8.7 Interest on Late Payments. If Genfit does not receive payment of any sum due to it on or before the due date, interest shall thereafter accrue on the sum due to Genfit until the date of payment at the per annum rate of [***] or the maximum rate allowable by applicable Laws, whichever is lower, with such interest compounded [***].

8.8 Records; Audits.

(a) Terns shall, and shall cause its Affiliates and their respective Sublicensees to, maintain in accordance with Accounting Standards, reasonably complete and accurate records in sufficient detail to permit Genfit to confirm the accuracy of the calculation of royalty payments and the achievement of the milestone events. All payments and other relevant amounts under this Agreement shall be accounted for in accordance with Accounting Standards. Upon reasonable prior written notice, in any event no less than [***] prior written notice, such records shall be available for examination during regular business hours and in a manner that does not interfere with Tern's business activities for a period of [***] from the end of the Fiscal Year to which they pertain, and not more often than [***] each Fiscal Year, by an independent certified public accountant selected by Genfit and reasonably acceptable to Terns, for the sole purpose of verifying the accuracy of the financial reports furnished by Terns pursuant to this Agreement and any payments with respect thereto. Any such auditor shall not disclose Terns' Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Terns or the amount of payments due under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report, plus interest (as set forth in Section 8.7) from the original due date. [***].

(b) Genfit shall, and shall ensure that its Affiliates and its and their respective employees, agents and contractors, maintain complete and accurate records with respect to Genfit's pharmacovigilance-related obligations set forth in Section 5.8. Upon reasonable prior notice, such records shall be available for examination during regular business hours for a period of [***] from the end of the Fiscal Year to which they pertain, and not more often than [***] each Fiscal Year, by Terns or its designee that is reasonably acceptable to Genfit, for the sole purpose of ensuring compliance with NMPA and other Regulatory Authority regulations. Any such records shall be deemed Confidential Information of Genfit.

8.9 Taxes.

(a) Taxes on Income. Except as set forth in this Section 8.9, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Withholding Taxes. If Terns is required by applicable Laws to make any tax deduction, tax withholding or similar payment (other than value-added tax, any goods and services tax, harmonized sales tax and any similar provincial sales tax) from any amount paid or payable by Terns to Genfit (a "**Tax Withholding**") under this Agreement, then in the case of any payments to be made by Terns to Genfit under this Agreement (including pursuant to Sections 8.1, 8.2, 8.3, and 8.4), Terns will (A) [***] and (B) [***]. [***]. In the event that (x) a Tax Withholding is required, but some or all of the tax required to be withheld and remitted by Terns is not withheld and/or is not remitted by Terns, and (y) instead Genfit pays the relevant amount of any required Tax Withholding to the appropriate Governmental Authority, [***].

(c) Tax Cooperation. Without limiting Section 8.9(b), the Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate Tax Withholding or similar obligations in respect of payments made by Terns to Genfit under this Agreement (including pursuant to Sections 8.1, 8.2, 8.3, and 8.4). To the extent Terns is required to make any Tax Withholdings for any payment to Genfit, Terns shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Genfit an official tax certificate or other evidence of such withholding sufficient to enable Genfit to claim such payment of taxes from any applicable Government Authority. Genfit shall provide Terns any tax forms or other similar documentation that may be reasonably necessary in order for Terns not to make any Tax Withholdings or to make Tax Withholdings at a reduced rate under an applicable bilateral income tax treaty, and shall update such forms and documentation from time to time as necessary to reflect changes in facts. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of Tax Withholdings, VAT or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT. Specifically, in the event that any tax has been withheld upon a payment made under this Agreement or has otherwise been remitted to a Governmental Authority, if requested by Terns and if, and for so long as, the Parties acting in good faith mutually agree that there is a reasonable prospect of successfully obtaining a refund of such tax, then Genfit shall, at Terns' sole cost and expense, seek a refund of such tax from the proper Governmental Authority. In the event that any taxes withheld or reimbursed by Terns under this Section 8.9 are subsequently refunded to Genfit by the appropriate Governmental Authority, Genfit shall pay over the amount of such refund, less any cash Taxes attributable to the receipt thereof and any reasonable expenses incurred by Genfit in obtaining such refund. Genfit agrees to reasonably cooperate with Terns and its Affiliates in the pursuit of such tax refund (including, if required by applicable Laws or by the applicable Governmental Authority, permitting Terns to seek such tax refund in Genfit's name and participating in any application or appeal that requires that Genfit be the party applying for such tax refund, solely with Genfit's prior written consent); provided that, Terns agrees to assume responsibility for direct payment of lawyers' and other advisors' fees and any other costs associated with seeking such refund.

(d) VAT. All payments due to Genfit from Terns pursuant to this Agreement shall be paid exclusive of, and without reduction for, any value-added tax (including, for greater certainty, any goods and services tax, harmonized sales tax and any similar taxes) ("**VAT**") (which, if applicable, shall be payable by Terns). Terns shall be responsible for the payment of all VAT applicable to the payments made by Terns to Genfit under this Agreement and shall file all applicable VAT tax returns. Genfit shall cooperate, to the extent reasonably required, with the filing of any such VAT tax returns. Terns shall indemnify Genfit for any VAT imposed on Genfit

with respect to the payments made to it by Terns under this Agreement and if Genfit directly pays any VAT, Terns shall promptly reimburse Genfit for such VAT including all reasonable related costs. If Genfit determines that it is required to report any such tax, Terns shall promptly provide Genfit with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 8.9(d) is not intended to limit Terns' right to deduct VAT in determining Net Sales.

ARTICLE 9
INTELLECTUAL PROPERTY MATTERS

9.1 Ownership; License Grants.

(a) Data. Genfit shall solely own all Data generated by Genfit. For clarity, all Data Controlled by Genfit are included in the Genfit Licensed Know-How and licensed to Terns under Section 2.1(a). Terns shall solely own all Data generated by Terns in the Development of Licensed Products in the Field in the Terns Territory. Terns hereby grants to Genfit (i) an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive license, with the right to grant sublicenses, to use such Data generated and owned by Terns for all purposes, and (ii) upon expiration or termination of the Agreement (other than termination of the Agreement by Terns pursuant to Sections 13.4 or 13.5), an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive license, with the right to grant sublicenses, to use such Data generated and owned by Terns for the Development, Manufacture and Commercialization of the Licensed Compound or Licensed Products in the Field in the Terns Territory. Notwithstanding the foregoing, no rights shall be granted by either Party to the other Party under this Section 9.1(a) with respect to the Development, Manufacture or Commercialization of any product containing the Licensed Compound together with one or more APIs other than the Licensed Compound.

(b) Product Materials. Subject to the terms and conditions of this Agreement, each Party hereby grants to the other Party a fully-paid up, royalty-free license, with the right to grant sublicenses under multiple tiers, to use Product Materials generated and owned by such Party, solely to the extent reasonably necessary for the Development, Manufacture (with respect to Terns, solely to the extent applicable under Section 7.2) and Commercialization of the Licensed Compound and Licensed Product in the Field in the other Party's respective territory during the Term of this Agreement. Notwithstanding the foregoing, no rights shall be granted by either Party to the other Party under this Section 9.1(b) with respect to the Development, Manufacture or Commercialization of any products containing the Licensed Compound together with one or more APIs other than the Licensed Compound.

(c) Inventions. Inventorship of any Invention will be determined in accordance with the standards of inventorship and conception under U.S. patent laws.

(i) Genfit Inventions. Any Invention generated, developed, conceived or reduced to practice (constructively or actually) solely by or on behalf of Genfit, its Affiliates and their respective licensees (including Genfit Partners), including their employees, agents and contractors ("**Genfit Inventions**") shall be solely and exclusively owned by Genfit. For clarity, any and all Genfit Inventions that are Controlled by Genfit and reasonably necessary for the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Product in the Field in the Terns Territory shall be included in the Genfit Technology licensed to Terns under Section 2.1(a), including any Patent rights therein.

(ii) Terns Inventions. Any Inventions generated, developed, conceived or reduced to practice (constructively or actually) solely by or on behalf of Terns, its Affiliates and their respective Sublicensees, including their employees, agents and contractors ("**Terns Inventions**") shall be solely and exclusively owned by Terns. Terns shall disclose in writing to Genfit all Terns Inventions promptly following the generation, development, conception or reduction to practice thereof. Terns hereby grants Genfit (A) an irrevocable, perpetual, royalty-free, fully paid-up, exclusive license, with the right to grant sublicenses, under the Terns Inventions in the Genfit Territory, and (B) upon expiration or termination of this Agreement (other than termination of this Agreement by Terns pursuant to Sections 13.4 or 13.5) an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive license, with the right to grant sublicenses, under the Terns Inventions in the Terns Territory, in each case of (A) and (B), solely for the Development, Manufacture and Commercialization of the Licensed Compound or Licensed Products in the Field. Notwithstanding the foregoing, no rights shall be granted to Genfit under this Section 9.1(c)(ii) with respect to the Development, Manufacture or Commercialization of any product containing the Licensed Compound together with one or more APIs other than the Licensed Compound, or with respect to any API other than a Licensed Compound.

(iii) Joint Inventions. Any Invention generated, developed, conceived or reduced to practice (constructively or actually) jointly by or on behalf of Terns and Genfit, their Affiliates and respective Sublicensees, including their employees, agents and contractors ("**Joint Inventions**") shall be jointly owned by the Parties, and, subject to the licenses set forth in this Agreement, each Party may freely exploit such Joint Inventions without any duty to account to the other Party. Each Party shall disclose in writing to the other Party all Joint Inventions promptly following the generation, development, conception or reduction to practice thereof. Terns hereby grants Genfit an irrevocable, perpetual, royalty-free, fully paid-up, exclusive license, with the right to grant sublicenses, under its rights in such Joint Inventions (i) in the Genfit Territory, and (ii) upon termination of the Agreement (other than termination of the Agreement by Terns pursuant to Sections 13.2(b), 13.4 or 13.5), in the Terns Territory, in each case of (i) and (ii), solely for the Development, Manufacture and Commercialization of the Licensed Compound or Licensed Product in the Field, but excluding any product containing the Licensed Compound together with one or more APIs other than the Licensed Compound.

(d) Terns' Affiliates, Sublicensees and Subcontractors. Terns shall ensure that each of its Affiliates, Sublicensees and subcontractors under this Agreement has a contractual obligation to disclose to Terns all Data, Product Materials and Inventions generated, invented, discovered, developed, made or otherwise created by them or their employees, agents or independent contractors, and to provide sufficient rights with respect thereto, so that Terns can comply with its obligations under Sections 9.1(a), 9.1(b) and 9.1(c).

9.2 Patent Prosecution.

(a) Definition. For the purpose of this Article 9, "prosecution" of Patents shall include, without limitation, all communication and other interaction with any patent office or patent authority having jurisdiction over a Patent application throughout the world in connection with any pre-grant proceedings and post-grant proceeding, including opposition proceedings.

(b) Genfit Licensed Patents; Joint Patents. Except as set forth in Section 9.2(d), as between the Parties, Genfit shall have the sole right to prepare, file, prosecute and maintain or abandon the Genfit Licensed Patents on a worldwide basis. Genfit will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Genfit Product-Specific Licensed Patents in the Terns Territory; *provided, however*, that Genfit does not represent or warrant that any patent will issue or be granted based on patent applications contained in the Genfit Product-Specific Licensed Patents. Except as set forth in Section 9.2(d), as between the Parties, Genfit shall have the sole right to prepare, file, prosecute and maintain or abandon the Joint Patents on a worldwide basis. Genfit will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Joint Patents in the Terns Territory; *provided, however*, that Genfit does not represent or warrant that any patent will issue or be granted based on patent applications contained in the Joint Patents. Genfit shall provide Terns with a copy of the draft prepared for the filing of a Joint Patent, before the filing of such Joint Patent and will consider in good faith comments thereto provided by Terns in connection with the filing thereof. Genfit shall provide Terns with regular updates on the prosecution of the Genfit Product-Specific Licensed Patents and Joint Patents in the Field in the Terns Territory. For clarity, Terns shall not have any rights pursuant to this Agreement with respect to any Genfit Licensed Patents in the Genfit Territory (including any Step-In Rights relating thereto).

(c) Terns Patents. Except as set forth in Section 9.2(d), as between the Parties, Terns shall have the sole right to prepare, file, prosecute and maintain or abandon the Terns Patents. Terns shall provide Genfit with a copy of the draft prepared for the filing of a Terns Patent, before the filing of such Terns Patent and will consider in good faith comments thereto provided by Genfit in connection with the filing thereof. Terns shall provide Genfit with regular updates on the prosecution of the Terns Patents in the Field in the Terns Territory.

(d) Step-In Rights. Either Party may cease prosecution and/or maintenance of any Patent that such Party is responsible for prosecuting and maintain pursuant to this Section 9.2 on a country-by-country basis by providing the other Party written notice reasonably in advance of such due date. If the responsible Party elects to cease prosecution or maintenance of the relevant Patent in a country, the other Party, shall have the right, but not the obligation, at its sole discretion and cost, to continue prosecution or maintenance of such Patent and in such country ("**Step-In Rights**"), provided that Terns may only exercise its Step-In Rights with respect to Joint Patents and Genfit Product-Specific Licensed Patents in the Terns Territory. If the other Party elects to continue prosecution or maintenance or elects to file additional applications following the responsible Party's election to cease prosecution or maintenance pursuant to this Section 9.2(d), the responsible Party shall transfer the applicable patent files to such other Party or its designee and execute such documents and perform such acts at the responsible Party's expense as may be reasonably necessary to allow the other Party to initiate or continue such filing, prosecution or maintenance at the other Party's sole expense.

(e) Cooperation. Each Party shall provide the other Party with all reasonable assistance and cooperation in the patent prosecution efforts set forth in this Section 9.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.3 Patent Term Extensions in the Terns Territory. The JSC will discuss and recommend for which, if any, of the Patents within the Genfit Licensed Patents, Terns Patents and Joint Patents in the Terns Territory the Parties should seek patent term extensions. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as which Patents such extensions should be sought for, (a) Genfit, in the case of Genfit Licensed Patents and Joint Patents, and (b) Terns, in the case of Terns Patents, shall have the final decision-making authority with respect to applying for any such patent term extension in the Terns Territory, and will act with reasonable promptness in light of the development stage of Licensed Products to apply for any such patent term extension, where it so elects; provided, however, that if only one such Patent can obtain a patent term extension, the Parties will consult in good faith to determine which such Patent should be the subject of efforts to obtain a patent term extension, and *further provided* that, if a Genfit Licensed Patent is the only Patent that is eligible for a patent term extension with respect to a Licensed Product in the Terns Territory, then (i) Terns shall have the right, but not the obligation, to request Genfit to apply for such patent term extension at Terns' sole discretion and cost, and (ii) upon Genfit's receipt of such request, Genfit shall use Commercially Reasonable Efforts to apply for such patent term extension. Each Party will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required regulatory Data and Information and executing any required authorizations to apply for such patent term extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks patent term extensions pursuant to this Section 9.3 shall be borne by such Party.

9.4 Patent Enforcement.

(a) Notification; Information Sharing. If either Party becomes aware of any existing or threatened infringement of any Genfit Licensed Patent, Terns Patent or Joint Patent ("**Infringement**"), it shall promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Infringement. Each Party shall share with the other Party all Information available to it regarding such alleged Infringement, pursuant to a mutually agreeable "common interest agreement" executed by the Parties under which the Parties agree to their shared, mutual interest in the outcome of any suit or other action to enforce the Genfit Licensed Patents, Terns Patent and Joint Patent against such Infringement.

(b) Enforcement Rights.

(i) Genfit Product-Specific Licensed Patents; Joint Patents.

(1) Genfit shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Person engaged in the Infringement of any Genfit Product-Specific Licensed Patent or Joint Patent in the Terns Territory, at Genfit's cost and expense. If Genfit elects to commence a suit or other action to enforce the applicable Genfit Product-Specific Licensed Patent or Joint Patent against such Infringement in the Terns Territory, then Terns shall have the right to join such enforcement action upon written notice to Genfit, and the Parties shall share the cost and expense of such enforcement action equally. If Genfit notifies Terns in writing that it does not intend to commence a suit or other action to enforce the applicable

Genfit Product-Specific Licensed Patent or Joint Patent against such Infringement or to take other action to secure the abatement of such Infringement, or fails to take any such action after a period of [***] following either Party's receipt of the notice of Infringement pursuant to Section 9.4(a), then, to the extent that such Infringement is resulting from a Third Party's use or sale of a product that competes with a Licensed Product in the Field in the Terns Territory, Terns shall have the right, but not the obligation, to commence such a suit or take such action, at Terns' cost and expense; provided that, in the event the Person engaged in the Infringement of any Genfit Product-Specific Licensed Patent or Joint Patent in the Terns Territory is also engaged in such Infringement in the Genfit Territory, and Genfit has commenced a suit to secure the abatement of such Infringement in the Genfit Territory, then Genfit shall promptly notify Terns thereof and Terns shall not have the right to commence such suit or action without the prior written consent of Genfit, not to be unreasonably withheld. In such case, Genfit shall take appropriate actions in order to enable Terns to commence a suit or take the actions set forth in the preceding sentence.

(2) Neither Party shall settle any such suit or action under 9.4(b)(i)(1) in any manner that would negatively impact the Genfit Product-Specific Licensed Patents or Joint Patents or that would limit or restrict the ability of Terns to sell the Licensed Products in the Terns Territory, without the prior written consent of the other Party. For clarity, Terns shall not have the right to commence any such suit or action against any existing or threatened infringement of the Genfit Product-Specific Licensed Patents or Joint Patents outside the Terns Territory.

(ii) **Terns Patents**. Terns shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Person engaged in the Infringement of any Terns Patent, at Terns' cost and expense. If Terns elects to commence a suit to enforce the applicable Terns Patent against such Infringement, where such Infringement relates to the Commercialization in the Terns Territory of unauthorized products containing the Licensed Compound, then Genfit shall have the right to join such enforcement action upon notice to Terns, and in this case the Parties shall share the cost and expense of such enforcement action equally. If Terns notifies Genfit that it does not intend to commence a suit to enforce the applicable Terns Patent against such Infringement or to take other action to secure the abatement of such Infringement, or fails to take any such action after a period of [***] days, then Genfit shall have the right, but not the obligation, to commence such a suit or take such action, at Genfit's cost and expense. In such case, Terns shall take appropriate actions in order to enable Genfit to commence a suit or take the actions set forth in the preceding sentence.

(c) **Collaboration**. Each Party shall provide to the Party bringing a claim, suit or action under Section 9.4(b) (the "**Enforcing Party**") with reasonable assistance in such enforcement, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The Enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Enforcing Party.

(d) Expenses and Recoveries. The Enforcing Party shall be solely responsible for any expenses it incurs as a result of such enforcement action, except that the Parties shall share equally the cost and expense of the enforcement action when Genfit is the Enforcing Party and Terns elects to join the enforcement action. If the Enforcing Party recovers monetary damages in such claim, suit or action brought under Section 9.4(b), such recovery shall be allocated first to the reimbursement of any documented expenses incurred by the Parties in such enforcement action, and any remaining amounts shall be shared by the Parties as follows:

(i) if (A) Genfit is the Enforcing Party under Section 9.4(b)(i)(1) and Terns elects to join the enforcement action and share the cost and expenses related thereto, or (B) Terns is the Enforcing Party under Section 9.4(b)(ii) and Genfit elects to join the enforcement action and share the cost and expenses related thereto: [***] of the remaining amounts shall be retained by Genfit, and [***] of the remaining amounts shall be paid to Terns;

(ii) if Genfit is the Enforcing Party (A) under Section 9.4(b)(i)(1) and Terns does not elect to join the enforcement action and share the cost and expenses related thereto, or (B) under Section 9.4(b)(ii): [***] of the remaining amounts shall be retained by Genfit, and [***] of the remaining amounts shall be paid to Terns;

(iii) if Terns is the Enforcing Party (A) under Section 9.4(b)(ii) and Genfit does not elect to join the enforcement action and share the cost and expenses related thereto, or (B) under Section 9.4(b)(i)(1): [***] of the remaining amounts shall be retained by Terns, and [***] of the remaining amounts shall be paid to Genfit.

(e) Sections 9.4(c) and 9.4(d) shall survive the termination of this Agreement solely with respect to any pending enforcement action initiated during the Term under this Section 9.4.

9.5 Third Party Infringement Claims. If the Manufacture, use or sale of the Licensed Products in the Field in the Terns Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent infringement against Genfit or Terns (or their respective Affiliates, licensees or Sublicensees) (collectively, "**Infringement Actions**"), such Party shall promptly notify the other Party hereto in writing. Subject to Article 11, the Party for which the Infringement Action is brought against (the "**Accused Party**") shall have the right to direct and control the defense of such Infringement Action, at its own expense with counsel of its choice; *provided, however,* that the other Party may participate in the defense and/or settlement thereof, at its own expense with counsel of its choice. In any event, the Accused Party agrees to keep the other Party reasonably informed of all material developments in connection with any such Infringement Action for which the Accused Party exercises its right to direct and control the defense. The Accused Party agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would adversely affect the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. Subject to Article 11, if the Accused Party does not exercise its right to direct and control the defense of an Infringement Action that is brought against the other Party, then the other Party shall have such right and it shall agree to keep the Accused Party reasonably informed of all material developments in connection with such Infringement Action and it shall not settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would materially adversely affect the rights or interests of the Accused Party, without the prior written consent of the Accused Party, which shall not be unreasonably withheld or delayed.

9.6 Trademarks.

(a) Subject to Section 9.4(c) below, Terns shall Commercialize the Licensed Products in the Field in the Terns Territory under any trademark owned or Controlled by Terns (the "**Terns Product Mark**"); provided that, prior to finalizing any Terns Product Mark, Terns shall provide Genfit with such proposed trademark and related trade dress and shall reasonably consider in good faith Genfit's comments with respect thereto. Terns shall, and shall cause its Affiliates and Sublicensees to, use the Terns Product Mark solely in connection with the Development, Manufacturing, and Commercialization of the Licensed Products in the Field in the Terns Territory. Terns shall own all rights in the Terns Product Mark, and all goodwill in the Terns Product Mark shall accrue to Terns. Terns shall register and maintain, at Terns' cost and expense, the Terns Product Marks in the Terns Territory.

(b) Subject to Section 9.4(c) below, Terns shall have the right to brand the Licensed Products in the Field in the Terns Territory with those trademarks of Terns that are associated with Terns' name or identity ("**Terns Housemarks**"). Terns shall own all rights in the Terns Housemarks, and all goodwill in the Terns Housemarks shall accrue to Terns.

(c) In connection with Terns' use of any Terns Product Mark or Terns Housemark, subject to Section 9.6(d), Terns shall not, and shall cause its Affiliates and their respective Sublicensees to not: (i) make any use of trademarks that are confusingly similar to any trademarks or housemarks of Genfit or its Affiliates (including the corporate name of Genfit or any of its Affiliates), without the prior written consent of Genfit; or (ii) use any trademarks, other than the Terns Product Marks and the Terns Housemarks, in connection with the Commercialization of Licensed Products in the Field in the Terns Territory, without the prior written consent of Genfit.

(d) Notwithstanding anything to the contrary, to the extent required by applicable Laws, (i) Terns may include Genfit's name and corporate logo on the Licensed Product label, packaging, promotional/marketing materials to indicate that the Licensed Product is in-licensed from Genfit, and shall display Genfit's name and corporate logo with equal prominence and comparable size, resolution, print quality, and location, as instructed by Genfit from time to time, as Terns' name and corporate logo is displayed, and (ii) Genfit hereby grants to Terns a non-exclusive, fully paid-up, royalty free, sublicensable license to use Genfit's name and corporate logo for the Commercialization of the Licensed Product in the Terns Territory, to the extent consistent with the foregoing.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES; COVENANTS

10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party, as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated;

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar Laws affecting creditors' rights and remedies generally;

(c) No Conflict. The execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the Development Plan and the license to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Law existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation or by-laws (or other constating documents) of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a material default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date;

(d) No Violation. Neither such Party nor any of its Affiliates is under any obligation to any Person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of such Party's obligations hereunder;

(e) No Debarment. Neither such Party nor any of its Affiliates is debarred or disqualified under the Act or comparable applicable Laws outside the U.S.; and

(f) No Consents. No authorization, consent, approval of a Third Party, nor to such Party's knowledge, any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution and delivery of this Agreement by such Party; or (ii) the consummation by such Party of the transactions contemplated hereby.

10.2 Additional Representations and Warranties of Genfit. Genfit represents and warrants to Terns, as of the Effective Date, as follows:

(a) Title; Encumbrances. (i) It solely owns the Genfit Licensed Patents and otherwise has sufficient legal and/or beneficial title or ownership or license with respect to the Genfit Technology, as necessary to grant the licenses to Terns as purported to be granted pursuant to this Agreement, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreement, encumbrances, charges or claim of any kind, and (ii) to Genfit's knowledge, no Third Party has taken any action before the United States Patent and Trademark Office, or any counterpart thereof outside the U.S., claiming legal and/or beneficial title or ownership or license of any Genfit Technology;

(b) Notice of Infringement or Misappropriation. It has not received any written notice from any Third Party asserting or alleging that (i) any research, development, manufacture, or commercialization of a Licensed Product by Genfit prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party, or (ii) the Development, Manufacture, or Commercialization of the Licensed Products in the Terns Territory would infringe or misappropriate the intellectual property rights of such Third Party;

(c) Non-Infringement of Rights by Third Parties. To Genfit's knowledge, no Third Party is infringing or has infringed the Genfit Product-Specific Licensed Patents as of the Effective Date;

(d) Non-Assertion by Third Parties. To Genfit's knowledge, no Third Party has asserted in writing that the issued patents within the Genfit Licensed Patents set forth in **Exhibit A** are invalid or unenforceable;

(e) No Proceeding. [***], there is no pending, and to Genfit's knowledge, no threatened, adverse action, suit or proceeding against Genfit involving any Genfit Technology or the safety (including any product liability claim) of a Licensed Product;

(f) Prosecution of Genfit Licensed Patents. Except with respect to any Genfit Product-Specific Licensed Patents for which Genfit has ceased prosecution and/or maintenance and granted Terns Step-In Rights therewith pursuant to Section 9.2(d), all maintenance fees, annuity payments, and similar payments relating to the Genfit Product-Specific Licensed Patents in the Terns Territory have been made, and during the Term will be made, in a timely manner. To Genfit's knowledge, prior to the Effective Date, Genfit has not taken action or failed to undertake an action, in connection with filing, prosecuting and maintaining the Genfit Product-Specific Licensed Patents set forth in **Exhibit A** in the Terns Territory in violation of any applicable Law;

(g) Compliance with Laws. To Genfit's knowledge, Genfit has complied with all applicable Laws in connection with the prosecution of the Genfit Product-Specific Licensed Patents, including the duty of candor owed to any patent office pursuant to such Laws;

(h) Genfit Licensed Patents. Genfit does not have knowledge of any Information which leads it to believe that any issued patents included in the Genfit Licensed Patents set forth in **Exhibit A** are invalid or unenforceable;

(i) No Conflicts. Genfit has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to Terns under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to Terns under this Agreement, or that would otherwise materially conflict with or adversely affect Terns' rights under this Agreement.

10.3 Additional Representations and Warranties of Terns. Terns represents and warrants to Genfit that, to Terns' knowledge as of the Effective Date Terns does not Control any Patent that is necessary to make, use, import, offer for sale or sell Licensed Products in the Field.

10.4 Compliance with Laws.

(a) Each Party shall, and shall ensure that its Affiliates and their respective Sublicensees will, comply in all respects with Proper Conduct Practices, and all applicable Laws in the Development, Manufacturing, and Commercialization of Licensed Products and performance of its obligations under this Agreement, including the ICH, GCP, GLP and any Regulatory Authority and Governmental Authority health care programs having jurisdiction in such Party's respective territory, each as may be amended from time to time.

(b) Each Party shall immediately notify the other Party if it has any information or suspicion that there may be a violation of any applicable Laws (including Anti-Corruption Laws) in connection with its performance under this Agreement or the Development or Commercialization of any Licensed Product hereunder. In the event that either Party has violated or been suspected of violating any of its obligations, representations, warranties or covenants in Section 10.4(a), such Party will take reasonable actions to remedy such breach and to prevent further such breaches from occurring.

(c) Notwithstanding the foregoing, each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to audit the other Party's books and records in the event that a suspected violation of any Anti-Corruption Law needs to be investigated (in such Party's reasonable, good-faith discretion). Such audit shall be conducted by such Party's audit team comprised of qualified auditors who have received anticorruption training. For clarity, a credible finding, after a reasonable investigation, of any breach of Section 10.4(a) or 10.4(b) with respect to any Anti-Corruption Law, shall be deemed a material breach of this Agreement and allow the non-breaching Party to terminate this Agreement in accordance with Section 13.4.

10.5 Additional Covenants. In addition to any covenants made by Terns elsewhere in this Agreement:

(a) Terns hereby covenants to Genfit that neither Terns nor any of its Affiliates or Sublicensees, will employ or use the services of any Person who is debarred or disqualified under the Act, or comparable applicable Laws outside the U.S., in connection with activities relating to any Licensed Product; and in the event that Terns becomes aware of the debarment or disqualification or threatened debarment or disqualification of any Person providing services to Terns or any of its Affiliates with respect to any activities relating to any Licensed Product, Terns will immediately notify Genfit in writing and Terns will cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to any Licensed Product;

(b) Each Party hereby covenants to the other Party that neither such Party nor any of its Affiliates, nor any of their respective employees shall use any confidential information obtained from any Third Party (including any prior employer) to which such Party or any of its Affiliates, or any of their respective employees has a duty to keep in confidence such information, directly or indirectly, whether obtained prior to the Effective Date or during the Term, in connection with activities performed under this Agreement, unless consented to in writing by such Third party, and such Party shall be solely responsible and liable for, and shall indemnify the other Party pursuant to Article 11 in connection with, any breach of this covenant by such Party, any of its Affiliates, or their respective employees.

10.6 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY OR ITS AFFILIATES, AND ALL

REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. FOR CLARITY AND WITHOUT LIMITING THE FOREGOING, GENFIT MAKES NO REPRESENTATION OR WARRANTY CONCERNING THE LICENSED PRODUCTS OR GENFIT TECHNOLOGY EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 10.

ARTICLE 11
INDEMNIFICATION

11.1 Indemnification by Genfit. Genfit shall defend, indemnify, and hold Terns and its Affiliates and their respective officers, directors, employees, and agents (the "**Terns Indemnitees**") harmless from and against any and all losses, damages, liabilities, actually incurred expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**") to which any Terns Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (collectively, "**Claims**") arising out of, based on, or resulting from (a) the Development, Manufacture, or Commercialization of Licensed Products in the Terns Territory by or on behalf of Genfit or its Affiliates prior to the Effective Date, (b) the Development, Manufacture, or Commercialization of Licensed Products in the Genfit Territory, (c) the breach of any of Genfit's obligations under this Agreement, including Genfit's representations, warranties or covenants set forth herein, (d) the conduct of any pharmacovigilance-related activities set forth in Section 5.8 by or on behalf of Genfit (except to the extent that such Claim arises from Terns' provision of false, misleading, inaccurate or incomplete information to Genfit under Section 5.8 or Terns' breach of its obligations under the Pharmacovigilance Agreement) or (e) the willful misconduct or negligent acts of any Genfit Indemnitee. The foregoing indemnity obligation shall not apply to the extent that (i) the Terns Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Genfit's defense of the relevant Claim is materially prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which Terns is obligated to indemnify the Genfit Indemnitees under Section 11.2.

11.2 Indemnification by Terns. Terns shall defend, indemnify, and hold Genfit and its Affiliates and their respective officers, directors, employees, and agents (the "**Genfit Indemnitees**") harmless from and against any and all Losses to which any Genfit Indemnitee may become subject as a result of any Claims arising out of, based on, or resulting from (a) the Development, Manufacture, or Commercialization of Licensed Products by or on behalf of Terns or its Affiliates or Sublicensees on or after the Effective Date (except to the extent that any such activities are conducted by or on behalf of Genfit or its Affiliates) (including any Infringement Actions), (b) the breach of any of Terns' obligations under this Agreement, including Terns' representations, warranties, or covenants set forth herein and its covenants set forth in Section 10.5, or (c) the willful misconduct or negligent acts of any Terns Indemnitee. The foregoing indemnity obligation shall not apply to the extent that (i) the Genfit Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Terns' defense of the relevant Claim is materially prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which Genfit is obligated to indemnify the Terns Indemnitees under Section 11.1

11.3 Indemnification Procedures. The Party claiming indemnity under this Article 11 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim and shall offer control of the defense of such Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however,* the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 11. Notwithstanding anything contained in this Section 11.3, the provisions of Section 9.5 shall govern the defense of any Infringement Actions. Additionally, in the event that Genfit has elected to defend any such Infringement Action, then Terns shall not be obligated to indemnify Genfit for any Claims related to such Infringement Action; rather, the Parties shall share equal responsibility for any Losses resulting therefrom.

11.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 or 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS EXCLUSIVITY OBLIGATIONS IN SECTION 2.5 OR ITS CONFIDENTIALITY OBLIGATIONS IN ARTICLE 12.

11.5 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material change in such insurance.

ARTICLE 12
CONFIDENTIALITY

12.1 Confidentiality. Each Party agrees that, during the Term and for a period of [***] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliate in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate without any confidentiality obligations by a Third Party who, to the Party's knowledge, had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without use of or reference to the other Party's Confidential Information, as evidenced by a contemporaneous writing.

12.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 12.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated herein; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of Licensed Product; or (iii) for the prosecuting or defending litigation as contemplated herein;

(b) such disclosure is reasonably necessary to its or its Affiliate's employees, agents, consultants, contractors, licensees or Sublicensees, (including Genfit Partners) on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights hereunder; provided that in each case, the disclosees are bound by written obligations of confidentiality consistent with those contained in this Agreement; or

(c) such disclosure is reasonably necessary to comply with applicable Laws, including regulations or rules promulgated by applicable securities commissions (or other securities regulatory authorities), security exchanges, court order, administrative subpoena or order; and

(d) solely with respect to the terms of this Agreement and excluding disclosure of any other Confidential Information, such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating or carrying out an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and require each disclosee to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.2(a), 12.2(c) or 12.2(d), such Party shall promptly notify the other Party of such required disclosure, to the extent that it is legally authorized or permitted to so, and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

12.3 Publicity; Terms of Agreement.

(a) The Parties agree that the terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 12.3.

(b) If either Party desires to make a public disclosure concerning the terms of this Agreement, such Party shall give the proposed text of such disclosure to the other Party reasonably in advance (but in any case no less than [***] prior to the disclosure) for its prior review and approval (except as otherwise provided herein), which approval shall not be unreasonably withheld or delayed. A Party commenting on such a proposed disclosure shall provide its comments, if any, within [***] after receiving the proposed disclosure for review (or such shorter period of time as necessitated by regulatory requirements). In addition, where required by applicable Law, including regulations promulgated by applicable security exchanges, either Party shall have the right to make a press release or other public disclosure regarding the achievement of each milestone under this Agreement as it is achieved, the achievements of Regulatory Approval in the Terns Territory as they occur, or the occurrence of other events that affect either Party's rights or obligations under this Agreement, including the results of any Clinical Trial of Licensed Products, whether in the Terns Territory or the Genfit Territory; provided that such Party shall provide the proposed text of such disclosure to the other Party at least [***] in advance, and the other Party shall provide its comments thereto within such [***]. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.3.

(c) The Parties acknowledge that either or both Parties or their Affiliates may be obligated to file under applicable Laws a copy of this Agreement with Governmental Authorities, including, without limitation, the U.S. Securities and Exchange Commission (the "**SEC**"). Each Party and its Affiliates shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party or its Affiliate intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's timely comments thereon to the extent consistent with the legal requirements, with respect to the filing Party or Affiliate, governing disclosure of material agreements and material information that must be publicly filed.

12.4 Technical Publication. Neither Party may publish peer reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise pertaining to the Development of the Licensed Compound or Licensed Products in the Field in the Terns Territory, without the opportunity for prior review and comment by the other Party in accordance with this Section 12.4, except to the extent required by applicable laws. A Party seeking publication shall provide the other Party the opportunity to review and comment on any such proposed publication at least [***] for abstracts [***] for manuscripts prior to its intended submission for publication. The other Party shall provide the Party seeking publication with its comments in writing, if any, within [***] for abstracts and [***] for manuscripts after receipt of such proposed publication. The Party seeking publication shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party's request to remove any and all of such other Party's Confidential Information from the proposed publication. Further, if Genfit reasonably determines and notifies Terns that a proposed publication is reasonably likely to result in Adverse Risk in the Genfit Territory, Terns shall not submit such publication unless and until the Parties agree to a proposal to mitigate such Adverse Risk. In addition, the Party seeking publication shall delay the submission for a period up to [***] in the event that the other Party can demonstrate reasonable need for such delay for the preparation and filing of a patent application. If the other Party fails to provide its comments to the Party seeking publication within the specified time frame, such other Party shall be deemed to not have any comments, and the Party seeking publication shall be free to publish in accordance with this Section 12.4. The Party seeking publication shall provide the other Party a copy of the manuscript at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications in accordance with scientific practices.

12.5 Equitable Relief. Each Party acknowledges that its breach of this Article 12 will cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 12 by the other Party.

ARTICLE 13
TERM AND TERMINATION

13.1 Term. The term of this Agreement (the "**Term**") shall commence upon the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the expiration of the Royalty Term on a Region-by-Region basis. Upon the expiration (but not early termination) of this Agreement, on a Region-by-Region basis, the licenses granted hereunder by Genfit to Terns shall become fully paid-up, royalty free, irrevocable and perpetual; provided that such licenses shall thereafter be granted on a non-exclusive basis.

13.2 Termination by Terns.

(a) Terns may terminate this Agreement in its entirety for convenience upon (i) [***] prior written notice to Genfit (if such notice is provided before [***]) or (ii) [***] prior written notice to Genfit (if such notice is provided following [***]); *provided, however,* that in each case under (i) and (ii) Genfit may, in its discretion, upon prior written notice to Terns accelerate the effectiveness of such termination to the extent permitted by Law in the Terns Territory.

(b) Terns may terminate this Agreement on a Region-by-Region and/or Licensed Product-by-Licensed Product basis, upon [***] prior written notice to Genfit if a Regulatory Authority in a Region has ordered Terns to stop all sales of a Licensed Product in such Region due to a safety concern; *provided, however,* that Terns has, for a period of [***] prior to the provision of such notice by Terns, used Commercially Reasonable Efforts to resolve such safety concern.

13.3 Termination by Genfit.

(a) Genfit may terminate this Agreement upon written notice to Terns, if Terns ceases all Development (including all regulatory activities) and all Commercialization of Licensed Products (including through Sublicensees and contractors) in the Terns Territory for a period of [***], unless Development or Commercialization of Licensed Products was prevented throughout such period by a force majeure for which Terns provided notice pursuant to Section 15.2 prior to or at the start of such period and that persisted throughout such period despite Terns' Commercially Reasonable Efforts to remove or mitigate it. Such termination shall go into effect on the date specified in the applicable termination notice. For clarity, a delay by Regulatory Authorities and/or a decision by Regulatory Authorities to suspend a Clinical Trial (e.g., a "regulatory hold") shall not give Genfit the right to terminate this Agreement under this Section 13.3(a), so long as Terns continues to use Commercially Reasonable Efforts to remove such regulatory hold.

(b) Genfit may terminate this Agreement in its entirety upon [***] prior written notice to Terns, if Terns or its Affiliates or their respective Sublicensees (directly or indirectly, individually or in association with any other Person) challenges the validity, enforceability or scope of any Genfit Licensed Patent, unless during such [***] period the subject challenge is permanently dismissed or withdrawn and is not thereafter reinstituted or continued; provided that in the event a Sublicensee of Terns initiates such challenge, Genfit may not terminate this Agreement if (i) Terns successfully causes such Sublicensee to abort such challenge within such [***] period, or (ii) Terns (A) provides Genfit a written notice of its intent to terminate its sublicense with such Sublicensee within such [***] period, and (B) successfully terminates such sublicense within such [***] period.

13.4 Termination for Breach. Each Party shall have the right to terminate this Agreement in its entirety [***] upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [***] (or [***] in case of failure to make a payment due under this Agreement) [***] from the date of such notice; provided that, if either Party disputes (a) whether such material breach has occurred, or (b) whether the defaulting Party has cured such material breach, the Parties agree to resolve the dispute as expeditiously as possible under Article 14. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Notwithstanding the foregoing, to the extent the breach is limited to Terns' failure to use Commercially Reasonable Efforts to Develop Licensed Products in a specific Region in accordance with Section 4.1, then Genfit's termination right under this Section 13.4 shall be limited to such Region.

13.5 Termination Due to Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within [***] after the filing thereof, or if the other Party proposes or becomes a Party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors.

13.6 Effect of Termination. Upon any termination of this Agreement, the following shall apply (in addition to any other rights and obligations under this Agreement with respect to such termination), provided that, in the event such termination is limited to a specific Region or Licensed Product, then the following shall only apply to such Region or Licensed Product:

(a) Licenses. All licenses and other rights granted by Genfit to Terns under this Agreement shall terminate. Genfit shall have a reversion of all rights previously licensed to Terns hereunder for which the relevant licenses have terminated on a fully paid-up and royalty-free basis, itself or with or through an Affiliate or Third Party, to Develop and Commercialize the Licensed Products in the Field in the Terns Territory at Genfit's discretion.

(b) Wind-Down. Terns will (i) responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going Clinical Trials for which it has responsibility hereunder in which patient dosing has commenced or, (ii) unless if this Agreement is terminated by Terns pursuant to Sections 13.2(b), 13.4 or 13.5, at Genfit's reasonable request, (A) transfer to Genfit of its designee such Clinical Trial to the extent permitted under applicable Laws and accepted pharmaceutical industry norms and ethical practices, or (B) if reasonably practicable and not adverse to patient safety, complete such Clinical Trials and Genfit shall reimburse Terns its reasonable, out-of-pocket costs associated therewith. For clarity, except as provided for above, Terns may transfer to Genfit or its designee or wind-down any ongoing Clinical Trials prior to the date of termination in accordance with accepted pharmaceutical industry norms and ethical practices and Terns will be responsible for any costs associated with such transfer or wind-down. Notwithstanding the foregoing, if this Agreement is terminated by Terns pursuant to Sections 13.4 or 13.5, then Genfit will be responsible for any costs associated with such wind-down.

(c) Regulatory Materials; Data. Except if this Agreement is terminated by Terns pursuant to Sections 13.2(b), 13.4 or 13.5, Terns shall (i) provide and assign to Genfit or its designee all Regulatory Materials, including Regulatory Approvals, for the Licensed Products to the extent possible under applicable Law in the Terns Territory, (ii) promptly provide to Genfit all Data (to the extent not already provided to Genfit), including pharmacovigilance data, generated by or on behalf of Terns, and (iii) promptly return or destroy, at Genfit's election, all Confidential Information of Genfit.

(d) Trademarks. Except if this Agreement is terminated by Terns pursuant to Sections 13.2(b), 13.4 or 13.5, upon Genfit's written request, Terns shall grant to Genfit, effective as of the date of such request, an exclusive, transferable, fully paid-up, royalty free, sublicensable license to use Terns Product Marks in connection with the Commercialization of Licensed Products in the Terns Territory (and excluding, for clarity, any Terns Housemarks).

(e) Transition Assistance. Upon Genfit's reasonable request, (i) Terns shall provide such assistance as may be reasonably necessary or useful for Genfit to continue the Development and Commercialization of Licensed Products in the Terns Territory, to the extent Terns or its Affiliate is then performing or having performed such activities, including upon the reasonable request of Genfit, assigning (to the extent Terns has rights to assign) or using Commercially Reasonable Efforts to amend as appropriate any agreements or arrangements Terns or its Affiliate have with any Third Party for the Development, distribution, sale or otherwise Commercialization of Licensed Products; and (ii) Terns shall provide Genfit with copies of any promotional and marketing materials generated by or on behalf of Terns with respect to Licensed Products prior to the effective date of termination. If this Agreement is terminated by Terns pursuant to Sections 13.2(b), 13.4 or 13.5, [***] shall bear [***] costs arising out of any of the transition assistance activities set forth in clause (i) or (ii) performed by Terns. If this Agreement is terminated by Terns pursuant to Section 13.2(a) or by Genfit pursuant to Sections 13.3, 13.4, 13.5 or 15.5, [***] shall bear [***] costs arising out of any of the transition assistance activities set forth in clause (i) or (ii) performed by Terns.

(f) Inventory. In the event that this Agreement is terminated in its entirety, Genfit shall have the right, but not the obligation, to purchase any and all of the inventory of Licensed Products held by Terns or its Affiliates as of the date of termination, at a price equal to the transfer price paid by Terns to Genfit for such inventory. Notwithstanding the foregoing, if this Agreement is terminated by Terns pursuant to Sections 13.4 or 13.5, upon Terns' request, at its sole discretion, Genfit shall re-purchase any and/or all of its inventory of the Licensed Products, at a price equal to the transfer price paid by Terns to Genfit (if supplied by Genfit) or Terns' manufacturing cost (if manufactured by Terns or its subcontractor) therefor. Terns shall also have the right to continue to be permitted to sell such inventory for up to at least [***] after the effective date of termination of this Agreement.

13.7 Survival. Any expiration or termination of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of expiration or termination. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Articles 1 (Definitions, as applicable), 11 (Indemnification), 12 (Confidentiality), 14 (Dispute Resolution), and 15 (Miscellaneous), and Sections 2.4 (No Implied Licenses), 8.5 (Payment Method; Foreign Exchange), 8.6 (Interest on Late Payments), 8.7 (Records; Audits), 8.8 (Taxes), 9.1 (Ownership; License Grants), 10.6 (No Other Representations or Warranties), 13.6 (Effects of Termination), 13.7 (Survival) and 13.8 (Termination Not Sole Remedy).

13.8 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

ARTICLE 14
DISPUTE RESOLUTION

14.1 Disputes; Internal Resolution. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree that, except as otherwise provided in Section 3.2(d), if a dispute arises under or relates to this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, and the Parties are unable to resolve such dispute within [***] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to a senior executive of each of Genfit (or one of its Affiliates) and Terns (the "**Executive Officers**") for attempted resolution by good faith negotiations within [***] after notice referring to the dispute is received. If the dispute is not resolved within such [***], then the dispute shall be resolved by arbitration in accordance with Section 14.2 and thereafter neither Party shall have any further obligation under this Section 14.1. Notwithstanding the foregoing, and without waiting for the expiration of any such [***] periods, each Party shall each have the right to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of such Party.

14.2 Arbitration. All disputes arising out of or in connection with this Agreement, including any questions regarding its formation, existence, validity or termination, or the scope or applicability of this agreement to arbitrate, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") by a tribunal comprised of three arbitrators. Each Party shall nominate one arbitrator and the two Party-nominated arbitrators shall nominate the third arbitrator, who shall serve as the presiding arbitrator, within [***] after the second arbitrator's appointment.

(a) The seat, or legal place, of arbitration shall be [***]. The language of the arbitration shall be English. The arbitral award shall be final and binding on the Parties, and the Parties undertake to carry out any award without delay. Judgment on the award may be entered in any court of competent jurisdiction.

(b) Each Party retains the right to apply to any court of competent jurisdiction for interim and/or conservatory measures, including pre-arbitral attachments or preliminary injunctions, and any such request shall not be deemed incompatible with, or a waiver of, this agreement to arbitrate.

(c) The existence and content of the arbitral proceedings and any rulings or awards shall be kept confidential by the Parties and members of the arbitral tribunal except (i) to the extent that disclosure may be required of a Party to fulfill a legal duty, protect or pursue a legal right, or enforce or challenge an award in bona fide legal proceedings before a state court or other

judicial authority, (ii) with the consent of all Parties, (iii) where needed for the preparation or presentation of a claim or defense in this arbitration, (iv) where such information is already in the public domain other than as a result of a breach of this clause, or (v) by order of the arbitral tribunal upon application of a Party.

14.3 Governing Law. This Agreement shall be governed by and construed under, and all disputes arising under or in connection with this Agreement shall be resolved in accordance with, the laws of the State of New York, USA, without giving effect to any choice of law rules or principles. The United Nations Convention on International Contracts on the Sale of Goods does not apply to this Agreement and is expressly and entirely excluded.

ARTICLE 15
MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued only for so long as (a) the condition constituting force majeure continues and (b) the nonperforming Party takes all reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the applicable Party, which may include an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, action or inaction of any Governmental Authority, and failure of plant or machinery. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [***], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

15.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Genfit:

Genfit SA
Parc Eurasanté
885 avenue Eugène Avinée
59120 LOOS
FRANCE
Attn: [***]

with copies to (which shall not constitute notice):

If to Genfit:

Cooley LLP
500 Boylston Street
Boston, MA 02116-3737
USA
Attn: [***]

If to Terns:

Terns Pharmaceuticals, Inc.
P. O. Box 613
Harbor Center
George Town, Grand Cayman KY1-1107
Cayman Islands
Attn: [***]

with copies to (which shall not constitute notice):

Fenwick & West LLP
801 California Street
Mountain View, CA 94041
USA
Attn: [***]

15.4 No Strict Construction; Headings. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this

Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

15.5 Assignment; Change of Control.

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that either Party may make such an assignment without the other Party's consent to an Affiliate of such Party.

(b) Notwithstanding Section 15.5(a), either Party may without such consent but with prior written notice to the other Party, assign this Agreement and its rights and obligations hereunder in connection with a Change of Control, provided that, however, if such assignee has an active program for developing, manufacturing or commercializing a Competing Product (a "**Competing Program**"), then, within [***] after the closing of such Change of Control transaction, such assignee shall either: (i) Divest the Competing Program (including all rights to the Competing Product) to a Third Party, or (ii) discontinue the Competing Program. In case of a Change of Control of Terns, if such assignee fails to either Divest or discontinue the Competing Program within such [***] period, Genfit shall have the right to terminate this Agreement without any obligation to Terns, by providing written notice thereof within [***] after the receipt of such notice from the Terns.

(c) Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Sections 15.5(a) and 15.5(b) shall be null, void and of no legal effect.

15.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitral tribunal constituted in accordance with Section 14.2, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.9 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.10 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.11 English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

15.12 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.13 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

{Signature Page Follows}

GENFIT SA

By: /s/ JEAN-FRANÇOIS MOUNEY
Name: Jean-François Mouney
Title: Chairman and CEO

TERNS PHARMACEUTICALS, INC.

By: /s/ WEIDONG ZHONG
Name: Weidong Zhong
Title: CEO

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) 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

   (c) 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: May 27, 2020

/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, Nathalie Huitorel, 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) 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

   (c) 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: May 27, 2020

/s/ Nathalie Huitorel

Name: Nathalie Huitorel
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, 2019 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: May 27, 2020

/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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nathalie Huitorel, 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: May 27, 2020

/s/ Nathalie Huitorel

Name: Nathalie Huitorel
Title: Chief Financial Officer
(*Principal Financial Officer*)