

PROSPECTUS

**6,650,000 Ordinary Shares**  
**(Including Ordinary Shares in the Form of American Depositary Shares)**



**€18.00 per Ordinary Share**

**\$20.32 per American Depositary Share**

We are offering an aggregate of 6,650,000 ordinary shares in a global offering.

We are offering 6,150,000 ordinary shares in the form of American Depositary Shares, or ADSs, in the United States and Europe, referred to herein as the ADS offering. Each ADS represents the right to receive one ordinary share and the ADSs may be evidenced by American Depositary Receipts, or ADRs.

We are concurrently offering 500,000 ordinary shares in Europe (including France) and countries outside of the United States in a private placement, referred to herein as the European private placement.

This is our initial public offering of our ADSs in the United States. Our ADSs have been approved for listing on the Nasdaq Global Select Market under the symbol "GNFT." Our ordinary shares are listed on Euronext Paris under the symbol "GNFT." The offering price is \$20.32 per ADS, corresponding to an offering price of €18.00 per ordinary share in the European private placement. On March 26, 2019, the last reported sale price of our ordinary shares on Euronext Paris was €21.90 per ordinary share, equivalent to a price of \$24.73 per ADS, based on an exchange rate of €1.00 = \$1.1291.

The closings of the ADS offering and the European private placement, which are together referred to as the global offering, will occur simultaneously. The total number of ordinary shares (including in the form of ADSs) in the ADS offering and the European private placement is subject to reallocation between these offerings as permitted under applicable laws and regulations.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

**Investing in the ordinary shares and ADSs involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus.**

Under the authority granted by our shareholders to conduct the global offering, the ordinary shares and ADSs that we are offering may only be purchased initially by industrial or commercial companies in the pharmaceutical/biotech sector or investment fund companies or fund management companies or collective savings managing funds governed by French or foreign law or any other legal entity (including a trust) or natural person, investing in the pharmaceutical/biotech sector, that is qualified to invest in a private placement. In order to purchase ordinary shares and/or ADSs in the global offering, you will be required to execute and provide to the underwriters an investor letter representing that you satisfy the foregoing investor criteria.

Neither the Securities and Exchange Commission nor any U.S. state or other securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	PER ORDINARY SHARE	PER ADS	TOTAL
Initial public offering price	€18.00	\$20.32	\$135,128,000
Underwriting commissions(1)	€1.26	\$1.4224	\$9,459,093
Proceeds to us, before expenses	€16.74	\$18.8976	\$125,668,907

(1) We refer you to "Underwriting" beginning on page 221 of this prospectus for additional information regarding underwriting compensation.

We have granted an option to the underwriters, exercisable within 30 days from the date of the underwriting agreement, to purchase up to an aggregate of 997,500 additional ADSs and/or ordinary shares (representing 15% of the initial size of the global offering) in the global offering to be sold to the several underwriters at the applicable offering price. If the underwriters exercise this option in full, the total underwriting commissions payable by us will be €9.6 million (\$10.9 million) and the total proceeds to us, before expenses, will be €128.0 million (\$144.5 million), based on the exchange rate on March 26, 2019.

The underwriters expect to deliver the ADSs to purchasers in the ADS offering on or about March 29, 2019 through the book-entry facilities of The Depository Trust Company. The underwriters expect to deliver the ordinary shares to purchasers in the European private placement on or about March 29, 2019 through the book-entry facilities of Euroclear France.

**SVB Leerink**

**Barclays**

**Bryan, Garnier & Co.**

**Natixis**

**Roth Capital Partners**

**H.C. Wainwright & Co.**

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**For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit the global offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the global offering of the ADSs and ordinary shares and the distribution of this prospectus outside the United States.**

We are incorporated in France, and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the Securities and Exchange Commission, or SEC, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Our financial statements included in this prospectus are presented in euros and, unless otherwise specified, all monetary amounts are in euros. All references in this prospectus 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 prospectus, references to ADSs mean ADSs or ordinary shares represented by such ADSs, as the case may be.

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**EXCHANGE RATE INFORMATION**

The following table sets forth, for each period indicated, the low and high exchange rates for euros expressed in U.S. dollars, the exchange rate at the end of such period and the average of such exchange rates on the last day of each month during such period, based on the noon buying rate of the Federal Reserve Bank of New York for the euro. As used in this prospectus, the term "noon buying rate" refers to the rate of exchange for the euro, expressed in U.S. dollars per euro, as certified by the Federal Reserve Bank of New York for customs purposes. The exchange rates set forth below demonstrate trends in exchange rates, but the actual exchange rates used throughout this prospectus may vary.

	YEAR ENDED DECEMBER 31,					
	2013	2014	2015	2016	2017	2018
High	1.3816	1.3927	1.2015	1.1516	1.2041	1.2488
Low	1.2774	1.2101	1.0524	1.0375	1.0416	1.1281
Rate at end of period	1.3779	1.2101	1.0859	1.0552	1.2022	1.1456
Average rate per period	1.3281	1.3297	1.1096	1.1072	1.1396	1.1817

The following table sets forth, for each of the last six months for which such information is available, the high and low exchange rates for euros expressed in U.S. dollars and the exchange rate at the end of the month based on the noon buying rate as described above.

	SEPTEMBER 2018	OCTOBER 2018	NOVEMBER 2018	DECEMBER 2018	JANUARY 2019	FEBRUARY 2019
High	1.1773	1.1594	1.1459	1.1456	1.1524	1.1474
Low	1.1566	1.1332	1.1281	1.1300	1.1322	1.1268
Rate at end of period	1.1622	1.1332	1.1323	1.1456	1.1454	1.1379

On December 31, 2018, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = \$1.1456.

On March 22, 2019, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = \$1.1282. For purposes of determining the final price per ADS, we and the underwriters have agreed to use the exchange rate as reported by the European Central Bank, or ECB, on March 26, 2019, which was €1.00 = \$1.1291.

Unless otherwise indicated, currency translations in this prospectus reflect the March 26, 2019 ECB exchange rate.

## **MARKET, INDUSTRY AND OTHER DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

## **TRADEMARKS AND SERVICE MARKS**

"GENFIT," the GENFIT logo and other trademarks or service marks of GENFIT S.A. appearing in this prospectus are the property of GENFIT S.A. or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus 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 prospectus 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.

## PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our ordinary shares (including ordinary shares in the form of ADSs). You should read the entire prospectus carefully, including "Risk Factors" and our financial statements and the related notes appearing elsewhere in this prospectus. You should carefully consider, among other things, the matters discussed in the sections of this prospectus titled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. Unless otherwise indicated, "GENFIT," "the company," "our company," "we," "us" and "our" refer to GENFIT S.A. and its consolidated subsidiaries.

### 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. We are evaluating our most advanced drug candidate, elafibranor, in a pivotal Phase 3 clinical trial as a potential treatment for nonalcoholic steatohepatitis, or NASH, and in a Phase 2 clinical trial as a potential treatment for primary biliary cholangitis, or PBC. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial in PBC. 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, 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. In January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space. Our scientific and clinical expertise, translational disease-driven approach and strong bioinformatics capabilities have allowed us to build a scientific platform through which we discover and develop our drug candidates and diagnostic tools. We believe elafibranor, if approved, has the potential to become a first-line treatment as a monotherapy and the backbone of combination regimens.

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.

The following table summarizes our drug candidate and diagnostic development pipeline. We have retained worldwide rights to all of our programs.

PROGRAM	INDICATION	TARGET	DEVELOPMENT STAGE				TIMELINE
			PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	
Elafibranor	ADULT NASH	PPAR $\alpha/\delta$	PHASE 3				Publication of Phase 3 interim results End 2019
	PBC	PPAR $\alpha/\delta$	PHASE 2				Positive Phase 2 data announced December 2018
	PEDIATRIC NASH	PPAR $\alpha/\delta$	PHASE 2				Phase 2 In progress; enrollment expected to begin in 2019
Nitazoxanide	FIBROSIS	Stellate cell activation	PHASE 2				Phase 2 proof of concept initiated December 2018
TGFTX1	AUTO-IMMUNE DISEASES (eg., psoriasis, respiratory)	ROR $\gamma$ t	PHASE 1				Pre-IND studies In progress (mild to moderate psoriasis)
PROGRAM	INDICATION	DEVELOPMENT				TIMELINE	
Diagnostic	NASH	<ul style="list-style-type: none"> <li>Currently finalizing analytical and clinical study designs</li> <li>2018: alignment with FDA on path forward to validate NIS4</li> <li>Discovery of two key mRNA biomarkers in 2015</li> </ul>				<ul style="list-style-type: none"> <li>License agreement with LabCorp – January 2019</li> <li>LDT anticipated release in 2019</li> <li>Regulatory submission for IVD clearance in 2020</li> </ul>	

Elafibranor, a dual agonist of the nuclear receptors PPAR $\alpha$  and PPAR $\delta$ , is currently in Phase 3 development for the treatment of NASH. In our Phase 2b clinical trial, elafibranor achieved resolution of NASH without worsening of fibrosis, which is the primary endpoint of our ongoing global Phase 3 clinical trial. In our Phase 2b clinical trial, elafibranor achieved resolution of NASH without worsening of fibrosis, which has been defined by the FDA for drug registration and is the primary endpoint of our ongoing global Phase 3 clinical trial. However, we did not achieve statistical significance on the pre-specified primary endpoint of our Phase 2b clinical trial, which was based on an outdated definition of resolution of NASH. We have already achieved the enrollment necessary to perform an interim cohort analysis and expect to report interim results by the end of 2019. We believe these results, if positive, could support accelerated approval from the U.S. Food and Drug Administration, or FDA, and conditional approval from the European Medicines Agency, or EMA, as early as 2020. Elafibranor has received fast track designation from the FDA for the treatment of NASH.

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 in NASH, 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 pruritis that have been associated with approved PBC treatments. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial evaluating elafibranor for the treatment of PBC. Elafibranor met the primary endpoint of the trial, which was the change at week 12 in serum alkaline phosphatase, or ALP, from baseline, with statistical significance compared to placebo in both doses evaluated. Elafibranor also achieved with high statistical significance when compared to placebo, the composite endpoint of ALP and bilirubin. That endpoint, which has been used for drug registration, is 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%. Based on these positive results, we plan to advance our PBC program into Phase 3 development.

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 diagnosis 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 IVD test is a novel, standalone diagnostic 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 our IVD test has the potential to benefit patients, improve overall clinical care and facilitate the identification of NASH patients to be treated. We anticipate marketing our IVD test first as a laboratory developed test, or LDT, in 2019, and then submitting our IVD test for FDA marketing authorization in 2020. In January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space.

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. 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 fibrosis.

Our TGFTX1 preclinical program is focused on the discovery and development of innovative drug candidates targeting ROR $\gamma$ t, 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.

Our current chief executive officer co-founded our company in 1999 and our shares have been listed on Euronext Paris first on Alternext and then on the regulated market under the symbol "GNFT" since 2006. 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 over 150 employees at our offices in Lille and Paris, France and Cambridge, Massachusetts. The chair of our scientific advisory board, Bart Staels, is a 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.

## Our Strengths

We believe the following strengths will allow us to continue to build upon our leadership position in drug and diagnostic development for metabolic and liver-related diseases and achieve our goal of commercializing our drug and diagnostic candidates:

- **Our lead product candidate, elafibranor, is in Phase 3 development for the treatment of NASH, an indication for which there are no approved drugs today, but which presents significant market opportunity.** In April 2018, we announced that we had achieved the recruitment goal of 1,000 patients for the interim cohort in our global Phase 3 clinical trial being conducted in 25 countries. We expect to report the results of our interim cohort analysis by the end of 2019, which, if positive, could support accelerated approval from the FDA and conditional approval from the EMA as early as 2020. If approved, we believe elafibranor could be among the first FDA-approved therapies shown to achieve resolution of NASH without worsening of fibrosis.
- **We recently announced positive preliminary results from our Phase 2 clinical trial of elafibranor for the treatment of PBC and plan to commence Phase 3 development.** In December 2018, we announced that elafibranor met the primary endpoint of our Phase 2 clinical trial, which was the change at week 12 in serum 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, the elafibranor 80 mg and 120 mg treatment groups achieved with high statistical significance mean response rates of 67% and 79%, respectively, as compared to 6.7% for the placebo group. We plan to advance our PBC program into Phase 3 development in 2019.
- **Elafibranor's results on NASH resolution, its good tolerability and lack of demonstrated safety concerns make it well-positioned among late-stage NASH programs.** We believe elafibranor has a favorable tolerability profile based on the results of our Phase 1 and Phase 2 trials. Also, in our Phase 2b clinical trial, we observed elafibranor's ability to resolve NASH without the worsening of fibrosis, which is the primary endpoint of our ongoing global Phase 3 clinical trial, while also showing a decrease in cardiovascular risk factors, an important observation considering the close link between NASH and cardiometabolic disease, and one that has not been reported in other drugs in Phase 3 development for NASH. Elafibranor is, to our knowledge, the only drug currently permitted to be developed for the treatment of children with NASH. We hold over 350 patents and patent applications relating to elafibranor, and the patent covering the use of elafibranor for the treatment of NASH does not expire until 2030, without taking into account any extensions.
- **We are a recognized leader in the NASH field.** We are actively involved in the NASH stakeholder community, as a member of the steering committee and co-leader of a working group of The Liver Forum. We also participate in academic consortia, such as the biomarkers

consortia in the United States and Europe, and 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. These programs provide us with insight from the key stakeholders in NASH and our leadership position enables us to establish credibility with and convey these insights to regulators and payors.

- **Our diagnostic program has the potential to expand market opportunity through better patient identification and stratification.** Our IVD test is designed to identify NASH patients who may be appropriate candidates for drug intervention. We believe that broad adoption of our non-invasive, accessible test, if validated and authorized for marketing, could not only help solve the problem of NASH under-diagnosis, but also provide physicians with a tool to identify patients who would benefit from treatment with elafibranor or any other appropriate drug. Our license agreement with LabCorp allows for the deployment of our IVD test in the clinical research space through its central laboratories, which we believe will provide expanded access to, and further validation of our IVD test and generate new biological insights on NASH disease pathogenesis.
- **Our pipeline extends beyond elafibranor.** 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 fibrosis. If this Phase 2 trial demonstrates anti-fibrotic activity in these patients, we plan to develop NTZ as a combination therapy with elafibranor 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.
- **Our experienced team is comprised of industry leaders in metabolic and liver-related diseases.** 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.

### **Our Strategy**

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

- Obtain regulatory approval for, and commercialize, elafibranor for the treatment of NASH.
- Rapidly advance the clinical development of elafibranor for the treatment of PBC.
- Complete development and prepare for potential commercialization of our NASH IVD test.
- Advance other drug candidates in our pipeline, both alone and in combination with elafibranor.
- Actively manage our development pipeline and opportunistically enter into strategic collaborations.
- Increase public awareness of NASH through The NASH Education Program.

### **Summary Risk Factors**

An investment in our ordinary shares (including ordinary shares in the form of ADSs) involves a high degree of risk. Any of the factors set forth under "Risk Factors" may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth



in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our securities. Among these important risks are the following:

- We have never generated profits from product sales. Currently, we have no products approved for commercial sale, and to date we have not generated any 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.
- 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.
- We will require substantial additional funding to commercialize our products, if approved, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- We 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. As a result, our development approach involves new endpoints and methodologies. There is risk that the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.
- 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 we, or our potential future collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, whether it be via an internal infrastructure or an arrangement with a commercial partner, we may not be successful in commercializing those product candidates if and when they are approved.
- Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may adversely affect our results of operations.
- Our ability to compete may decline if we do not adequately protect our proprietary rights.
- 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.
- 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 ordinary shares.

#### **Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management's discussion and analysis of financial condition and results of operations in the registration statement for the global offering of which this prospectus forms a part;

- exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002; and
- to the extent that we no longer qualify as a foreign private issuer, (1) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (2) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.07 billion in total annual gross revenue, have more than \$700 million in market value of our capital stock held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in this prospectus, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide shareholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Since International Financial Reporting Standards make 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.

### **Implications of Being a Foreign Private Issuer**

We are also considered a "foreign private issuer" under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. 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.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold equity securities.

### **Corporate Information**

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. In 2006, we completed the initial public offering of our ordinary shares on Alternext market of Euronext in Paris and were transferred to the regulated market of Euronext Paris in 2014. 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 website address is [www.genfit.com](http://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 prospectus is not part of this prospectus.

## THE GLOBAL OFFERING

Global offering	6,650,000 ordinary shares offered by us, consisting of 6,150,000 ordinary shares in the form of ADSs offered in the ADS offering and 500,000 ordinary shares offered in the European private placement. The closings of the ADS offering and the European private placement will occur simultaneously. The total number of ordinary shares (including in the form of ADSs) in the ADS offering and European private placement is subject to reallocation between these offerings as permitted under applicable laws and regulations.
ADS offering	6,150,000 ADSs, each representing one ordinary share
European private placement	500,000 ordinary shares
Offering price	The offering price is \$20.32 per ADS in the ADS offering, corresponding to €18.00 per ordinary share in the European private placement.
Purchaser Restrictions	Under the authority granted by our shareholders to conduct the global offering, the ordinary shares and ADSs that we are offering may only be purchased initially by industrial or commercial companies in the pharmaceutical/biotech sector or investment fund companies or fund management companies or collective savings managing funds governed by French or foreign law or any other legal entity (including trust) or natural person, investing in the pharmaceutical/biotech sector, that is qualified to invest in a private placement. In order to purchase ordinary shares and/or ADSs in the global offering, you will be required to execute and provide to the underwriters an investor letter representing that you satisfy the foregoing investor criteria.
Ordinary shares (including ordinary shares in the form of ADSs) to be outstanding after the global offering	37,833,921 ordinary shares
Option to purchase additional ADSs and/or ordinary shares in the global offering	We have agreed to issue, at the option of the underwriters, within 30 days after the date of the underwriting agreement, up to an aggregate of 997,500 additional ADSs and/or ordinary shares (representing 15% of the initial size of the global offering).
American Depositary Shares	Each ADS represents one ordinary share, nominal value €0.25 per share. Purchasers of ADSs in the ADS offering will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and all holders and beneficial owners of ADSs issued thereunder. To better understand the terms of the ADSs, purchasers of ADSs should carefully read the section in this prospectus titled "Description of American Depositary Shares." We also encourage purchasers of ADSs to read the deposit agreement, which is filed as an exhibit to the registration statement of which this prospectus forms a part.
Depositary	The Bank of New York Mellon

Use of proceeds

We estimate that we will receive net proceeds from the global offering of approximately €108.4 million (\$122.4 million), at the initial public offering price of \$20.32 per ADS in the ADS offering, corresponding to €18.00 per ordinary share in the European private placement, after deducting underwriting commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the global offering, together with our existing resources, to:

- prepare for the potential commercialization of elafibranor in NASH by building out our commercial infrastructure;
- complete our ongoing Phase 3 clinical development of elafibranor for the treatment of NASH through to, at least, the submission of an NDA to the FDA and EMA and the launch of the Phase 4 clinical trial;
- conduct a global Phase 3 clinical trial of elafibranor for the treatment of PBC;
- advance the commercial development of our IVD test to identify NASH patients through the launch of the LDT and completion of the work required to obtain regulatory approval for our IVD kit;
- advance our research program on the use of elafibranor as a potential backbone for combination therapies in order to launch two proof-of-concept studies; and
- the remainder, if any, for working capital and for general corporate purposes.

See "Use of Proceeds" for more information.

Dividend policy

We do not expect to pay any dividends on the ordinary shares or ADSs in the foreseeable future.

Risk factors

You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in the ordinary shares or ADSs.

Nasdaq Global Select Market symbol for our ADSs

"GNFT"

Euronext Paris trading symbol for our ordinary shares

"GNFT"

The number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering is based on 31,183,921 ordinary shares outstanding as of December 31, 2018 and excludes:

- 548,882 new ordinary shares issuable upon the exercise of redeemable share warrants (BSAAR), share warrants (BSA), free shares and stock options granted but not exercised as of December 31, 2018 at a weighted average exercise price of €19.72 (\$22.59) per new ordinary share based on the exchange rate in effect as of December 31, 2018 (this weighted average exercise price does not include the 83,726 new ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price paid);
- 200,066 ordinary shares reserved for future issuance under our share-based compensation plans and other delegations of authority from our shareholders; and
- 9,000,000 ordinary shares reserved to date pursuant to a delegation of authority from our shareholders for share capital increases by us through rights issuances and public or private offerings.

Except as otherwise noted, the information in this prospectus assumes no exercise by the underwriters of their option to purchase 997,500 additional ADSs and/or ordinary shares in the global offering.

## SUMMARY CONSOLIDATED FINANCIAL DATA

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

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read this summary consolidated financial data together with our consolidated financial statements and related notes beginning on page F-1 of this prospectus, as well as the sections of this prospectus titled "Exchange Rate Information," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

### Summary Consolidated Statement of Operations Data:

<u>(in thousands of euros, except loss per share data)</u>	Year Ended December 31,	
	2017	2018
	Restated*	
<b><u>Revenues and other income</u></b>		
Revenue	€ 118	€ 69
Other income	6,737	7,425
Revenues and other income	6,856	7,494
<b><u>Operating expenses and other operating income (expenses)</u></b>		
Research and development expenses	(54,189)	(67,024)
General and administrative expenses	(9,421)	(9,793)
Other operating income (expenses)	60	(162)
Operating loss	(56,695)	(69,484)
Financial income	642	728
Financial expenses	(3,096)	(11,118)
Financial loss	(2,453)	(10,391)
Net loss before tax	(59,148)	(79,875)
Income tax benefit	3,420	354
Net loss	€ (55,728)	€ (79,521)
Basic and diluted loss per share	€ (1.79)	€ (2.55)

\* In the context of the preparation of its 2018 consolidated financial statements, we restated the financial statements previously published for the 2017 fiscal year under IFRS. These changes do not affect the cash position or the operating results, and are mainly related to the application of IFRS to deferred taxes on the OCEANE bonds issued in October 2017. The corrections lead mainly to a decrease in the consolidated net loss of €2.9 million. More information is provided in Note 2.3 of our consolidated financial statements.

**Summary Consolidated Statement of Financial Position Data:**

(in thousands)	As of December 31, 2018	
	Actual	As Adjusted(1)
Cash and cash equivalents	€ 207,240	€ 315,662
Total assets	229,478	337,900
Total shareholders' equity	20,939	129,361
Total non-current liabilities	169,291	169,291
Total current liabilities	39,248	39,248
Total liabilities	208,539	208,539
Total liabilities and shareholders' equity	229,478	337,900

- (1) The as adjusted summary condensed consolidated statement of financial position data reflects our issuance and sale of ADSs and ordinary shares in the global offering at an initial public offering price of \$20.32 per ADS in the ADS offering, corresponding to €18.00 per ordinary share in the European private placement, after deducting underwriting commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our ordinary shares (including ordinary shares in the form of ADSs) involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes, before deciding whether to purchase our securities. If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the market price of our securities could decline, and you could lose part or all of your investment.*

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

***We have never generated profits from product sales. Currently, we have no products approved for commercial sale, and to date we have not generated any 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.***

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 net losses in each of the past eleven years, including a net loss of €79.5 million for the year ended December 31, 2018. Our revenue and other income result principally from tax credits, including research tax credits, in France, and, until June 30, 2018, 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.

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 *in vitro* diagnostic, or 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.

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, which is our lead drug candidate, our other drug candidates and our IVD test. We also expect to incur losses as we prepare for and begin the commercialization of any approved products, and add 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 our pivotal Phase 3 clinical trial of elafibranor, referred to as the RESOLVE-IT trial, in NASH, launch a Phase 3 clinical trial of elafibranor in primary biliary cholangitis, or PBC, and finalize other planned activities for regulatory approval of elafibranor in NASH. In parallel with our potential commercialization of elafibranor, we also plan to seek U.S. Food and Drug Administration, or FDA, marketing authorization of our IVD test. During the regulatory development process for elafibranor and our IVD test, our expenses could increase if we are required by the FDA or the European Medicines Agency, 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. We also anticipate that we will continue to increase our product development, scientific, commercial and administrative personnel significantly and expand our facilities and infrastructure in the United States, France and other countries as part of our longer-term growth strategy.



***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.***

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. 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 pivotal Phase 3 RESOLVE-IT trial for elafibranor in NASH and our other trials of elafibranor in PBC;
- regulatory bodies determining that our Phase 3 clinical data in NASH are sufficient, without further clinical data, to support an application for approval, whether or not conditional or accelerated;
- obtaining approval to market elafibranor for the treatment of NASH, PBC and other indications and patient populations;
- obtaining positive results in our formal validation studies required to commercialize our IVD test;
- expanding our manufacturing of commercial supply for elafibranor;
- establishing sales, marketing and distribution capabilities to effectively market and sell elafibranor 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 our IVD test as a diagnostic complement to liver biopsy;
- negotiating and securing coverage and adequate reimbursement from third-party payors for elafibranor and our IVD test; and
- expanding our contract manufacturing for the commercial supply of elafibranor.

We are conducting pre-commercial activities, such as patient profiling, intended to better understand how physicians care for NASH patients. NASH is a disease with no approved drug therapy. As such, there is significant uncertainty in the degree of market acceptance elafibranor will have among NASH patients and their healthcare providers as well as third-party payors. Even if we receive marketing approvals for elafibranor to treat NASH and commence our commercial launch, we may not be able to generate significant revenues in the near term. We cannot foresee if elafibranor will ever be accepted as a therapy in NASH 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 NASH. NASH is currently an under-diagnosed disease, and we believe that our non-invasive IVD test will facilitate the diagnosis and identification of NASH patients who may be well suited for drug therapy. If our IVD test does not obtain marketing authorization, we may not be able to reach enough NASH patients to successfully generate significant revenues.

If elafibranor, our IVD test or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if elafibranor, our IVD test 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 on acceptable terms, or at all, and, if not so available, may require us 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 our IVD test in preparation for submitting the test for marketing authorization. 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 our IVD test, 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 our IVD test, 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 are uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products under development.

***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 of April 16, 2018. 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. 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.

### **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.***

We are developing elafibranor in several clinical trials, including a pivotal Phase 3 clinical trial, RESOLVE-IT, for the treatment of NASH that, if successful, we believe could support regulatory approval, and a Phase 2 clinical trial for the treatment of PBC. In parallel, we are also developing our IVD test to identify patients with NASH who may be appropriate candidates for drug therapy. 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 for the treatment of NASH and other indications, our IVD test and our other product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of drug candidates and diagnostic tests 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 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), respectively. We have not submitted any marketing applications for any of our product candidates. 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.

Our RESOLVE-IT trial began in the first quarter of 2016 and is expected to enroll approximately 2,000 patients at approximately 270 sites throughout the world. Considering the importance of NASH in terms of public health, we can submit an NDA to the FDA for accelerated approval under Subpart H and to the EMA for conditional approval on the basis of an interim analysis of the surrogate endpoint in the first 1,000 patients after 72 weeks of treatment. In addition, we evaluated elafibranor for the treatment of PBC in a Phase 2 clinical trial and recently announced preliminary results. We cannot predict whether our ongoing or 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. In NASH, following discussion with the FDA, and based on elafibranor achieving, in our Phase 2b trial, resolution of NASH without worsening of fibrosis, which is the FDA-recommended primary endpoint for our Phase 3 trial, we elected to proceed to a Phase 3 study without conducting additional Phase 2 studies after not achieving statistical significance on our prespecified endpoints in our Phase 2b 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.

Similarly, we will not be permitted to market our IVD test until it is authorized for marketing by the FDA in the United States and receives CE Mark approval in Europe. We have not submitted any marketing applications for our IVD test and, as with approval of our drug candidates, the process for obtaining marketing authorization of diagnostic candidates is lengthy, uncertain and expensive. We plan to initially offer our IVD test as an LDT for use in clinical research in order to provide additional evidence of its clinical utility. 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. There can be no assurance that FDA will continue to exercise enforcement discretion over LDTs, or that the FDA will agree with our characterization of the test as an LDT. Should the FDA not agree with our characterization of the IVD test as a LDT, the IVD test may be subject to additional regulatory requirements for clinical use including pre-market review and post-market regulatory requirements, and we may not be permitted to continue to market our test as an LDT pending clearance of the IVD. We may be subject to fines, penalties, and removal of the LDT from the market, which could further result in lost revenues, damage to our reputation, and delays in the validation of the IVD. 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, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. To be commercially distributed in the United States, medical devices must receive from the FDA prior to marketing, unless subject to an exemption, approval of a premarket approval application, or PMA, for most Class III devices, clearance of a 510(k) premarket notification, or classification pursuant to a *de novo* submission. A clinical trial is almost always required to support a 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.

There can be no assurance that a diagnostic test will be classified as a Class II medical device, and even if it is, there can be no assurance that it will receive marketing authorization from the FDA.

In parallel with the FDA approval process for our IVD test, we are progressing towards submitting a data package which would enable CE marking and associated marketing approval in key European markets during 2020. As with the United States approval process, the CE marking process in the European Economic Area, or the EEA, can be lengthy and expensive.

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

***We 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. As a result, our development approach involves new endpoints and methodologies. There is risk that the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.***

We are focused on developing therapeutics for the treatment of NASH, a disease for which there are currently no approved treatments. 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. Our pivotal Phase 3 RESOLVE-IT clinical trial of elafibranor in NASH incorporates a surrogate endpoint that may serve as the basis for an NDA filing for accelerated approval by the FDA in the United States and conditional approval by the EMA in Europe.

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.

If the results of our interim cohort analysis in our pivotal Phase 3 RESOLVE-IT clinical trial are positive, the FDA may grant accelerated approval, and the EMA may grant conditional approval, for elafibranor in the treatment of NASH. However, there can be no assurance that our interim results will be positive and even if results from our interim results are highly significant and we believe reasonably likely to predict clinical benefit, the FDA and EMA may not accept the results of such trial as sufficiently significant to grant accelerated or conditional approval of elafibranor for NASH, without obtaining additional clinical data. In addition, even if we obtain accelerated or conditional marketing approval for our product candidate, elafibranor in NASH on the basis of an interim analysis, like all companies using the Subpart H and conditional approval pathway, we must continue the RESOLVE-IT trial post-marketing in order to demonstrate the efficacy of elafibranor on clinical benefit based on a composite endpoint of clinical outcomes, which include all-cause mortality, the progression to cirrhosis, and a full list of cirrhosis-related events such as liver transplantation, Model for End-Stage Liver Disease, or MELD score <sup>315</sup>, and hepatocellular carcinoma, or HCC, on the full trial population, with the goal of obtaining full marketing approval. Depending on the outcome, the FDA or EMA could revoke the previously granted approval, and additional clinical data to submit for marketing approval may be required.

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 final acceptability of these regulatory pathways (accelerated or conditional approval) for elafibranor for the treatment of NASH will depend upon the clinical results from the RESOLVE-IT trial and the review by the FDA and EMA of our applications. As a result, we 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 receive regulatory approval of elafibranor for the treatment of NASH, the labeling for our product candidates in the United States, Europe or other countries in which we have received or seek approval may include limitations that could impact the commercial success of our product candidates.

Additionally, the successful commercialization of elafibranor depends in part on our ability to obtain regulatory approval to market our IVD test. NASH is currently an under-diagnosed disease, and we believe that our non-invasive IVD test will reduce barriers to entry for elafibranor by facilitating the diagnosis and identification of NASH patients who may be well suited for drug therapy. If our IVD test does not obtain marketing authorization, we may not be able to generate significant revenues even if such diagnostic were to be marketed as a laboratory developed test, or LDT.

***We have obtained fast track designation from the FDA for elafibranor in the treatment of NASH and we may seek to avail ourselves of such mechanisms to expedite the development or approval of our other drug candidates in the future, but such mechanisms may not actually lead to a faster development or regulatory review or approval process.***

In 2014, the FDA granted fast track designation for elafibranor in the treatment of NASH. We may also seek fast track designation for our other drug candidates, and we may seek priority review or accelerated approval for elafibranor or any other drug candidate we may pursue in the future. The FDA's fast track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. The fast track designation for elafibranor in NASH permits more frequent contact between us and the FDA. Even though elafibranor has received fast track designation for the treatment of NASH, and even if we do obtain fast track or priority review designation or pursue an accelerated approval pathway in elafibranor or our other drug candidates in the future, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Additionally, the FDA may withdraw a particular designation, including our fast track designation for the development of elafibranor in the treatment of NASH, if it believes that the designation is no longer supported by data from our clinical development program.

***A breakthrough therapy designation by the FDA for a drug candidate may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that a drug candidate will receive marketing approval.***

We may seek a breakthrough therapy designation for elafibranor in PBC or any other drug candidate we may pursue 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.

***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 on the basis of 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 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.

***Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for elafibranor and our other product candidates.***

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our drug candidates and IVD test. We currently have underway a number of trials including our pivotal Phase 3 RESOLVE-IT clinical study of elafibranor in NASH. We may also be required to conduct additional clinical trials of elafibranor, our other drug candidates or our IVD test. In the past, we have experienced some delays in enrollment in our clinical trials. We continue to work towards expanding our overall elafibranor development program with additional trials and studies, including in pediatric patients, and we plan on conducting additional development activities in other diseases. The results from these trials may not be available when we expect or we 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 are subject to a number of variables and contingencies, such as the results of other trials, patient enrollments or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies in elafibranor or our other product candidates will begin on time or will be completed on schedule, if at all.

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

- inability to demonstrate sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- inability to validate test methods to support quality testing of the drug substance and drug product;
- inability to determine dosing and clinical trial design;
- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- inability to reach agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA, EMA or other non-U.S. regulators regarding the scope or design of our clinical trials, which may occur at various times, including subsequent to the initiation of the clinical trial;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- varying interpretations of our data, and regulatory commitments and requirements by the FDA, EMA and similar regulatory agencies;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;



- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- lack of effectiveness of product candidates during clinical trials;
- suspension or termination by a data and safety monitoring board, or DSMB, that is overseeing the clinical trial;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- 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; 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 competition for enrolling 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. While we announced the completion of enrollment of the first approximately 1,000 patients in the interim analysis cohort in April 2018, and continuously evaluate and implement a variety of options to complete enrollment as quickly as possible, there can be no assurance that we will be able to enroll and retain a sufficient number of patients or complete the interim analysis and trial on a timely basis. As we engage in other large and complicated trials and trials in advanced disease populations, we may experience a number of complications that may negatively affect our plans or our development programs.

While we have not had difficulties in the past retaining patients after enrollment in our clinical trials, changes in the treatment of NASH, such as the approval of a drug therapy for the treatment of NASH by one of our competitors, could result in difficulties retaining or enrolling patients in our clinical trials. 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 are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability 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 we or our potential future 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. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. 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, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development, even after seeing promising results in earlier clinical trials.

Although our Phase 2b clinical trial of elafibranor in NASH, GOLDEN-505, achieved resolution of NASH without worsening of fibrosis, which is the FDA-recommended primary endpoint of our ongoing Phase 3 RESOLVE-IT clinical trial, this was not the original endpoint for our Phase 2b trial. Despite the results of our retrospective analysis of the Phase 2b results to correct for baseline severity and site heterogeneity by a standardized statistical analysis, we cannot assure you that our RESOLVE-IT trial will achieve positive results with this Phase 3 endpoint, and 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 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 product candidates are found to be unsafe or lack efficacy for any indication, we will not be able to obtain regulatory approval for them, and our prospects and business may be materially and adversely affected.

If elafibranor or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed. For example, if the results of our Phase 3 RESOLVE-IT trial of elafibranor do not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of elafibranor would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes or differences in trial protocols, patient distribution by clinical investigator site, standards of care across sites, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we 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 to amend clinical trial protocols or to otherwise alter the regulatory approval or clearance process and timeline for our drug candidates and/or our IVD test. Regulatory authorities could also impose additional clinical trial requirements. Amendments to our clinical trial protocols 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.

***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 IVD test. 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. 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 fulfill 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 generally would not have the ability 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 IVD test for preclinical studies and clinical trials, 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 or IVD test that we plan to sell. 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. 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. 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 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 would be critical. We are also in the process of qualifying one or more back-up suppliers for our active ingredient and therapeutic units; however, 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 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 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 may seek to enter into collaborations with third parties for the development and potential commercialization of our early stage and preclinical product candidates, 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 our IVD test 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. 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 to use our IVD test 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 our IVD test.

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.

***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 our IVD test for identifying NASH patients 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.***

While we have not observed any significant side effects in our product candidates to date, 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 will not develop in future clinical trials or commercial use, which could delay or preclude regulatory approval of elafibranor or limit its commercial use.

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 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 to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

***Even if we successfully complete clinical trials 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 our IVD test 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, our IVD test or any of our other drug candidates, if approved or cleared;
- inability to secure market acceptance by patients and the medical community of elafibranor, our IVD test 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, our IVD test 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, we do not know the degree to which elafibranor will 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 our IVD test 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 our IVD test is used, a physician may still order a liver biopsy to confirm the diagnosis. The degree of market acceptance of elafibranor, our IVD test 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 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 to access the under-diagnosed NASH market;
- 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 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 candidates are designated under physician treatment guidelines for the treatment of the indications for which we 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 are unable to establish sales, marketing and distribution capabilities for our product candidates, whether it be via an internal infrastructure or an arrangement with a commercial partner, 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 will continue to do so, even prior to any confirmation that elafibranor or any of our other product candidates will be approved. In particular, if elafibranor obtains marketing authorization in NASH and/or PBC, 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. Additionally, in connection with the development of our IVD test, we entered into a license agreement with LabCorp to allow them to deploy the test in the clinical research space. 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, 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 partners 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 may form or seek strategic alliances or enter into licensing or co-marketing arrangements in the future 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 our IVD test. For example, in January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space. Any of these relationships may require us to incur non-recurring and other charges, 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 our IVD test, 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, our IVD test 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, our IVD test 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 obtain marketing approval will be subject to ongoing regulation and could be subject to post-marketing restrictions or withdrawal from the market. Furthermore, we 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 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. For instance, a regulatory approval may limit the indicated uses for which we 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 labeling 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 obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the 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 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. 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 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 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 obtain accelerated or conditional marketing approval for our product candidate, elafibranor in NASH on the basis of an interim analysis, like all companies using the Subpart H and conditional approval pathway, we must continue the RESOLVE-IT trial post-marketing in order to demonstrate the efficacy of elafibranor 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, 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 civil, criminal and administrative penalties.

Similarly, if our IVD test is authorized for marketing in the United States, the test will be subject to quality system regulation, or QSR, labeling 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 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 to generate revenues even if we obtain regulatory approval to market a product.***

Our ability to successfully commercialize any of our product candidates, 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 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 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 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 commercialization prospects, including:

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

Our 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, 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 may commercialize and, if reimbursement is available, what the level of reimbursement will be. Since no drug has yet been commercialized in NASH, 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, which are not expected to be available for elafibranor in NASH before the end of 2019, as of the date of this prospectus, 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 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. On June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. Plaintiffs were denied a rehearing, but retain the right to appeal to the U.S. Supreme Court. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In addition, the Centers for Medicare & Medicaid Services, or CMS, recently promulgated regulations that will 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.

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. 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 inseparable 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. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, 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. 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. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, Office of Inspector General of the U.S. Department of Health and Human Services proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While any 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 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 our IVD test, if commercialized, 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 to commercialize our IVD test 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 our IVD test, if commercialized. 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 our IVD test is reimbursed could have a material adverse effect on our revenues. If we and our collaborators are unable to establish and maintain broad coverage and adequate reimbursement for our IVD test 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 ability to penetrate international markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability will depend on our ability to commercialize our product candidates in the United States, Europe and other territories around the world. If we 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 or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for elafibranor 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 Production and Manufacturing of Our Product Candidates**

***The manufacturing facilities of our third-party manufacturers are subject to significant government regulations and approvals. If our third-party manufacturers fail to comply with these 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 products we 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 to suspend or put on hold one or more of our clinical trials;
- suspending or withdrawing regulatory approvals;



- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us or our third-party manufacturers to suspend manufacturing activities or product sales, imports or exports;
- requiring us to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to our reputation, business, financial condition or operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing 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 to commercialize our product candidates in the United States, Europe or elsewhere.

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

We contract to have our product candidates manufactured according to manufacturing best practices applicable to drugs for clinical trials and to specifications approved by the applicable regulatory authorities. If any of our products 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 product 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 growth, which could disrupt our operations.***

As of December 31, 2018, we had 148 full-time employees, and we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, including the potential commercialization of our product candidates in Europe, the United States and

other territories, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, 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 development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. 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. The physical expansion of 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 our expected development and expansion, 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 the future development and expansion of our company.

***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, Jean-François Mouney, our chairman and chief executive officer, and Dean Hum, our chief operating officer. The loss of the services of Messrs. 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. 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.

***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 represented €7.3 million for the year ended December 31, 2018. 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, it is possible that the CIR tax audit may lead to a challenge of the CIR for the years audited and to potential penalties. The audits could, therefore, have an adverse effect on our results of operations and our financial position.

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

Although the majority of our operations are denominated in euros, an increasing portion of our expenses are denominated in U.S. dollars, including expenses resulting from clinical trials and amounts paid to our wholly owned subsidiary, Genfit Corp., and growing expenses in U.S. dollars incurred by Genfit S.A. Additionally, as we expand our operations and conduct clinical trials in the United States, we will incur expenses in U.S. dollars and will be required to enter into additional contracts denominated in other foreign currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. If our currency exposure were to increase, we would put in place additional hedging instruments. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ADSs being sold in the ADS offering will be quoted in U.S. dollars on the Nasdaq Global Select Market, while our ordinary shares (including those being sold in the European private placement and the underlying ordinary shares of the ADSs being sold in the ADS offering) trade in euros on the Euronext Paris exchange. Our financial statements are prepared in euros. Therefore, fluctuations in the exchange rate between the euro and the U.S. dollar will also affect, among other matters, the value of our ordinary shares and ADSs.

***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 and biomarker 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 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. 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. 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.

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

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 could be sought after by patients participating in the clinical trials in the context of the development of the therapeutic products tested and unexpected side effects resulting from the administration of these products. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, 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.

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, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims by us or our collaborators, licensees or subcontractors, which could 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.

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

Despite the implementation of security measures, our internal information technology systems and those of our 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. Significant events 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 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. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of 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 partners 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 may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.***

Our current growth strategy includes 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.

#### **Risks Related to Legal and Other Compliance Matters**

***We are subject to 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 will play a primary role in the recommendation and prescription of our products, if approved. 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, 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 and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the U.S. 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 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, 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, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts; and
- the Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates 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.

In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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, individual 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 may be subject to laws and regulations related to data privacy, both in the United States and the European Union.***

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.

The collection and use of personal health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals a number of rights as data subjects, including the opportunity to object to the processing of their personal information and the right to request deletion of personal information in certain circumstances. It also provides a right for the data subject to obtain the portability of its personal data in certain cases, including when processing of the personal data is based on consent, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, especially in respect of the processing of personal data concerning health, may result in fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring 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. Enforcement uncertainty and the costs



associated with ensuring GDPR compliance be onerous and 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. In connection with the global offering, 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.

### **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 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.

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 process. 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 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 U.S. Food and Drug Administration, or 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.

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 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 to develop our product candidates or sell our products if 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 commonplace. 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 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 an allowed U.S. patent application which claims the use of NTZ in liver fibrosis. This may prevent or delay us from obtaining issued patents with similar claims in the U.S. and if granted, may prompt 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. 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 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. 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.

***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. 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 in 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" (see, two landmark Supreme Court cases, *Mayo Collaborative v. Prometheus Laboratories* ("Prometheus"), and *Association for Molecular Pathology v. Myriad Genetics* ("Myriad")).

In view of the Supreme Court decisions in Prometheus, Myriad, and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* ("Alice Corp."), as well as other 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 protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation 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. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, 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 the Global Offering, Ownership of Our Ordinary Shares and ADSs and Our Status as a Non-U.S. Company with Foreign Private Issuer Status**

***There has been no market for our ADSs prior to the ADS offering and an active and liquid market for our securities may fail to develop, which could harm the market price of our ADSs.***

Although our ordinary shares have been traded on Euronext Paris since April 2014, there has been no public market on a U.S. national securities exchange for our ADSs or our ordinary shares in the United States. Although our ADSs have been approved for listing on the Nasdaq Global Select Market, an active trading market for our ADSs may never develop or be sustained following the ADS offering. The offering price of our ADSs was determined through negotiations between us and the underwriters based on a number of factors. This offering price may not be indicative of the market price of our ADSs or ordinary shares after the global offering. In the absence of an active trading market for our ADSs or ordinary shares, investors may not be able to sell their ADSs at or above the offering price or at the time that they would like to sell.

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

The market price for our ADSs and ordinary shares may be volatile. 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 of 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:

- 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.

***After the completion of the global offering, we may be at an increased risk of securities class action litigation.***

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. If we were to be sued, it could result in substantial costs, which could be insufficiently covered by insurance, and a diversion of management's attention and resources, which could harm our business.

***We have broad discretion in the use of the net proceeds from the global offering and may use them in ways with which you do not agree and in ways that may not increase the value of your investment.***

Our management will have broad discretion in the application of the net proceeds that we receive from the global offering. We may spend or invest these proceeds in a way with which our shareholders and ADS holders disagree. The failure by our management to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from the global offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

***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. Please see the section of this prospectus titled "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares—Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)" for further details on the limitations on our ability to declare and pay dividends and the taxes that may become payable by us if we elect to pay a dividend. 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.

***If you purchase ordinary shares or ADSs in the global offering, you will experience substantial and immediate dilution.***

If you purchase ordinary shares or ADSs in the global offering, you will experience substantial and immediate dilution of \$16.47 per ADS and €14.60 per ordinary share in net tangible book value as of December 31, 2018, after giving effect to the global offering at an initial public offering price of \$20.32 per ADS in the ADS offering, corresponding to €18.00 per ordinary share in the European private placement because the price that you pay will be substantially greater than the net tangible book value per ADS or ordinary share, as applicable, that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the offering price when they purchased their ordinary shares. You will experience additional dilution upon exercise of any outstanding warrants to purchase ordinary shares or if we otherwise issue additional ordinary shares or ADSs below the offering price. For a further description of the dilution that you will experience immediately after the global offering, see the section of this prospectus titled "Dilution."

***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.***

Future sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs and/or ordinary shares. Based upon the number of shares outstanding as of December 31, 2018, after giving effect to the closing of the global offering, we will have 37,833,921 ordinary shares outstanding (including ordinary shares in the form of ADSs), assuming the underwriters do not exercise their option to purchase 997,500 additional ADSs and/or ordinary shares. ADSs and ordinary shares issued and sold in the global offering may be resold in the public market immediately without restriction, unless purchased by our affiliates. A significant portion of these ordinary shares and ADSs will be subject to the lock-up agreements described in "Shares and ADSs Eligible for Future Sale" and "Underwriting." If, after the end of such lock-up agreements, these shareholders or ADS holders sell substantial amounts of ordinary shares or ADSs in the public market, or the market perceives that such sales may occur, the market price of our ADSs or ordinary shares and our ability to raise capital through an issuance of equity securities in the future could be adversely affected.

***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 prospectus titled "Management—Corporate Governance Practices" and "Description of Share Capital."

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

Certain members of our board of directors and senior management and certain experts named in this prospectus 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. See the section of this prospectus titled "Enforcement of Civil Liabilities."

***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.; see the section of this prospectus titled "Limitations Affecting Shareholders of a French Company;"
- 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 of this prospectus titled "Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 9, 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 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.

Purchasers of ADSs in the ADS offering may instruct the depositary of their ADSs to vote the ordinary shares underlying their ADSs. Otherwise, purchasers of ADSs in the ADS offering will not be able to exercise voting rights unless they withdraw the ordinary shares underlying the ADSs they hold. However, a holder of ADSs may not know about the meeting 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.

***Purchasers of ADSs are not holders of our ordinary shares.***

A holder of ADSs will not be treated as one of our shareholders and will not have direct shareholder rights. French law governs our shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs held by purchasers of ADSs in the ADS offering. Purchasers of ADSs in the ADS offering will have ADS holder rights. The deposit agreement among us, the depositary and

purchasers of ADSs in the ADS offering, as ADS holders, and all other 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 purchasers of ADSs in the ADS offering.***

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 in the ADS offering 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.

***Purchasers of ADSs in the ADS offering 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. See the section of this prospectus titled "Description of American Depositary Shares."

***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 expect 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 will be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

***As a foreign private issuer, we are permitted and we expect to follow certain home country 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 will be 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 intend 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 "Management—Corporate Governance Practices."

***We are an "emerging growth company" under the JOBS Act and will be 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 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 will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of the global offering; (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, 2019. 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.***

On December 22, 2017, the Tax Cuts and Jobs Act was signed into law and significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), implementation of a "base erosion anti-abuse tax" which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxation of certain non-U.S. corporations' earnings considered to be "global intangible low taxed income" (also referred to

as "GILTI"), repeal of the alternative minimum tax, or AMT, for corporations and changes to a taxpayer's ability to either utilize or refund the AMT credits previously generated, changes to the limitation on deductions for certain executive compensation particularly with respect to the removal of the previously allowed performance based compensation exception, changes in the attribution rules relating to shareholders of certain "controlled foreign corporations", limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the U.S. corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Cuts and Jobs Act on holders of our ordinary shares or ADSs is also uncertain and could be adverse. For example, recent changes in U.S. federal income tax law resulting in additional taxes owed by U.S. holders (as defined below under "Material United States Federal Income Tax and French Tax Considerations—Material U.S. Federal Income Tax Considerations") under the new GILTI tax rules or related to "controlled foreign corporations" may discourage U.S. investors from owning or acquiring 10% or greater of our outstanding ordinary shares or ADSs, which other shareholders may have viewed as beneficial or may otherwise negatively impact the trading price of our ordinary shares or ADSs. We are unable to predict what federal tax law may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge our shareholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ordinary shares or ADSs.

***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, we believe that we were not classified as a passive foreign investment company, or PFIC, for the taxable year ending December 31, 2018 and we believe that we will not be classified as a PFIC for the taxable year ending December 31, 2019; however, there can be no assurance that we will not be considered a PFIC for any future taxable year. Under 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 "Material United States Federal Income Tax and French Tax Considerations—Material U.S. Federal Income Tax Considerations") 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 prospectus titled "Material United States Federal Income Tax and French Tax Considerations—Material U.S. Federal Income Tax Considerations".

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

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Our group currently includes one U.S. subsidiary and, therefore, under current law our non-U.S. subsidiaries should 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 at the end of each fiscal year. Depending on the success of our listing in the U.S. market, we may have to start reporting under Section 404 of the Sarbanes Oxley Act as early as for the year ending December 31, 2020 and the filing of our second annual report on Form 20-F with the SEC.

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 up to five fiscal years following the date of the global offering. 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 will be 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. Additional information describing this matter is included in Note 2.3 to our consolidated financial statements contained in this prospectus.

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 intend to engage additional personnel, both internal and external, with appropriate training, as well as to redesign our supervision controls, including with respect to the documentation of assumptions used and the development of accounting positions, and to reassess the necessary qualifications for any external consultants. There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weakness 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 remediate the material weakness or to meet the demands that will be 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 remediate the material weakness in a timely manner, or at all, 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 successful, 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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, particularly the sections of this prospectus titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements. All statements other than present and historical facts and conditions contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this prospectus, 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, our IVD test 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 IVD 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 successfully conduct, supervise and monitor clinical trials for our product candidates;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to maintain, protect and enhance our intellectual property rights and 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;
- our expected use of proceeds of the global offering; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

You should refer to the section of this prospectus titled "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 prospectus 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. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with the global offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.



## USE OF PROCEEDS

We estimate that we will receive net proceeds from the global offering of approximately €108.4 million (\$122.4 million), based on an initial public offering price of \$20.32 per ADS in the ADS offering, corresponding to €18.00 per ordinary share in the European private placement, after deducting underwriting commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase 997,500 additional ADSs and/or ordinary shares. If the underwriters exercise in full their option to purchase additional ADSs and/or ordinary shares in the global offering, we estimate that we will receive net proceeds from the global offering of approximately €125.1 million (\$141.3 million), after deducting underwriting commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from the global offering as follows:

- approximately €13.3 million (\$15.0 million) to prepare for the potential commercialization of elafibranor in NASH by building out our commercial infrastructure;
- approximately €44.3 million (\$50.0 million) to complete our ongoing Phase 3 clinical development of elafibranor for the treatment of NASH through to, at least, the submission of an NDA to the FDA and EMA and the launch of the Phase 4 clinical trial;
- approximately €31.0 million (\$35.0 million) to conduct and complete our planned global Phase 3 clinical trial of elafibranor for the treatment of PBC;
- approximately €5.3 million (\$6.0 million) to advance the commercial development of our IVD test to identify NASH patients through the launch of the LDT and completion of the work required to obtain regulatory approval for our IVD kit;
- approximately €5.3 million (\$6.0 million) to advance our research program on the use of elafibranor as a potential backbone for combination therapies in order to launch two proof-of-concept studies; and
- the remainder for working capital and for general corporate purposes.

Even with the expected net proceeds from the global offering, and depending on our ability to generate sufficient revenues from the future potential commercialization of our drug candidates and IVD test, we may need to raise additional capital in the future to develop and commercialize our drug candidates and IVD test, including future clinical trials that may be required by regulatory authorities. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

This expected use of the net proceeds from the global offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of the global offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our drug candidates and any unforeseen cash needs. As a result, our future financing needs remain uncertain and our management will retain broad discretion over the allocation of the net proceeds from the global offering.

Pending our use of the net proceeds from the global offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

## **DIVIDEND 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 the section of this prospectus titled "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares—Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)" 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.

**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2018:

- on an actual basis; and
- on an as adjusted basis to reflect (i) the issuance and sale of a total of 6,650,000 ordinary shares, consisting of (a) 6,150,000 ADSs in the ADS offering at an initial public offering price of \$20.32 per ADS, and (b) 500,000 ordinary shares in the European private placement at an offering price of €18.00 per ordinary share, after deducting underwriting commissions and estimated offering expenses payable by us and (ii) the application of net proceeds from the global offering described under "Use of Proceeds."

The table should be read in conjunction with the information contained in "Use of Proceeds," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our consolidated financial statements and the related notes included elsewhere in this prospectus.

<b>(in thousands of euros)</b>	<b>As of December 31, 2018</b>	
	<b>Actual</b>	<b>As Adjusted</b>
Cash and cash equivalents	€ 207,240	€ 315,662
Total debt, including current portion	€ 169,593	€ 169,593
<b>Shareholders' equity:</b>		
Share capital, nominal value €0.25 per share; 31,183,921 shares issued and outstanding, actual; 37,833,921 shares issued and outstanding, as adjusted	7,796	9,459
Share premium net of treasury shares	250,824	357,583
Accumulated deficit	(158,167)	(158,167)
Currency translation adjustment	6	6
Net loss	(79,521)	(79,521)
<b>Total shareholders' equity</b>	<b>20,939</b>	<b>129,361</b>
<b>Total capitalization</b>	<b>€ 190,532</b>	<b>€ 298,954</b>

The number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering is based on 31,183,921 ordinary shares outstanding as of December 31, 2018 and excludes:

- 548,882 new ordinary shares issuable upon the exercise of redeemable share warrants (BSAAR), share warrants (BSA), free shares and stock options granted but not exercised as of December 31, 2018 at a weighted average exercise price of €19.72 (\$22.59) per new ordinary share based on the exchange rate in effect as of December 31, 2018 (this weighted average exercise price does not include the 83,726 new ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price paid);
- 200,066 ordinary shares reserved for future issuance under our share-based compensation plans and other delegations of authority from our shareholders; and
- 9,000,000 ordinary shares reserved to date pursuant to a delegation of authority from our shareholders for share capital increases by us through rights issuances and public or private offerings.

Except as otherwise noted, the information in this prospectus assumes no exercise by the underwriters of their option to purchase additional ordinary shares (which may be in the form of ADSs).

**DILUTION**

If you invest in our ADSs or ordinary shares in the global offering, your ownership interest will be diluted to the extent of the difference between the offering price per ADS or ordinary share paid by purchasers in the global offering and the as adjusted net tangible book value per ADS or ordinary share, as applicable, after completion of the global offering. Our net tangible book value as of December 31, 2018 was €20.1 million (\$23.0 million), or €0.64 per ordinary share (equivalent to \$0.74 per ADS), based on the exchange rate in effect as of December 31, 2018. Net tangible book value per ordinary share is determined by dividing (1) our total assets less our intangible assets and our total liabilities by (2) the number of ordinary shares outstanding as of December 31, 2018, or 31,183,921 ordinary shares.

After giving effect to our sale of a total of 6,650,000 ordinary shares, consisting of (i) 6,150,000 ADSs in the ADS offering at an initial public offering price of \$20.32 per ADS, and (ii) 500,000 ordinary shares in the European private placement at an offering price of €18.00 per ordinary share, after deducting underwriting commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at December 31, 2018 (based on the exchange rate in effect as of December 31, 2018) would have been €128.6 million (\$145.5 million), or €3.40 per ordinary share (equivalent to \$3.85 per ADS). This represents an immediate increase in net tangible book value of €2.76 per ordinary share (equivalent to \$3.11 per ADS) to existing shareholders and an immediate dilution in net tangible book value of €14.60 per ordinary share (equivalent to \$16.47 per ADS) to new investors.

The following table illustrates this dilution to new investors on a per ordinary share and per ADS basis:

	As of December 31, 2018	
	Per Ordinary Share	Per ADS
Initial public offering price	€ 18.00	\$ 20.32
Historical net tangible book value per ordinary share or ADS as of December 31, 2018	€ 0.64	\$ 0.74
Increase in net tangible book value per ordinary share or ADS attributable to new investors participating in the global offering	2.76	3.11
As adjusted net tangible book value per ordinary share or ADS after the global offering	3.40	3.85
Dilution in as adjusted net tangible book value per ordinary share or ADS to new investors participating in the global offering	€ 14.60	\$ 16.47

If the underwriters exercise their option to purchase 997,500 additional ADSs and/or ordinary shares in full, the as adjusted net tangible book value after the global offering would be €3.74 per ordinary share (equivalent to \$4.23 per ADS), the increase in the as adjusted net tangible book value to existing shareholders would be €3.10 per ordinary share (equivalent to \$3.49 per ADS), and the dilution to new investors participating in the global offering would be €14.26 per ordinary share (equivalent to \$16.09 per ADS).

The following table sets forth, as of December 31, 2018, on the as adjusted basis described above, consideration paid to us in cash for ordinary shares (including ordinary shares in the form of ADSs) purchased from us by our existing shareholders and by new investors participating in the global offering

based on an initial public offering price of \$20.32 per ADS and before deducting underwriting commissions and estimated offering expenses payable by us.

	Ordinary Shares Purchased(1)		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Existing shareholders	31,183,921	82%	€ 225,157,961	68%	€ 8.18	
New investors	6,650,000	18	119,677,619	32	€ 18.00	\$ 20.32
<b>Total</b>	<b>37,833,921</b>	<b>100%</b>	<b>€ 374,835,580</b>	<b>100%</b>		

(1) Including ordinary shares in the form of ADSs.

The table above assumes no exercise of the underwriters' option to purchase 997,500 additional ADSs and/or ordinary shares in the global offering. If the underwriters exercise their option to purchase additional ADSs and/or ordinary shares in full, the number of ordinary shares (including ordinary shares in the form of ADSs) held by the existing shareholders after the global offering would be reduced to 80% of the total number of ordinary shares (including ordinary shares in the form of ADSs) outstanding after the global offering, and the number of ordinary shares (including ordinary shares in the form of ADSs) held by new investors participating in the global offering would increase to 20% of the total number of ordinary shares (including ordinary shares in the form of ADSs) outstanding after the global offering.

Other than translations of the offering price into U.S. dollars and translations of corresponding proceeds of the global offering, which have been determined at the exchange rate of €1.00 = \$1.1291, the exchange rate as reported by the European Central Bank on March 26, 2019, translations included in "Dilution" are calculated based on the exchange rate of €1.00 = \$1.1456, the noon buying rate of the Federal Reserve Bank of New York on December 31, 2018.

The tables and calculations above are based on the number of ordinary shares (including ordinary shares in the form of ADSs) that will be outstanding after the global offering, which is based on 31,183,921 ordinary shares outstanding as of December 31, 2018 and excludes:

- 548,882 new ordinary shares issuable upon the exercise of redeemable share warrants (BSAAR), share warrants (BSA), free shares and stock options granted but not exercised as of December 31, 2018 at a weighted average exercise price of €19.72 (\$22.59) per new ordinary share based on the exchange rate in effect as of December 31, 2018 (this weighted average exercise price does not include the 83,726 new ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price paid);
- 200,066 ordinary shares reserved for future issuance under our share-based compensation plans and other delegations of authority from our shareholders; and
- 9,000,000 ordinary shares reserved to date pursuant to a delegation of authority from our shareholders for share capital increases by us through rights issuances and public or private offerings.

**SELECTED CONSOLIDATED FINANCIAL DATA**

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

The following selected consolidated financial data for the years and as of the dates indicated are qualified by reference to and should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1 of this prospectus, as well as the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Exchange Rate Information" included elsewhere in this prospectus. Our historical results and the results for the year ended December 31, 2018 are not necessarily indicative of our results to be expected for any future period.

**Selected Consolidated Statement of Operations Data:**

<u>(in thousands, except loss per share data)</u>	<u>Year Ended December 31,</u>	
	<u>2017</u>	<u>2018</u>
	<u>Restated*</u>	
<b><u>Revenues and other income</u></b>		
Revenue	€ 118	€ 69
Other income	6,737	7,425
Revenues and other income	6,856	7,494
<b><u>Operating expenses and other operating income (expenses)</u></b>		
Research and development expenses	(54,189)	(67,024)
General and administrative expenses	(9,421)	(9,793)
Other operating income (expenses)	60	(162)
Operating loss	(56,695)	(69,484)
Financial income	642	728
Financial expenses	(3,096)	(11,118)
Financial loss	(2,453)	(10,391)
Net loss before tax	(59,148)	(79,875)
Income tax benefit	3,420	354
Net loss	€ (55,728)	€ (79,521)
Basic and diluted loss per share	€ (1.79)	€ (2.55)

(\*) In the context of the preparation of its 2018 consolidated financial statements, we restated the financial statements previously published for the 2017 fiscal year under IFRS. These changes do not affect the cash position or the operating results, and are mainly related to the application of IFRS to deferred taxes on the OCEANE bonds issued in October 2017. The corrections lead mainly to a decrease in the consolidated net loss of €2.9 million. More information is provided in Note 2.3 to our consolidated financial statements.

**Selected Consolidated Statement of Financial Position Data:**

(in thousands of euros)	As of December 31,	
	2017	2018
Cash and cash equivalents	€ 273,820	€ 207,240
Total assets	293,183	229,478
Total shareholders' equity	101,457	20,939
Total non-current liabilities	164,620	169,291
Total current liabilities	27,106	39,248
Total liabilities	191,726	208,539
Total liabilities and shareholders' equity	293,183	229,478

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements.*

*Our audited consolidated financial statements have been prepared in accordance with IFRS, as issued by the IASB, as of and for the years ended December 31, 2017 and 2018.*

### 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. We are evaluating our most advanced drug candidate, elafibranor, in a pivotal Phase 3 clinical trial as a potential treatment for nonalcoholic steatohepatitis, or NASH, and as a potential treatment for primary biliary cholangitis, or PBC. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial in PBC. 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, 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. We believe elafibranor, if approved, has the potential to become a first-line treatment as a monotherapy and the backbone of combination regimens.

Elafibranor, a dual agonist of the nuclear receptors PPAR $\alpha$  and PPAR $\delta$ , is currently in Phase 3 development for the treatment of NASH. In our Phase 2b clinical trial, elafibranor achieved resolution of NASH without worsening of fibrosis, which is the primary endpoint of our ongoing global Phase 3 clinical trial. We have already achieved the enrollment necessary to perform an interim cohort analysis and expect to report interim results by the end of 2019. We believe these results, if positive, could support accelerated approval from the U.S. Food and Drug Administration, or FDA, and conditional approval from the European Medicines Agency, or EMA, as early as 2020. Elafibranor has received fast track designation from the FDA for the treatment of NASH.

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 pruritis that have been associated with approved PBC treatments. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial of elafibranor for the treatment of PBC. Elafibranor met the primary endpoint of the trial, which was the change at week 12 in serum alkaline phosphatase, or ALP, from baseline, with statistical significance compared to placebo in both doses evaluated. Elafibranor also achieved with high



statistical significance compared to placebo, the composite endpoint of ALP and bilirubin. That endpoint, which has been used for drug registration, is 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%. Based on these positive results, we plan to advance our PBC program into Phase 3 development.

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 diagnosis 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 IVD test is a novel, standalone diagnostic 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 our IVD test has the potential to benefit patients, improve overall clinical care and greatly reduce barriers to entry for innovative therapies like elafibranor by facilitating the diagnosis and identification of NASH patients to be treated. We anticipate submitting our IVD test for FDA marketing authorization in 2020.

We are also conducting 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. An investigator-initiated Phase 2 proof-of-concept trial to evaluate NTZ for the treatment of NASH patients with significant fibrosis began in December 2018.

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

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.

Since our inception, we have incurred significant operating losses. Our net loss was €79.5 million for the year ended December 31, 2018. 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, as well as our IVD test 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.

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. We use this tax credit to finance the increases in our headcount and to purchase scientific equipment.

#### *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 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 and information technology;
- grants to The NASH Education Program for the year 2017 (primarily for the purpose of 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; 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 our global Phase 3 clinical trial of elafibranor for the treatment of NASH. 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 our diagnostic test.

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 Education Program for 2018, primarily to support the creation of the first International NASH Day;
- fees for third-party providers of administrative services, including 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 increase in the future as we grow our support functions for the expected increase in our research and development activities and the potential commercialization of our drug and diagnostic candidates. We also anticipate increased 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 need 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.

### **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 and therefore generate only a modest amount of interest income.

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

### **Results of Operations for the Years Ended December 31, 2017 and 2018**

Our results of operations for the years ended December 31, 2017 and 2018 are summarized in the table below.

<u>(in thousands of euros)</u>	<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
	<u>Restated*</u>	
<b><u>Revenues and other income</u></b>		
Revenue	€ 118	€ 69
Other income	6,737	7,425
Revenues and other income	<u>6,856</u>	<u>7,494</u>
<b><u>Operating expenses and other operating income (expenses)</u></b>		
Research and development expenses	(54,189)	(67,024)
General and administrative expenses	(9,421)	(9,793)
Other operating income (expenses)	60	(162)
Operating loss	<u>(56,695)</u>	<u>(69,484)</u>
Financial income	642	728
Financial expenses	<u>(3,096)</u>	<u>(11,118)</u>
Financial loss	<u>(2,453)</u>	<u>(10,391)</u>
Net loss before tax	<u>(59,148)</u>	<u>(79,875)</u>
Income tax benefit	<u>(3,420)</u>	<u>354</u>
<b>Net loss</b>	<b><u>€ (55,728)</u></b>	<b><u>€ (79,521)</u></b>

(\*) In the context of the preparation of its 2018 consolidated financial statements, we restated the financial statements previously published for the 2017 fiscal year under IFRS. These changes do not affect the cash position or the operating results, and are mainly related to the application of IFRS to deferred taxes on the OCEANE bonds issued in October 2017. The corrections lead mainly to a decrease in the consolidated net loss of €2.9 million. More information is provided in Note 2.3 of our consolidated financial statements.

*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:

<u>(in thousands of euros)</u>	<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
CIR tax credit	€ 6,545	€ 7,295
CICE tax credit and other	171	130
Other government grants and subsidies	21	—
<b>TOTAL</b>	<b>€ 6,737</b>	<b>€ 7,425</b>

*Operating Expenses*

The tables below summarize our operating expenses for the years ended December 31, 2017 and 2018.

*Year Ended December 31, 2017*

<u>Operating expenses and other operating income (expenses) (in thousands of euros)</u>	<u>Total</u>	<u>Raw materials &amp; consumables used</u>	<u>Contracted research &amp; development activities conducted by third parties</u>	<u>Employee expenses</u>	<u>Other expenses (maintenance, fees, travel, taxes)</u>	<u>Depreciation, amortization &amp; impairment charges</u>	<u>Gain / (loss) on disposal of property, plant &amp; equipment</u>
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)
<b>TOTAL</b>	<b>€ (63,550)</b>	<b>€ (2,229)</b>	<b>€ (35,095)</b>	<b>€ (13,406)</b>	<b>€ (11,280)</b>	<b>€ (1,532)</b>	<b>€ (8)</b>

Year Ended December 31, 2018

Operating expenses and other operating income (expenses) (in thousands of euros)	Total	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 property, plant & equipment
Research and development expenses	€ (67,024)	€ (1,724)	€ (47,659)	€ (9,431)	€ (6,502)	€ (1,707)	—
General and administrative expenses	(9,793)	(130)	(2)	(4,194)	(5,738)	272	—
Other operating income (expenses)	(162)	—	—	—	(164)	—	2
<b>TOTAL</b>	<b>€ (76,979)</b>	<b>€ (1,855)</b>	<b>€ (47,662)</b>	<b>€ (13,625)</b>	<b>€ (12,403)</b>	<b>€ (1,435)</b>	<b>€ 2</b>

#### 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 nitazoxanide. 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 €9.8 million, or 13% of our total operating expenses, for the year ended December 31, 2018. These expenses consisted primarily of €5.7 million of costs and fees for third-party service providers, as well as €4.2 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 €2.4 million in other expenses was primarily the result of increases and fees and expenses in the preparation for the commercialization of elafibranor in NASH, 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 €1.3 million in employee-related expenses over the prior year period was primarily due to the exceptional 2017 bonuses not replicated in 2018.

### ***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.

### **Liquidity and Capital Resources**

#### **Overview**

As of December 31, 2017 and 2018, we had €273.8 million and €207.2 million, respectively, in cash and cash equivalents.

Since our inception, we have financed our operations primarily through the issuance of new ordinary shares and bonds convertible into new ordinary shares in public offerings and private financing transactions. In 2006, we completed the initial public offering of our ordinary shares on the Alternext market of Euronext in Paris. The listing of our ordinary shares was transferred to the regulated market of Euronext Paris in 2014. Between 2010 and 2016, we raised a total of over €220.0 million in gross proceeds from the issuance of additional ordinary shares for cash. In October 2017, we issued €180.0 million in bonds convertible into new ordinary shares or exchangeable for existing ordinary shares.

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 and €3.2 million associated with these types of arrangements as of December 31, 2017 and 2018, respectively. We also entered into loans with commercial banks and had an outstanding balance of €3.5 million and €4.0 million in bank loans as of December 31, 2017 and 2018, respectively.

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.

### Cash Flows

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

<u>(in thousands of euros)</u>	<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Cash flows used in operating activities	€ (49,856)	€ (56,081)
Cash flows used in investing activities	(2,948)	(3,986)
Cash flows provided by (used in) financing activities	174,348	(6,514)
	<u>€ 121,544</u>	<u>€ (66,580)</u>

#### Operating Activities

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

#### 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.

#### 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.



## Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. Our net loss was €55.7 million for the year ended December 31, 2017 and €79.5 million for the year ended December 31, 2018. 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, as well as our IVD test and our other drug candidates, in the United States, Europe and elsewhere. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- initiate and conduct our planned preclinical studies and clinical trials of our drug candidates, including our ongoing pivotal Phase 3 clinical 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 our IVD test 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 our IVD test 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, 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 prospectus 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 and the proceeds of the global offering. 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, 2018 will be sufficient to fund our operations for at least the next 12 months.

## Contractual Obligations

The following table discloses aggregate information about our material contractual obligations and the periods in which payments are due as of December 31, 2018. Future events could cause actual payments and timing of payments to differ from the contractual cash flows set forth below.

Contractual obligations (in thousands of euros)	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 bonds	1,312	—	159,176	—	160,489
Bank loans	1,319	2,047	598	—	3,964
Equipment leases	520	1,048	333	—	1,900
Pension and employee benefits	—	—	—	1,085	1,085
Other	10	—	—	—	10
<b>Total liabilities</b>	<b>3,161</b>	<b>3,095</b>	<b>160,108</b>	<b>4,314</b>	<b>170,678</b>
Operating leases	1,213	2,426	836	316	4,791
<b>Total contractual obligations</b>	<b>€ 4,374</b>	<b>€ 5,521</b>	<b>€ 160,944</b>	<b>€ 4,630</b>	<b>€ 175,469</b>

The nominal amount of the convertible loan of €180.0 million is due in less than 4 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 precommercial 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 cancelable contracts and are not included in the contractual obligations in the foregoing table.

We also make donations to 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, 2018, our board of directors approved a maximum grant of €1.6 million primarily to support the creation of the first International NASH Day, while also continuing to contribute funds to patient registry, our contribution was limited to €959 to The NASH Education Program during the year.

For the year 2019, our board of directors approved a grant of an amount of €200 to the Nash Education Program.

#### ***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, 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.

#### ***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 7.3%, 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 and 2018, 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 and €4.0 million as of December 31, 2017 and 2018, 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.

### **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.

### **Off-Balance Sheet Arrangements**

During the periods presented, we did not and do not currently have any off-balance sheet arrangements as defined under Securities and Exchange Commission, or SEC, rules, such as relationships with other 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 statements of financial position.

### **Critical Accounting Policies and Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with IFRS as issued by IASB. Some of the accounting methods and policies used in preparing our consolidated financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. The actual value of our assets, liabilities and shareholders' 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 2 to our consolidated financial statements for a description of our significant accounting policies.

### **Recent Accounting Pronouncements**

#### ***Adopted as of January 1, 2018***

We adopted the following new standards, interpretations and amendments to standards, including any consequential amendments to other standards, with a date of initial application as of January 1, 2018:

- IFRS 9 *Financial Instruments*. The IASB issued the final version of IFRS 9 Financial Instruments in July 2014. IFRS 9 is effective for annual periods beginning on or after January 1, 2018, with early adoption permitted. We applied IFRS 9 initially on January 1, 2018 and will not restate comparative information for prior periods. The first application of IFRS 9 did not have a material impact on our consolidated financial statements.
- IFRS 15 *Revenue from Contracts with Customers* establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces existing revenue recognition guidance, including IAS 18 Revenue, IAS 11 Construction Contracts, IFRIC 13

Customer Loyalty Programmes, IFRIC 15 Agreements for the Construction of Real Estate, IFRIC 18 Transfers of Assets from Customers and SIC 31 Barter Transactions Involving Advertising Services. IFRS 15 is effective for the annual periods beginning on or after January 1, 2018, with early adoption permitted. The standard establishes a five-step model that will apply to revenue earned from a contract with a customer. Extensive disclosures will be required, including disaggregation of total revenue, information about performance obligations, changes in contract asset and liability account balances between periods and key judgements and estimates. The first application of IFRS 15 did not have a material impact on our consolidated financial statements.

- Classification and Measurement of Share-based Payment Transactions (Amendments to IFRS 2) issued on June 20, 2016 covers three accounting areas: the measurement of cash-settled share based payments; the classification of share-based payments settled net of tax withholdings; and the accounting for a modification of a share-based payment from cash-settled to equity-settled. The amendments are effective for annual periods commencing on or after January 1, 2018. As a practical simplification, the amendments can be applied prospectively so that prior periods do not have to be restated. Retrospective, or early application is permitted if companies have the required information. The amendments did not have a material impact on our consolidated financial statements.
- IFRIC 22 *Foreign currency transactions and Advance consideration* issued on December 8, 2016, clarifies the transaction date to be used to determine the exchange rate for translating foreign currency transactions involving an advance payment or receipt. The interpretation is effective for annual periods beginning on or after January 1, 2018, with earlier adoption permitted. The amendments did not have a material impact on our consolidated financial statements.

The adoption of these standards, interpretations and amendments to standards did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2018.

### **Not Yet Adopted**

A number of new standards, amendments to standards and interpretations were not yet effective for the years ended December 31, 2017 or 2018 and have not been applied in preparing our consolidated financial statements:

- IFRS 16 *Leases*, published on January 13, 2016, makes a distinction between a service contract and a lease based on whether the contract conveys the right to control the use of an identified asset and introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognizes a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are optional exemptions for short term leases and leases of low value items. Lessor accounting remains similar to the current standard—i.e. lessors continue to classify leases as finance or operating leases. For lessors, there is little change to the existing accounting in IAS 17 Leases. IFRS 16 replaces existing leases guidance including IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. The standard is effective for annual periods beginning on or after January 1, 2019. Early adoption is permitted for entities that apply IFRS 15 Revenue from Contracts with Customers at or before the date of initial application of IFRS 16. We will adopt IFRS 16 as of January 1, 2019. An assessment of the impact of IFRS 16 has not been finalized to date, but we expect that the most significant impact will be that we will recognize new assets and liabilities for our operating leases. In addition, the nature and recognition of expenses related to those leases will change as IFRS 16 replaces the straight-line operating lease

expense with a depreciation charge for right-of-use assets and interest expense on lease liabilities.

- Annual improvements to IFRS's 2015-2017 Cycle, issued on December 12, 2017, covers the following minor amendments:
  - IFRS 3 *Business Combinations*: the amendments clarify that a company remeasures its previously held interest in a joint operation when it obtains control of the business;
  - IFRS 11 *Joint Arrangements*: the amendments clarify that a company does not remeasure its previously held interest in a joint operation when it obtains joint control of the business;
  - IAS 12 *Income Taxes*: the amendments clarify that a company accounts for all income tax consequences of dividend payments consistently with the transactions that generated the distributable profits—i.e. in profit or loss, OCI or equity; and
  - IAS 23 *Borrowing Costs*: the amendments clarify that a company treats as part of general borrowings any borrowing originally made to develop an asset when the asset is ready for its intended use or sale.
- IFRIC 23 *Uncertainty over Income Tax Treatments* issued on June 7, 2017, clarifies how to apply the recognition and measurement requirements in IAS 12 when there is uncertainty over income tax treatments. In such a circumstance, an entity shall recognize and measure its current or deferred tax asset or liability applying the requirements in IAS 12 based on taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates determined applying this Interpretation. An entity is required to assume that a tax authority with the right to examine and challenge tax treatments will examine those treatments and have full knowledge of all related information. Detection risk is not considered in the recognition and measurement of uncertain tax treatments. The entity should measure the impact of the uncertainty using the method that best predicts the resolution of the uncertainty; either the most likely amount method or the expected value method. The interpretation is effective for annual periods beginning on or after January 1, 2019, with earlier adoption permitted. The amendments are not expected to have a material impact on our consolidated financial statements.
- Amendments to IAS 19: *Plan Amendment, Curtailment or Settlement*. This amendment to IAS 19, applicable for fiscal years beginning on January 1, 2019, clarified the assumptions to use for the remeasurement and the effect on the requirements regarding the asset ceiling when a plan amendment, curtailment or settlement occurs. The amendments are not expected to have a material impact on our consolidated financial statements.

## 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 portion of our operating expenses is denominated in U.S. dollars, and as result we may be exposed to foreign currency risk. For the year ended December 31, 2018, these expenses totaled \$9.6 million based on the exchange rate in effect at December 31, 2018, or less than 10% of our total operating expenses for the year. 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 €1.0 million for the year. For the year ended December 31, 2018, we realized a foreign exchange rate loss of €26, 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.

In 2018, we considered the implementation of appropriate hedging arrangements without ultimately using any such arrangements.

We do not currently have material revenues in dollars or any currency other than euros.

### ***Interest Rate Risk***

We are exposed to interest rate risk related to our cash and cash equivalents. We had cash and cash equivalents of €207.2 million as of December 31, 2018, 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 have not been significant.

We had net outstanding debt of €160.5 million as of December 31, 2018 in the form of convertible loans, which loans accrue interest at a fixed rate of 3.5% and for which the gross amount is €180,000. We also had outstanding at December 31, 2018 a total of €3.2 million in conditional advances from BPI France, €1.9 million of obligations under finance leases and €4.0 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.

### **JOBS Act Exemptions and Foreign Private Issuer Status**

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than \$1.07 billion in total annual gross revenue, have more than \$700.0 million in market value of our ordinary shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these provisions that allow for reduced reporting and other burdens.

We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act of 1933, as amended, 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.

Upon consummation of the global offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private

issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and
- Regulation FD, which regulates selective disclosures of material information by issuers.



## BUSINESS

### 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. We are evaluating our most advanced drug candidate, elafibranor, in a pivotal Phase 3 clinical trial as a potential treatment for nonalcoholic steatohepatitis, or NASH, and as a potential treatment for primary biliary cholangitis, or PBC. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial in PBC. 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, 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. We believe elafibranor, if approved, has the potential to become a first-line treatment as a monotherapy and the backbone of combination regimens.

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.

Elafibranor, a dual agonist of the nuclear receptors PPAR $\alpha$  and PPAR $\delta$ , is currently in Phase 3 development for the treatment of NASH. In our Phase 2b clinical trial, elafibranor achieved resolution of NASH without worsening of fibrosis, which is the primary endpoint of our ongoing global Phase 3 clinical trial. We have already achieved the enrollment necessary to perform an interim cohort analysis and expect to report interim results by the end of 2019. We believe these results, if positive, could support accelerated approval from the U.S. Food and Drug Administration, or FDA, and conditional approval from the European Medicines Agency, or EMA, as early as 2020. Elafibranor has received fast track designation from the FDA for the treatment of NASH.

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 pruritis that have been associated with approved PBC treatments. In December 2018, we announced positive preliminary results from our Phase 2 clinical trial evaluating elafibranor for the treatment of PBC. Elafibranor met the primary endpoint of the trial, which was the change at week 12 in serum alkaline phosphatase, or ALP, from baseline, with statistical significance compared to placebo in both doses evaluated. Elafibranor also achieved with high statistical significance compared to placebo, the composite endpoint of ALP and bilirubin. That endpoint, which has been used for drug registration, is 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%. Based on these positive results, we plan to advance our PBC program into Phase 3 development.

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 diagnosis 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 IVD test is a novel, standalone diagnostic 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 our IVD test has the potential to benefit patients, improve overall clinical care and facilitate the identification of NASH patients to be treated. We anticipate marketing our IVD test first as a laboratory-developed test, or LDT, in 2019, and then submitting our IVD test for FDA marketing authorization in 2020. In January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space.

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.

Our TGFTX1 preclinical program is focused on the discovery and development of innovative drug candidates targeting ROR $\gamma$ t, 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. We have retained worldwide rights to all of our programs.

PROGRAM	INDICATION	TARGET	DEVELOPMENT STAGE				TIMELINE
			PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	
Elafibranor	ADULT NASH	PPAR $\alpha/\delta$	PHASE 3				Publication of Phase 3 interim results End 2019
	PBC	PPAR $\alpha/\delta$	PHASE 2				Positive Phase 2 data announced December 2018
	PEDIATRIC NASH	PPAR $\alpha/\delta$	PHASE 2				Phase 2 In progress; enrollment expected to begin in 2019
Nitazoxanide	FIBROSIS	Stellate cell activation	PHASE 2				Phase 2 proof of concept initiated December 2018
TGFTX1	AUTO-IMMUNE DISEASES (eg., psoriasis, respiratory)	ROR $\gamma$ t	Pre-IND studies				In progress (mild to moderate psoriasis)
PROGRAM	INDICATION	DEVELOPMENT				TIMELINE	
Diagnostic	NASH	<ul style="list-style-type: none"> <li>Currently finalizing analytical and clinical study designs</li> <li>2018: alignment with FDA on path forward to validate NIS4</li> <li>Discovery of two key miRNA biomarkers in 2015</li> </ul>				<ul style="list-style-type: none"> <li>License agreement with LabCorp – January 2019</li> <li>LDT anticipated release in 2019</li> <li>Regulatory submission for IVD clearance in 2020</li> </ul>	

Our current chief executive officer co-founded our company in 1999 and our shares have been listed on the Euronext Paris under the symbol "GNFT" since 2006. 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 over 150 employees at our offices in Lille and Paris, France and Cambridge, Massachusetts. The chair of our scientific advisory board, Bart Staels, is a 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.

## Our Strengths

We believe the following strengths will allow us to continue to build upon our leadership position in drug and diagnostic development for metabolic and liver-related diseases and achieve our goal of commercializing our drug and diagnostic candidates:

- **Our lead product candidate, elafibranor, is in Phase 3 development for the treatment of NASH, an indication for which there are no approved drugs today, but which presents significant market opportunity.** In April 2018, we announced that we had achieved the recruitment goal of 1,000 patients for the interim cohort in our global Phase 3 clinical trial being conducted in 25 countries. We expect to report the results of our interim cohort analysis by the end of 2019, which, if positive, could support accelerated approval from the FDA and conditional approval from the EMA as early as 2020. If approved, elafibranor has the potential to be the first FDA-approved therapy to achieve resolution of NASH without worsening of fibrosis that could also have the benefit of addressing cardiovascular risk factors.
- **We recently announced positive preliminary results from our Phase 2 clinical trial of elafibranor for the treatment of PBC and plan to commence Phase 3 development.** In December 2018, we announced that elafibranor met the primary endpoint of our Phase 2 clinical trial, which was the change at week 12 in serum 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, 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 plan to advance our PBC program into Phase 3 development in 2019.
- **Elafibranor's results on NASH resolution, its good tolerability and lack of demonstrated safety concerns make it well-positioned among late-stage NASH programs.** We believe elafibranor has a favorable tolerability profile based on the results of our Phase 1 and Phase 2 trials. Also, in our Phase 2b clinical trial, we observed elafibranor's ability to resolve NASH without the worsening of fibrosis, which is the primary endpoint of our ongoing global Phase 3 clinical trial. We also observed a decrease in cardiovascular risk factors, an important observation considering the close link between NASH and cardiometabolic disease, and one that has not been reported in other drugs in Phase 3 development for NASH. Elafibranor is, to our knowledge, the only drug currently permitted to be developed for the treatment of children with NASH. We hold over 350 patents and patent applications relating to elafibranor, and the patent covering the use of elafibranor for the treatment of NASH does not expire until 2030, without taking into account any extensions.
- **We are a recognized leader in the NASH field.** We are actively involved in the NASH stakeholder community, as a member of the steering committee and co-leader of a working group of The Liver Forum. We also participate in academic consortia, such as the biomarkers consortia in the United States and Europe, and 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. These programs provide us with insight from the key stakeholders in NASH and our leadership position enables us to establish credibility with and convey these insights to regulators and payors.
- **Our diagnostic program has the potential to expand market opportunity through better patient identification and stratification.** Our IVD test is designed to identify NASH patients who may be appropriate candidates for drug intervention. We believe that broad adoption of our non-invasive, accessible test, if validated and authorized for marketing, could not only help solve the problem of NASH under-diagnosis, but also provide physicians with a tool to identify

patients who would benefit from treatment with elafibranor or any other appropriate drug. In January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space.

- **Our pipeline extends beyond elafibranor.** 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 with elafibranor 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.
- **Our experienced team is comprised of industry leaders in metabolic and liver-related diseases.** 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.

## Our Strategy

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

- **Obtain regulatory approval for, and commercialize, elafibranor for the treatment of NASH.** We are currently conducting our Phase 3 registrational trial, RESOLVE-IT, evaluating the efficacy and safety of a once-daily 120 mg dose of elafibranor in patients with NASH and fibrosis. We expect to enroll approximately 2,000 patients in this double-blind, placebo-controlled trial and in April 2018, we announced that we had achieved the recruitment goal of 1,000 patients necessary for the interim cohort analysis. We plan to announce results from our interim analysis at the end of 2019 and, if positive, use these results to support an accelerated regulatory approval pathway (Subpart H) in the United States and conditional approval in Europe. If approved, we may decide to market elafibranor for NASH in certain territories on our own and in other territories in collaboration with one or more pharmaceutical partners or specialized local distributors.
- **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. We plan to discuss our clinical development program with the FDA and to advance our PBC program into Phase 3 development in 2019.
- **Complete development and prepare for potential commercialization of our NASH IVD test.** In 2017, we began the product and regulatory development phases for our novel, blood-based IVD test designed to identify patients with NASH who may be appropriate candidates for drug therapy and to offer an attractive means of decreasing the need for liver biopsies. We will initially market the test as an LDT in 2019 and then seek to obtain FDA marketing authorization of our IVD test in 2020 in parallel with commercialization of elafibranor. We believe that, if validated and authorized for marketing, our non-invasive, blood-based and accessible IVD test can easily integrate into routine clinical care for the comprehensive management of NASH. We are currently in discussions with multiple global diagnostic partners to discuss worldwide commercialization of our IVD test. Our license agreement with LabCorp allows for the deployment of our IVD test in the clinical research space through its central

laboratories which we believe will provide expanded access to, and further validation of our IVD test and generate new biological insights on NASH disease pathogenesis.

- **Advance other drug candidates in our pipeline, both alone and in combination with elafibranor.** In addition to developing our other drug candidates to independently target metabolic and liver-related diseases, we believe elafibranor's unique approach in targeting PPAR $\alpha$  and PPAR $\delta$  creates opportunities to explore combination therapies, either with our other drug candidates, third-party drug candidates or approved drugs. 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 and as combination therapy with elafibranor. We also plan to explore opportunities to expand the use of elafibranor through combination therapies such as with farnesoid X receptor, or FXR, agonists, Acetyl-CoA Carboxylase, or ACC, inhibitors and our drug candidate NTZ as part of our strategy in NASH.
- **Actively manage our development pipeline and opportunistically enter into strategic collaborations.** We plan to continue to strengthen our development pipeline by in-licensing rights to drug candidates in Phase 1 or Phase 2 clinical development in our therapeutic areas of interest. We may sign a licensing agreement or co-marketing agreement with one or more pharmaceutical laboratories with the financial capacity and specific expertise to successfully conduct clinical trials and bring drugs to market.
- **Increase public awareness of NASH through The NASH Education Program.** 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.

## Our Drug Candidates and Diagnostic Development Programs

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

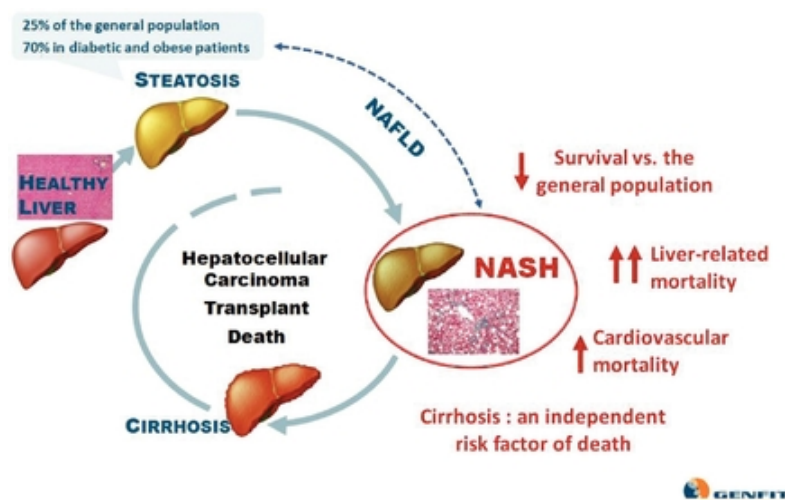
#### Overview

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.



### 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<sup>34</sup>) and significant fibrosis (F<sup>32</sup>) 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 our drug candidate elafibranor as a first-line treatment for patients with NASH and developing an IVD test to aid in the diagnosis of at-risk NASH patients.

Elafibranor (previously known as GFT505) is a dual-agonist acting simultaneously on two nuclear receptors, PPAR $\alpha$  and PPAR $\delta$ , 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 PPAR $\alpha$  as well as PPAR $\delta$  confer anti-inflammatory activities through the repression of independent and complementary pathways. Thus, the dual activation of PPAR $\alpha$  and PPAR $\delta$  is thought to be advantageous over single agonism of either of the targets alone.
- PPAR $\alpha$  and PPAR $\delta$  in the liver increase mitochondrial  $\beta$ -oxidation which can lead to fatty acid degradation, or catabolism, and the decrease of liver fat.
- The activation of PPAR $\alpha$  decreases oxidative stress, which occurs in part through the upregulation of anti-oxidant genes.
- PPAR $\alpha$  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 PPAR $\delta$  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.
- PPAR $\alpha$  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. Similarly 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. We believe that with its unique mechanism of action, by activating both PPARα and PPARδ, elafibranor has the potential to modulate many of the key hallmarks of NASH, and, if approved, could be well-positioned as a first-line treatment as a monotherapy and the backbone of combination regimens.

#### *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 250 sites throughout the world. We plan to perform an interim analysis of the first 1,000 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<sup>34</sup>) 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 will be performed on the interim cohort comprised of the first 1,000 patients enrolled and after a 72 weeks of treatment, is the proportion of elafibranor-treated patients achieving NASH resolution without worsening of fibrosis as compared to placebo. This will be done by comparing a patient's liver biopsy at the end of the 72 week treatment period with their initial liver biopsy. The trial also has a key secondary histological endpoint, fibrosis improvement without the worsening of NASH, which we believe may be included in the drug label if this endpoint is met and if elafibranor receives approval.

In April 2018, we announced that we had achieved enrollment of the first 1,000 patients in the interim cohort. The Subpart H approval pathway we are pursuing requires us to continue 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 will also 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 250 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.

Four pre-planned safety reviews of the data have been already performed by the DSMB. In each of the reviews, including the most recent one in December 2018, the DSMB has 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.

We expect to report data from the interim cohort analysis by the end of 2019. If the results of the interim analysis are positive, we expect to apply for accelerated approval from the FDA and conditional marketing approval from the EMA in 2020.

#### *GOLDEN-505—Our Phase 2b Clinical Trial*

The efficacy and safety of elafibranor, to date, 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<sup>3</sup> 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 <sup>(1)</sup>
274	All patients (ITT)	12% (n=92)	13% (n=93)	19% (n=89)	0.045
234	NAS $\geq$ 4	9% (n=76)	13% (n=83)	19% (n=75)	0.013
204	NAS $\geq$ 4 with fibrosis (any stage)	11% (n=66)	15% (n=67)	20% (n=71)	0.009

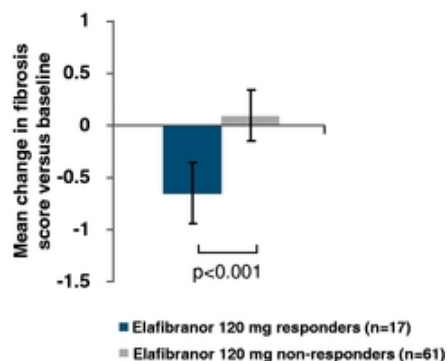
(1) P-value represents the statistical significance between two groups. A p-value <0.05 denotes significant difference and means that there is < 5% likelihood that the observed results occurred by chance. The p-values in the table are comparisons between the elafibranor 120 mg and placebo groups. The 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 $\geq$ 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 $\geq$ 4) and fibrosis (F $\geq$ 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.

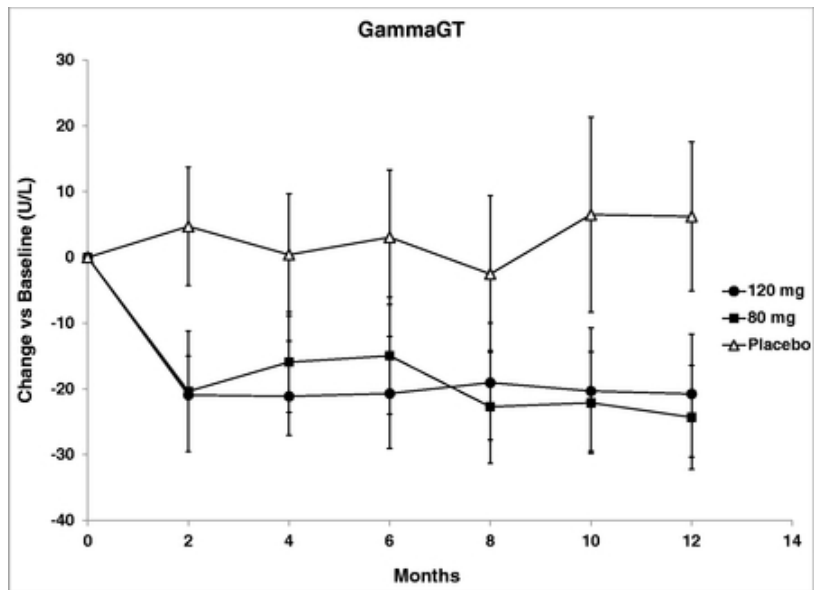
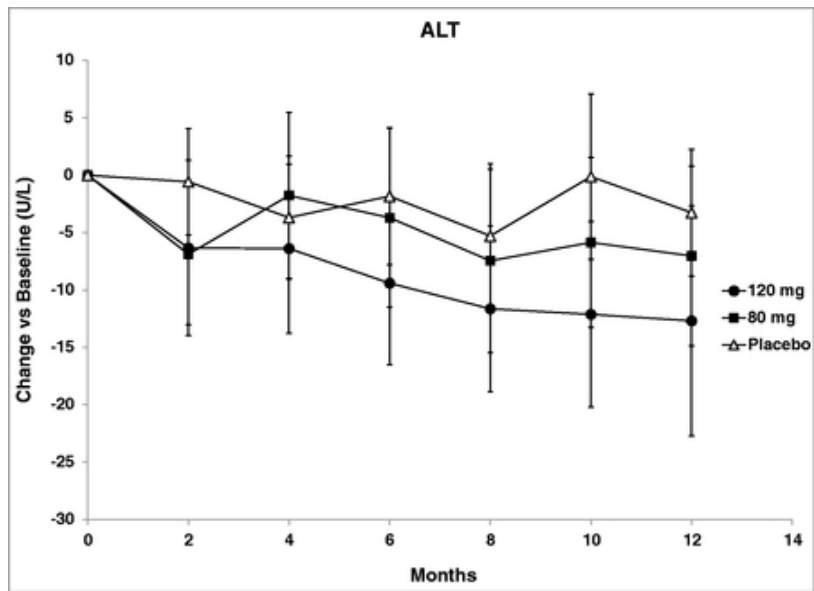
In addition, we conducted a post hoc analysis to take into account differences in the standard of care across centers and baseline severity. In patients recruited in centers with at least one patient with active NASH (NAS<sup>34</sup>) in the three treatment arms of the trial, 26% in the elafibranor 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.

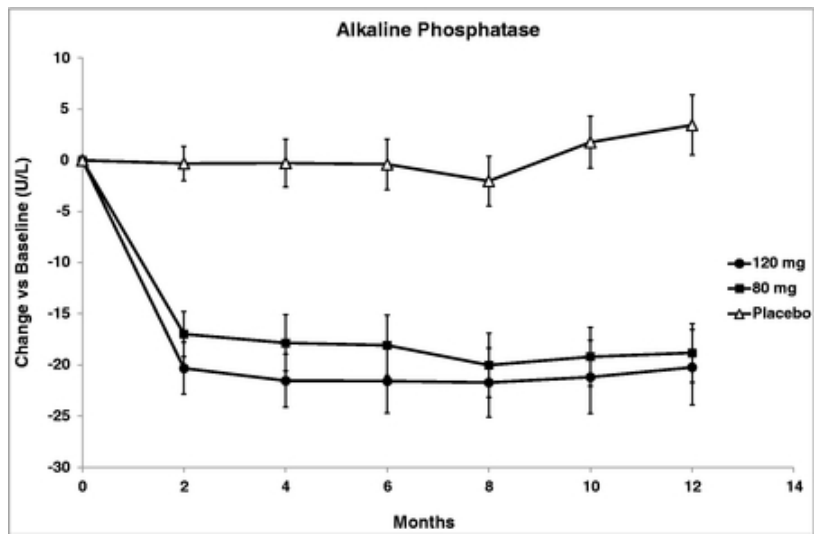
Importantly, patients who achieved NASH resolution when treated with elafibranor ("responders") experienced a parallel decrease in fibrosis score compared to elafibranor patients who did not achieve NASH resolution ("non-responders"), as depicted in the figure below. Although the trial was not designed 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**



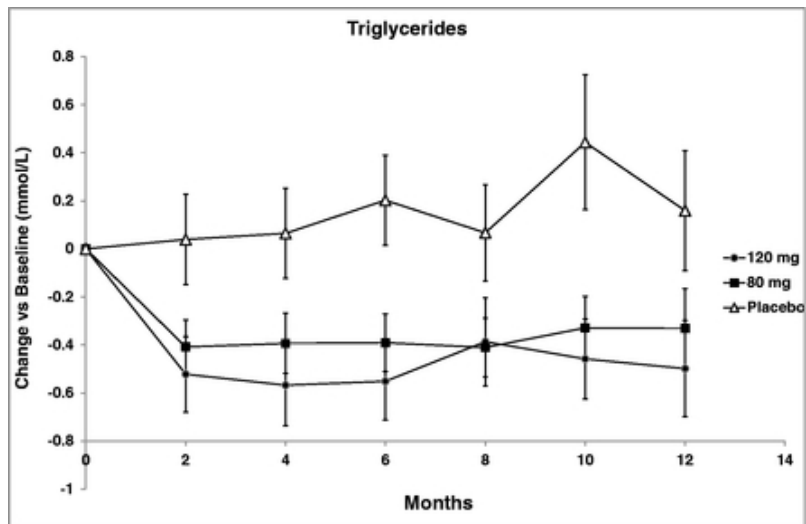
Patients treated with elafibranor experienced improvement in circulating markers of liver dysfunction such as ALT, GGT and alkaline phosphatase, or ALP. The charts below show the changes in ALT, GGT and ALP from baseline over the course of the treatment period of the trial. These results were published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

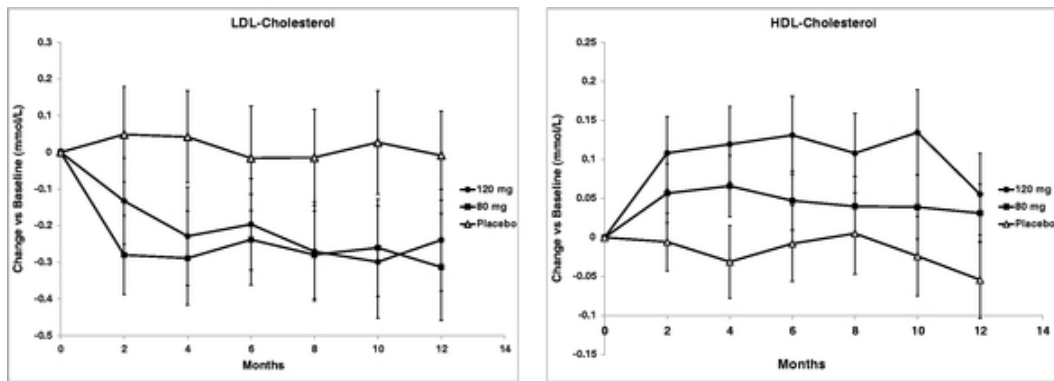




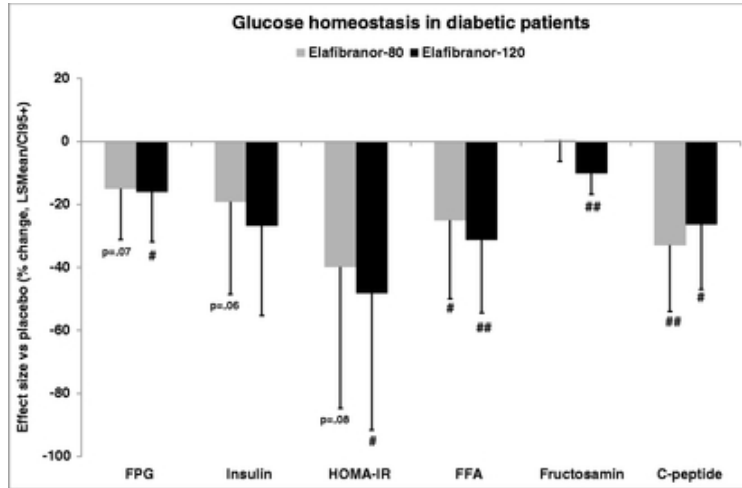
In addition, in our evaluation of the secondary endpoints, we observed therapeutic activity of elafibranor 120 mg on the following cardiometabolic risk factors associated with NASH, which we believe is commensurate with elafibranor providing a beneficial cardiometabolic profile:

*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.

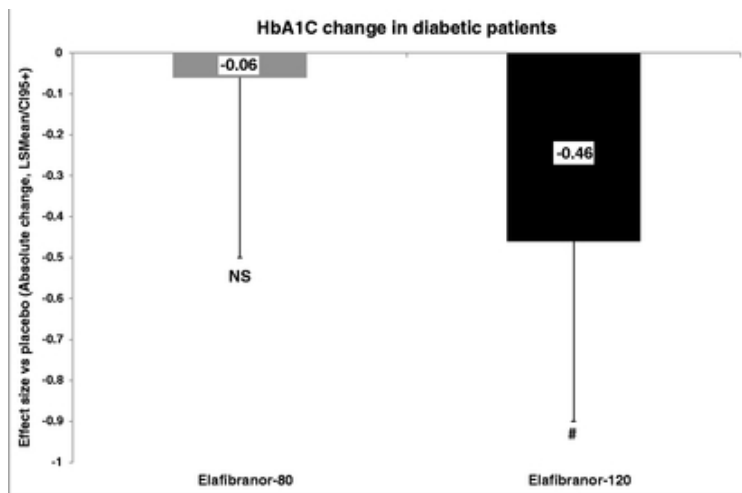




*Improved insulin sensitivity and glucose metabolism in diabetic patients.* The following charts show the effects of elafibranor compared to placebo on a number of insulin sensitivity and glucose metabolism measures observed during the trial.

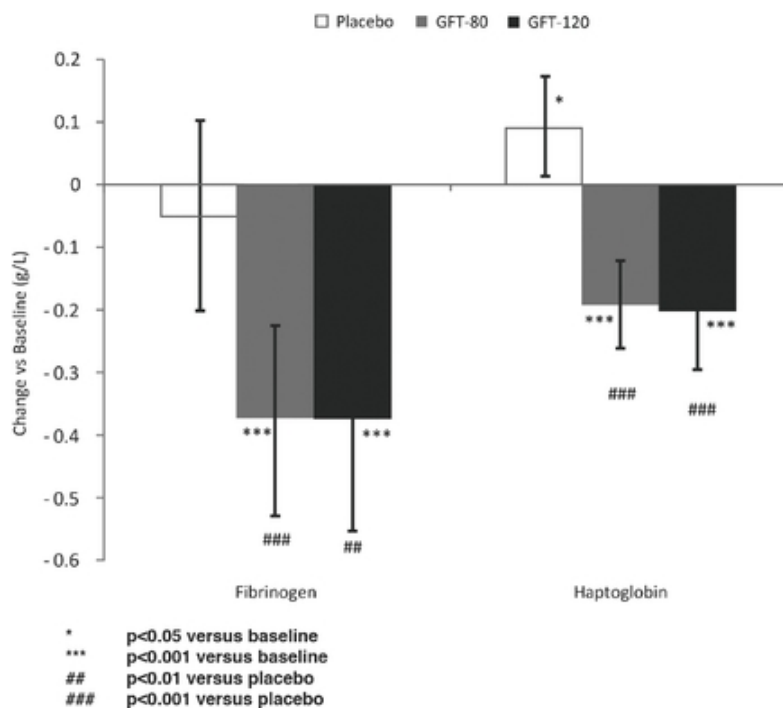


# p<0.05 versus placebo  
## p<0.01 versus placebo



# 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-naïve 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 mIU/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 mIU/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

To date, the elafibranor Phase 1 program to assess the safety and tolerability as well as pharmacokinetic profile of elafibranor comprises 12 clinical trials performed in single Phase 1 clinical research centers. This Phase 1 program has included 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.

To date, 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 PPAR $\gamma$ . This confirmed selectivity of elafibranor for the two other forms of PPARs: PPAR $\alpha$  and PPAR $\delta$ .

#### *Regulatory Pathway for Treatment of NASH*

In February 2014, the FDA granted fast track designation to elafibranor for the treatment of NASH. If the results of the interim analysis of our Phase 3 clinical trial are positive, we plan to apply for accelerated marketing approval from the FDA under Subpart H and conditional approval from the EMA in 2020. Like all companies using the Subpart H and conditional approval pathway, we must continue the trial post-marketing in order to demonstrate the efficacy of elafibranor on clinical benefit within the full 2,000 patient population. We will evaluate a composite endpoint of clinical outcomes which include all-cause mortality, the progression to cirrhosis, and a full list of cirrhosis-related events such as liver transplantation, Model for End-Stage Liver Disease, or MELD score  $\geq 15$ , and hepatocellular carcinoma, or HCC, on the full trial population, with the goal of obtaining full marketing approval. The Phase 3 trial will remain blinded, and all patients will be maintained under treatment and followed until the occurrence of a pre-defined number of progressions to clinical outcomes.

#### *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 will be conducted in U.S. clinical centers specializing in NASH pediatrics. We expect to begin enrolling patients in this clinical trial in 2019.

#### *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 evaluating 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.

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.

Finally, at the annual meeting of the AASLD in San Francisco in November 2018, 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.

## ***IVD Test for the Diagnosis of NASH***

As part of our strategy to address the unmet needs in NASH, we have advanced a diagnostic program based on the in-house discovery that specific microRNA, or miRNA, which are short non-coding RNA molecules that are master regulators of many biological processes, are expressed at different levels in patients with NASH. This discovery kicked off a multi-year effort that has resulted in the development of what we target to be the first validated diagnostic test to identify patients with NASH who may be appropriate candidates for treatment. In January 2019, we entered into a license agreement with LabCorp to allow them to deploy our IVD test in the clinical research space.

### *Circulating Biomarkers and miRNA*

Biomarkers are characteristics of the body that can be objectively measured and correlate to a biological state or 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 different markers can be used to not only identify but also monitor the evolution 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.

### *Today's Challenges in Diagnosing NASH*

NASH is a silent, asymptomatic disease. Patients with NASH are often unaware of their disease until their condition progresses to more serious and life-threatening stages. The identification of patients with NASH and early fibrosis is a key area of major unmet need since medical intervention at this stage can help prevent or attenuate adverse clinical outcomes.

A liver biopsy is the clinical standard to formally diagnose NASH and assess the stage of fibrosis in a patient suspected of having NASH. However, the liver biopsy is an invasive procedure that presents a number of limitations, including:

- pain, discomfort and bleeding;
- potential mortality;
- high cost; and
- low levels of patient acceptance.

In addition, there are a limited number of specialists who are able to perform and interpret liver biopsies when considering the anticipated increase in clinical cases over the next 10 years. Furthermore, there are roughly 1,000 to 2,000 practicing hepatologists in the United States, which limits the

availability of the liver biopsy procedure to adequately diagnose these patients. As such there is a clear unmet need and market opportunity for the development of non-invasive diagnostics in NASH.

No FDA-cleared diagnostic tests indicated for NASH exist and the currently available diagnostics are either general tools for the management of chronic liver disease patients, such as FibroScan or Magnetic Resonance Elastography, or are not widely accessible, such as MRI-based technologies. The following table depicts some of the currently available diagnostic approaches for NAFLD and liver fibrosis, including their benefits and limitations:

NAFLD	Liver Fibrosis
<ul style="list-style-type: none"> <li>• <b>Ultrasound</b> <ul style="list-style-type: none"> <li>• Adequate for detection of fatty liver in patients at risk of NAFLD</li> <li>• Low accuracy for mild steatosis</li> <li>• Low cost and wide availability</li> </ul> </li> <li>• <b>MRI</b> <ul style="list-style-type: none"> <li>• High performance in detecting low grade of steatosis</li> <li>• Low availability, high costs and long exam time, potentially limiting use in daily medical practice</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Ultrasound Elastography (Fibroscan, ElastQ)</b> <ul style="list-style-type: none"> <li>• Diagnostic performances for F3 and F4 are good but limited when F&lt;3</li> <li>• Limited to specialist's office</li> </ul> </li> <li>• <b>MRE</b> <ul style="list-style-type: none"> <li>• Potential for detecting F&lt;3</li> <li>• Low availability, high costs, long exam time</li> </ul> </li> <li>• <b>Fibrosis scores (NASH FibroSure and equivalent scores)</b> <ul style="list-style-type: none"> <li>• Diagnostic performances are good for F3 and F4 but degrade when F&lt;3</li> <li>• Not validated in large cohorts of NAFLD/NASH patients in intended use NAFLD</li> </ul> </li> </ul>

Therefore, there is a high unmet need for a validated, highly-specific test to identify patients with NASH and fibrosis as an alternative to the liver biopsy for use in the clinical research and clinical care settings. We believe our diagnostic test, if validated and approved for marketing, may directly address this clinical gap.

#### *Our Solution: IVD Test Based on Our Biomarker Algorithm*

Aware of the challenges associated with diagnosing NASH, we initiated a program to combine our technical expertise in informatics, machine learning and next-generation sequencing 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 differentially expressed in patients with NASH and early fibrosis.

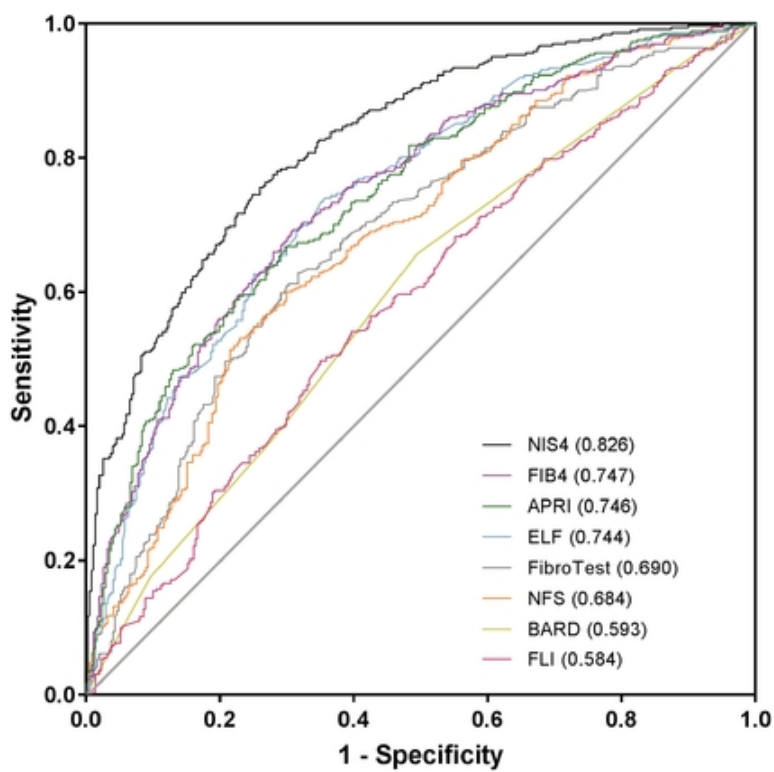
Since then, we have further refined the diagnostic test and have ultimately found four unique biomarkers that we believe provide the best overall diagnostic performance: alpha-2-macroglobulin, chitinase-3-like protein 1, hemoglobin A1c, and microRNA-34a. Our diagnostic test combines the results from these four independent assays through a single proprietary algorithm, referred to as NIS4, to assist in identifying patients with both NASH and significant fibrosis who should be considered for therapeutic intervention with elafibranor or any other suitable therapeutic. We intend to market our IVD test, if it receives 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.

Using data from our elafibranor development program, we have assessed the predictive value of our IVD test in samples from 687 patients, representing a merged cohort comprising 220 patients from our GOLDEN-505 Phase 2b clinical trial and the first 467 patients screened in our RESOLVE-IT Phase 3 clinical trial. In testing our IVD test, we utilized the initial liver biopsy and blood sample from each patient. We compared the results of our IVD test on the blood sample to the patient's initial liver biopsy to evaluate whether our IVD test was an accurate predictor of the patient's levels of NASH and fibrosis. We tested our IVD test's ability to sort patients with NAS<sup>3</sup>4 and F<sup>3</sup>2 from patients with



NAS<4 or F<2 in this cohort of prospectively enrolled patients suspected of 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. The AUROC is expressed as a ratio of these two measures, with the maximum score being 1.0.

Our IVD test outperformed currently available blood-based biomarkers when assessed in a head-to-head comparison from 687 patients with a full set of biochemical parameters. As depicted in the figure below, our IVD test, labeled as NIS4, achieved an AUROC = 0.83 (95% CI 0.7965 - 0.8557), compared to the following currently available biomarkers: the Fib-4 Index (FIB4), the NAFLD Fibrosis Score (NFS), the Enhanced Liver Fibrosis Score (ELF), the Fatty Liver Index Score (FLI), the BARD Score (BARD), the AST to Platelet Ratio Score (APRI) and the FibroTest.



An assessment of the NIS4 IVD test results based on fibrosis stage (F0-F4) or NAS category (0-1, 2-3, 4-5 or >6) revealed significant differences between fibrosis stages ( $p < 0.0001$  for all comparisons) and NAS categories ( $p < 0.01$  for all categories). We believe that these observations demonstrate that NIS4, our IVD test, has the potential to be used in medical practice, as well as in a clinical research setting, to accurately identify patients with NASH (NAS<sup>34</sup>) and significant fibrosis (F<sup>32</sup>).

#### *Regulatory and Commercial Strategy*

We began communications with the FDA in 2017 to discuss potential regulatory pathways for our IVD test. Based on these discussions, we are using blood samples and liver biopsy results from patients enrolled in our clinical trials of elafibranor conducted to date in order to provide support for the potential validation of our test. By applying our IVD test to a patient's blood sample, and then comparing the IVD test result to that patient's liver biopsy result, we can assess whether our IVD test is accurate in diagnosing patients with NASH and significant fibrosis who should be considered for therapeutic intervention. We are currently finalizing the analytical and clinical study designs which are required prior to initiating formal validation studies.

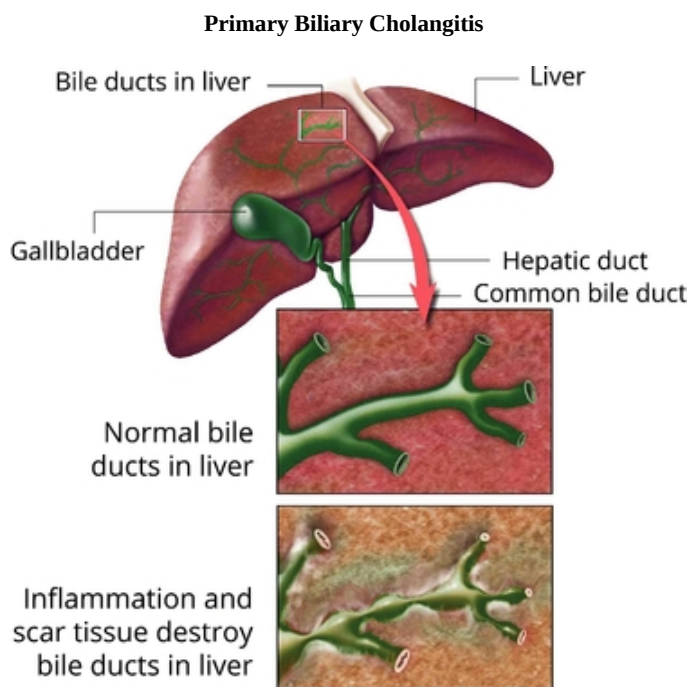
In January 2019, we entered into a license agreement with LabCorp for development and deployment in the clinical research space as a laboratory developed test, or LDT. We believe this agreement will provide expanded access to, and further validation of our IVD test which should be supportive in our plans to seek marketing authorization from the FDA. Initially, we will limit the use of the LDT for use in clinical research studies. LabCorp will serve as a central lab partner, processing samples and providing test results. LabCorp is permitted and accredited, and will be responsible for submitting the LDT for any validation that may be required under applicable state and federal laws. We believe that leveraging the capabilities of a large diagnostic company will allow for early test adoption, result in third-party publications and provide additional evidence of the clinical utility of our IVD test. We plan to use these benefits to further support the next stage of our commercial strategy, which is to first have the FDA grant our request for marketing of the IVD at a single site and then expand the IVD test to multi-site use through a second marketing authorization for use in routine clinical care. With the assistance of a partner, we plan to produce IVD test kits and commercialize the kit-based tests in the United States, which is a prerequisite for enabling our multi-site strategy.

In parallel, we are progressing towards submitting a data package to the EMA to enable CE marking and associated marketing approval in key European markets during 2020. In Europe, if approved, we plan to sell our kit-based IVD tests 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.



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 pruritus, as measured by a 5-D itch scale and visual analogue scale; and
- change from baseline in quality of life, as measured by PBC-40, a patient-derived questionnaire.

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

Elafibranor also achieved 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 and metabolic markers such as total cholesterol, low-density lipoprotein-C, and triglycerides. Improvement in pruritus was observed and will be confirmed in a study 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.

Based on these preliminary results, we plan to advance our PBC program into Phase 3 development in 2019.

### ***Nitazoxanide Program for the Treatment of Fibrosis***

#### ***About Fibrosis***

We are developing 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 nitazoxanide 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.

### **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 ROR $\gamma$ t, a key transcription factor that controls the function of IL-17-secreting lymphocytes. Recent data suggest that ROR $\gamma$ t inhibition may be a straightforward and efficient way to curb exacerbated immune responses caused by IL-17. In our TGFTX1 program, we have identified novel ROR $\gamma$ t antagonists. One of our proprietary molecules is a potent and selective ROR $\gamma$ t 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 ROR $\gamma$ t 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.

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**

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 three other companies that are also in Phase 3 development of a drug candidate for the treatment of NASH:

- Gilead Sciences, Inc., which has an ongoing Phase 3 trial of its drug candidate selonsertib targeting fibrosis only in patients with level F3 fibrosis due to NASH, but which recently announced that in its Phase 3 trial of selonsertib, in patients with level F4 fibrosis due to NASH, selonsertib did not meet the pre-specified week 48 primary endpoint of one stage or greater histologic improvement in fibrosis without worsening of NASH;
- Intercept Pharmaceuticals, Inc., which recently announced topline results for its Phase 3 clinical trial of obeticholic acid, or OCA, an FXR agonist for the treatment of NASH, with OCA having achieved one of its two primary endpoints, demonstrating statistically significant improvement in liver fibrosis without worsening of NASH at 18 months, but not meeting the other primary endpoint of NASH resolution without worsening of fibrosis; and
- Allergan plc, following its acquisition of Tobira Therapeutics, Inc., which is developing its drug candidate cenicriviroc for the treatment of NASH.

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

- Madrigal Pharmaceuticals, Inc., which has completed Phase 2 clinical trials of its drug candidate MGL-3196, a thyroid hormone receptor, or THR, b-selective agonist, for the treatment of NASH and which has announced plans to initiate a Phase 3 clinical program;
- NGM Biopharmaceuticals, Inc., which is in Phase 2 development of its drug candidate NGM282, an engineered variant of the human hormone known as FGF19 for the treatment of NASH;
- Inventiva S.A., which is in Phase 2 development of its drug candidate lanifibranor, a drug targeting PPAR $\alpha$ , PPAR $\delta$  and PPAR $\gamma$  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.

With respect to our IVD test in development to use blood-based biomarkers to identify patients with NASH who we believe could benefit from treatment with elafibranor, there are a number of clinical tools available for the management of chronic liver disease patients, but there are no validated diagnostic tests for NASH available on the market today that are an alternative to an invasive liver biopsy procedure.

### **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 has been the subject of continued safety concerns with respect to pruritus and serious liver injury or death, leading to the FDA issuing a Boxed 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 CymaBay Therapeutics, Inc., 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.

We believe that elafibranor's differentiated mechanism of action in targeting PPAR $\alpha$  and PPAR $\delta$ , 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.

### **Manufacturing and Supply**

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

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

With respect to our IVD test, 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 States 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."

### **Patents**

As of January 1, 2019, we own or have rights to 28 issued U.S. patents, over 450 issued foreign patents, and 11 pending U.S. applications, and over 135 pending foreign patent applications. Our patent portfolio contains 41 different patent families, which are made up of over 600 patents and patents applications. Eighteen 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 January 1, 2019, 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 six 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 January 1, 2019, we own two U.S. patent applications and four International patent applications designating the United States directed to the diagnosis of NASH using certain biomarkers. The U.S. application, if issued, would be expected to expire in 2036, and U.S. patent applications based on the corresponding International applications, if filed and issued, would be expected to expire in 2037-2038.

### ***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 RORyt. In addition, we are pursuing patent protection directed to our repositioning of nitazoxanide for treating cholestatic and fibrotic disease. As of January 1, 2019, 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.

### ***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 term 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 SPC, 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.

### ***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 patent 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 addition 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.

#### ***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.

#### ***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 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 mid-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 currently still comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, with the United Kingdom scheduled to leave the European Union as of March 29, 2019), 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.

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 in-vitro diagnostics (IVD) 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, 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.

We are developing an *in vitro* diagnostic test for the identification of NASH patients to treat, initially as an LDT. Our collaborators who develop the LDT will not seek or receive third-party reimbursement for the LDT because it will only be used in clinical research. Once we have been granted authorization to commercialize our IVD under FDA's device authorities, we or our collaborators will likely seek coverage and reimbursement from third party payors, including Medicare and Medicaid. We, or our collaborators, will be required to obtain coverage and reimbursement for this test separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. There is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement in the United States 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. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. 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.

Since its enactment 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 July 2018, the Centers for Medicare and 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 inseparable 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. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, 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 2027 unless additional Congressional action is taken. 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 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, Office of Inspector General of the U.S. Department of Health and Human Services proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. 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 and civil monetary penalty laws, including the federal civil False Claims Act, which can be enforced by private individuals through civil whistleblower or qui tam actions, 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 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, individual 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.

## **Employees**

As of December 31, 2018, we had 148 employees. Of these employees, 100 were engaged in research and development activities and 48 were engaged in administration and management, which includes business development, finance, investor relations, information systems, human resources and legal.

Of these 148 employees, 138 were employed by Genfit S.A. and seven were employed by our U.S. subsidiary, Genfit Corp. Employees employed by Genfit Corp. were mainly based in our Cambridge, Massachusetts office. Of the 138 employees employed by Genfit S.A., 130 were based at our corporate headquarters in Loos and 8 were based in our Paris office.

None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

## **Facilities**

Our corporate headquarters are located in Loos, France, where we lease approximately 5,500 square meters of office space. We have begun construction of an extension to the building to provide approximately 1,000 additional square meters of office space, and we expect this extension to be completed in the second half of 2019. The lease for our Loos headquarters continues through March 2022. We also lease office space in Paris, France and, for our U.S. subsidiary, Genfit Corp., in Cambridge, Massachusetts.

We believe that our existing facilities, including the extension to our corporate headquarters in Loos, France, are adequate for our near-term needs, and we believe that suitable additional or alternative office and manufacturing space will be available as required in the future on commercially reasonable terms.

## **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 23 of our consolidated financial statements for the year ended December 31, 2018 included in this prospectus. Other than the legal proceeding related to the research tax credit described elsewhere in this prospectus, 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.

## MANAGEMENT

## Senior Management and Directors

The following table sets forth information concerning our senior management and directors as of March 14, 2019:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Senior Management</b>		
Jean-François Mouney(1)	63	Chief Executive Officer and Chairman of the Board
Dean Hum, Ph.D	56	Chief Operating Officer
Nathalie Huitorel	57	Executive Vice President and Chief Financial and Administrative Officer
Pascal Prigent	50	Executive Vice President, Marketing and Commercial Development
Jean-Christophe Marcoux	41	Chief Strategy Officer
Laurent Lannoo	49	Corporate Secretary, Director of Legal Affairs
<b>Non-Employee Directors</b>		
Xavier Guille des Buttes(2)(3)	77	Vice-Chairman of the Board
Catherine Larue, Ph.D(1)	63	Director
Anne-Hélène Monsellato(4)	51	Director
Frédéric Desdouits	51	Director
Florence Séjourné(5)	47	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.

**Senior Management**

**Jean-François Mouney** has served as our Chief Executive Officer since September 1999 and as Chairman of our board of directors since June 2017. 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 master 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.

**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 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.

**Pascal Prigent** has served as our Executive Vice President, Marketing and Development since May 2018. 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.

**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.

**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**

**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. Ms. Monsellato has been a Certified Public Accountant in France since 2008 and received a board member certification from IFA Sciences Po (French Association of Directors) in 2014. She graduated from EM Lyon in 1990 with a degree in Business Management. Since May 2015, she has been an independent director, the Chairman of the Audit and Risk Committee and a member of the Corporate Governance and Nomination 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 Mona Bismarck American Center for Art and Culture, a U.S. public foundation based in New York. 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 IFA since 2013.

**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 Uetikon (Lahr, Germany), a member of the Novacap group in Ecully, France. Prior to joining 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 is a member of the supervisory board of CiToxLab. Between 2008 and 2011, Mr. Desdouits was a board member at Exonhit Therapeutics (now Diaxonhit Therapeutics) 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. 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.

## 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.

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.

	<u>CURRENT POSITION</u>	<u>YEAR OF INITIAL APPOINTMENT</u>	<u>TERM EXPIRATION YEAR</u>
Jean-François Mouney	Chairman	1999 <sup>(1)</sup>	2022
Xavier Guille des Buttes	Vice Chairman	2006 <sup>(2)</sup>	2022
SAS Biotech Avenir represented by Florence Séjourné	Director	2010 <sup>(3)</sup>	2022
Frédéric Desdouits	Director	2014 <sup>(4)</sup>	2022
Catherine Larue	Director	2017	2022
Anne-Hélène Monsellato	Director	2017	2022
Philippe Moons	Director	2015 <sup>(5)</sup>	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.
- (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.

### 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, subject to certain phase-in schedules. 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 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<sup>1</sup>/<sub>3</sub>% 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. See the section of this prospectus titled "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)."

## 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 an alliance 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 will comply 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 will only have 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.

**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, which we also refer to as our remuneration and appointments 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 remuneration and appointments committee:

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

remuneration levels and the breakdown between the various elements of the compensation, as well as the changes in compensation that may be proposed by the company to its senior management and corporate officers.

## Code of Business Conduct and Ethics

In connection with the global offering, 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. Following the closing of the global offering, the Code of Conduct will be available on our website at [www.genfit.com](http://www.genfit.com). Our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, senior management and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

## Compensation of Directors and Chief Executive Officer

### Director Compensation

At our combined general meetings of shareholders held on June 16, 2017 and June 15, 2018, shareholders set the total annual attendance fees (*jetons de présence*) to be distributed among non-employee directors at €225,000 for the period beginning with the shareholders' general meeting of June 15, 2018 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, 2018, which consisted solely of attendance fees.

<u>NAME</u>	
Jean-François Mouney(1)	—
Xavier Guille des Buttes	€ 53,330
Frédéric Desdouits	€ 21,174
SAS Biotech Avenir	—
Philippe Moons	€ 29,704
Anne-Hélène Monsellato	€ 37,075
Catherine Larue	€ 21,256

- (1) Mr. Mouney was appointed as chairman of the board of directors by the shareholders at the Shareholders' Meeting on June 16, 2017. Mr. Mouney does not receive compensation for his service on the board of directors. His compensation for the year ended December 31, 2018 is described in the section titled "Executive Compensation."

### Chief Executive Officer Compensation

The following table sets forth information regarding compensation earned by Jean-François Mouney, our Chief Executive Officer and sole executive officer under French law, during the year ended December 31, 2018.

<u>NAME AND PRINCIPAL POSITION</u>	<u>FIXED COMPENSATION (€)</u>	<u>VARIABLE COMPENSATION (€)</u>	<u>EQUITY AWARDS (€)</u>	<u>ALL OTHER COMPENSATION (€)</u>	<u>TOTAL (€)</u>
Jean-François Mouney, Chief Executive Officer	574,361(1)	566,074(2)	103,651(3)	7,200(4)	1,251,286

- (1) This gross amount consists of €534,295 in annual compensation and €40,066 paid for services as a director of Genfit Corp., our wholly owned U.S. subsidiary.

- (2) Mr. Mouney is eligible for a gross variable compensation of €566,074 for the year ended December 31, 2017 under our Incentive Plan, subject to approval and which was ultimately approved by the Shareholders' General Meeting of June 18, 2018.
- (3) The amount was calculated in accordance with the IFRS2 valuation of the grant to Mr. Mouney of (i) stock options to purchase 17,000 ordinary shares and (ii) 3,000 free shares.
- (4) This amount consists of use of a company car valued at €7,200.

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, 2018 are summarized below:

#### *Fixed Compensation*

Through his executive officer contract (*contrat de mandat social*), Mr. Mouney received a gross fixed annual compensation of €534,295 for the duties carried out within Genfit S.A. and a gross fixed annual compensation of \$45,916 for the performance of his office of chairman of the board of directors of our subsidiary, Genfit Corp., during the year ended December 31, 2018.

#### *Variable Compensation*

For the year ended December 31, 2018, all variable compensation linked to Mr. Mouney's performance was granted under the Incentive Plan in an amount of €566,074.

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.

#### *Equity Awards*

During the year ended December 31, 2018, Mr. Mouney was granted equity awards in the form of stock options to purchase 17,000 shares and 3,000 free shares.

#### *Other Compensation*

The benefits in kind granted to Mr. Mouney for the year ended December 31, 2018 consisted of a company car valued at €7,200.

#### ***Chief Executive Officer Change of Control and Severance Benefits***

Mr. Mouney also benefits from a severance payment falling within the scope of Article L.225-42-1 of the French Commercial Code equal to six months' gross compensation, calculated on the basis of the last twelve months, excluding variable compensation associated with the implementation of the Incentive Plan, plus an additional payment of one month's gross compensation per year of service within the Company, calculated on the same basis. In accordance with Recommendation R16 of the Middelnext Corporate Governance Code, this payment is limited to two years' gross compensation, excluding variable compensations associated with the implementation of the Incentive Plan, paid for the last 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:

- At least one collaboration agreement or licensing agreement for the rights to use our programs and products is in force with a biopharmaceutical group, as defined in the Incentive Plan;
- At least two of our products are in the clinical development phase; or
- We have changed control as part of the backing by a biopharmaceutical group, as defined in the Incentive Plan, in the two months prior to the time that his post is terminated.

Mr. Mouney is not subject to a non-compete clause.

As of the date of this prospectus, the second condition has been fulfilled.

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

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

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

### **Equity Incentives**

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

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

Our board of directors has authority to grant these equity incentive instruments and the aggregate amount authorized to be granted under these instruments must be approved by a two-thirds majority of the votes held by our shareholders present, represented or voting by authorized means, at the relevant extraordinary shareholders' meeting. Once approved by our shareholders, our board of directors can



grant share warrants (BSA) 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, 2018, share warrants, stock options and free shares were outstanding allowing for the purchase of an aggregate of 548,882 ordinary shares at a weighted average exercise price of €19.72 (equal to \$22.59) per ordinary share based on the exchange rate in effect as of December 31, 2018 (this weighted average exercise price does not include 83,726 ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price being paid).

#### **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, 2018, 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.

The main terms of the BSAAR plans are as follows:

<b>Plan title</b>	<b>BSAAR 2014-A</b>	<b>BSAAR 2014-B</b>	<b>BSAAR 2014-C</b>	<b>BSAAR 2016-A</b>	<b>BSAAR 2016-B</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, 2018	833	0	400	0	0
BSAAR cancelled or lapsed	14,367	0	833	0	0
BSAAR remaining as of December 31, 2018	0	22,155	23,046	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, 2018, we have issued three share warrants plans as follows:

<b>Plan title</b>	<b>BSA 2014-A</b>	<b>BSA 2014-B</b>	<b>BSA 2015-A</b>	<b>BSA 2015-B</b>	<b>BSA 2017-A</b>	<b>BSA 2017-B</b>
Meeting date	April 2, 2014	April 2, 2014	April 2, 2014	April 2, 2014	June 16, 2017	June 16, 2017
Dates of allocation	July 24, 2014	July 24, 2014	January 9, 2015	January 9, 2015	November 21, 2017	November 21, 2017
Exercise conditions(1)	1 warrant / 1.03 shares			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
Total number of BSAs granted	46,765	46,765	12,860	12,860	18,345	18,345
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
BSA expiry date	September 30, 2018	February 28, 2019	May 31, 2019	November 30, 2019	June 30, 2022	July 15, 2022
BSA issuance price	€0.01	€0.01	€0.01	€0.01	€2.00	€2.00
BSA exercise price per share	€23.50	€23.50	€35.95	€35.95	€19.97	€19.97
Number of shares subscribed as of December 31, 2018	0	0	0	0	0	0
Warrants cancelled or lapsed	46,765	0	0	0	0	0
Warrants remaining as of December 31, 2018	0	46,765	12,860	12,860	18,345	18,345

(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*). Currently, Mr. Mouney serves as both our chairman of the board and chief executive officer and we 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).

In 2017, the board of directors granted an aggregate of 41,196 free shares to all of our employees and senior management, and in 2018, the board of directors granted them an aggregate of 37,072 free shares.

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, 2018, we granted an aggregate of 107,705 free shares under the free shares plans which will vest as follows:

	MEETING DATE	DATE OF ALLOCATION	NUMBER OF FREE SHARES	EXERCISEABLE (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	0
AGA D and S 2017-1	June 16, 2017	December 21, 2017	27,468	January 1, 2021	€ 21.95	0
AGA D and S 2017-2	June 16, 2017	December 21, 2017	13,728	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

(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, 2018, 7,985 and 9,499 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*). Currently, Mr. Mouney serves as both our chairman of the board and chief executive officer and we 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 and 2018, the board of directors, using the authorizations granted to them by the extraordinary shareholders' meeting, decided to grant stock options to the members of the board of directors, including Mr. Mouney, and certain senior managers. These stock options were put in place as motivation and retention instruments for the current teams, to recruit new talents interested in participating in our future development and include them in obtaining operational and financial objectives.

These stock options allow us to continue to offer to new employees competitive packages compared to other companies in our sector, in particular U.S. companies; substantiate in shares a portion of the total profit-sharing of 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. 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 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:

<b>Plan title</b>	<b>SO 2016-1</b>	<b>SO 2016-2</b>	<b>SO 2017-1</b>	<b>SO 2017-2</b>	<b>SO 2018</b>
Meeting date	June 21, 2016	June 21, 2016	June 16, 2017	June 16, 2017	June 15, 2018
Dates of allocation	December 15, 2016	December 15, 2016	November 21, 2017	November 21, 2017	November 7, 2018
Exercise conditions(1)	1 option / 1 share				
Subscription periods	From December 15, 2016 to September 15, 2018 or December 15, 2019	From December 15, 2016 to December 15, 2019	From December 6, 2017 to December 31, 2020	From December 6, 2017 to December 31, 2020	From November 7, 2018 to December 31, 2021
Total number of SOs granted	48,917	24,458	72,830	36,420	139,500
Start date for the exercise of the SOs	December 16, 2019	December 16, 2019	January 1, 2021	January 1, 2021	January 1, 2022
SO expiry date	December 16, 2026	December 16, 2026	December 31, 2027	December 31, 2027	December 31, 2028
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)
Number of SO exercised as of December 31, 2018.	0	0	0	0	0
SO voided or lapsed	8,667	4,333	8,666	4,334	0
SO remaining as of December 31, 2018	40,250	20,125	64,164	32,086	139,500

- (1) Exercisable by 1/3 of the number of options held by each beneficiary.
- (2) Exercise price at €15.79 for SO 2016-1 and SO 2016-2 and €21.12 for SO US 2016-1 and SO US 2016-2.
- (3) Exercise price at €17.91 for SO 2016-1 and SO 2016-2 and €22.54 for SO US 2016-1 and SO US 2016-2.
- (4) Exercise price at €16.00 for SO 2018 and €21.65 for SO US 2018.

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Since January 1, 2016, 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.

### ***Employment Arrangements with Our Chief Executive Officer***

Prior to the change in our management structure on June 16, 2017, Mr. Mouney, our chief executive officer, was party to an employment contract with us. The main obligations contained in the most recent amendments to the contract were the following:

- fixed gross monthly salary of €35,385 and the payment of a 13th month;
- a company car, the value of which cannot exceed €65,000 if purchased new;
- subscription to the French social security regime for company managers and senior executives (*régime de garantie sociale des chefs d'entreprise et des dirigeants d'entreprise*, or GSC);
- a non-disclosure clause; and
- a severance payment, in the event of termination (provided there is no evidence of severe misconduct (*faute grave* under French law) or gross negligence (*faute lourde* under French law)), totaling six months in wages, calculated based on the monthly wages paid over the previous 12 months (including the 13th month), plus one month of his gross wages for every year he was employed by us. The amount of this severance is capped at two years of gross compensation.

The employment contract of Mr. Mouney was suspended and then terminated and replaced by a corporate mandate agreement (*contrat de mandat social*) in his capacity as our Chairman and Chief Executive Officer on June 16, 2017.

### ***Biotech Avenir***

Biotech Avenir SAS, our holding company, holds 6.06% of our share capital and 10.79% of our voting rights. Mr. Mouney, the Chairman of our board of directors and 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 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.

Pursuant to an agreement with effect from July 1, 2016, we decided to finance the creation by Pinnacle Clinical Research of a registry of NAFLD/NASH patients, which diseases are targeted by certain of our drug and biomarker candidates. Our 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, we decided on December 22, 2016, with effect from December 31, 2016, to assign the benefit and obligations of this agreement to our endowment fund, The NASH Education Program. The NASH Education Program was created on November 3, 2016 to educate the medical community and patients on the lessons that can be learned from these patients, in accordance with its objectives.

For the year ended December 31, 2017, we granted to The NASH Education Program a donation of €1,808 thousand so that The NASH Education Program could honor the obligations under the transfer of registry donation and carry out the other planned disease awareness activities to patients and doctors. For the year ended December 31, 2018, we donated €959,000 to The NASH Education Program, primarily to support the creation of the first International NASH Day, which occurred in June 2018.

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.

### **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. The policy will become effective immediately upon the closing of the global offering. 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.

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.

## PRINCIPAL SHAREHOLDERS

The following table sets forth, as of January 1, 2019, 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 March 2, 2019, the date that is 60 days after January 1, 2019 and stock options and warrants that are currently exercisable or exercisable by March 2, 2019. Shares subject to options and warrants currently exercisable or exercisable by March 2, 2019 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 prior to the global offering is based on 31,183,921 of our ordinary shares outstanding as of January 1, 2019. We have based our calculation of the percentage of beneficial ownership of our ordinary shares outstanding immediately after the closing of the global offering of an additional 6,650,000 ordinary shares (including ordinary shares in the form of ADSs) to be issued in the global offering, assuming no exercise of the underwriters' option to purchase additional ADSs and/or ordinary shares.

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 Beneficially Owned Before Global Offering	Percentage of Ordinary Shares Beneficially Owned	
		Before Global Offering	After Global Offering
<b>5% Shareholders:</b>			
Biotech Avenir SAS(1)	1,888,618	6.1%	5.0%
<b>Directors and Senior Management:</b>			
Jean-François Mouney(2)	1,913,920	6.1	5.1
Dean Hum, Ph.D(3)	13,009	*	*
Nathalie Huitorel(4)	16,858	*	*
Pascal Prigent	4,000	*	*
Jean-Christophe Marcoux(5)	3,296	*	*
Laurent Lannoo(6)	6,545	*	*
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	—	*	*
Philippe Moons(11)	5,310	*	*
All directors and senior management as a group (12 persons)(12)	1,998,841	6.4	5.3

\* 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, 12,474 BSAAR share warrants that are exercisable within 60 days of January 1, 2019 and 1,562 free shares that are exercisable within 60 days of January 1, 2019.
- (3) Consists of 11 ordinary shares, 11,585 BSAAR share warrants that are exercisable within 60 days of January 1, 2019 and 1,413 free shares that are exercisable within 60 days of January 1, 2019.
- (4) Consists of 2,879 ordinary shares, 12,474 BSAAR share warrants that are exercisable within 60 days of January 1, 2019 and 1,505 free shares that are exercisable within 60 days of January 1, 2019.
- (5) Consists of 554 ordinary shares, 2,533 BSAAR share warrants that are exercisable within 60 days of January 1, 2019 and 209 free shares that are exercisable within 60 days of January 1, 2019.
- (6) Consists of 5,893 ordinary shares and 652 free shares that are exercisable within 60 days of January 1, 2019.
- (7) Consists of 1,342 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of January 1, 2019.
- (8) Consists of 5,000 BSA share warrants that are exercisable within 60 days of January 1, 2019.
- (9) Consists of 5,000 BSA share warrants that are exercisable within 60 days of January 1, 2019.
- (10) Consists of 111 ordinary shares and 19,450 BSA share warrants that are exercisable within 60 days of January 1, 2019.
- (11) Consists of 310 ordinary shares and 5,000 BSA share warrants that are exercisable within 60 days of January 1, 2019.
- (12) Includes 1,888,618 shares (6.1%) held directly by Biotech Avenir.

## DESCRIPTION OF SHARE CAPITAL

### General

The following description of our share capital summarizes certain provisions of our bylaws. Such summaries do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of our bylaws, a copy of which has been filed as an exhibit to the registration statement of which this prospectus forms a part.

As of December 31, 2018, our outstanding share capital consisted of a total of 31,183,921 ordinary shares, with nominal value €0.25 per share.

As of December 31, 2018, to the best of our knowledge, none of our outstanding ordinary shares were held by shareholders of record in the United States.

Under French law, our bylaws set forth only our issued and outstanding share capital as of the date of the bylaws. Our fully diluted share capital represents all issued and outstanding shares, as well as all potential shares which may be issued upon exercise of outstanding free shares, stock options and share warrants, as approved by our shareholders and granted by our board of directors.

Upon closing of the global offering, based on the number of ordinary shares outstanding as of December 31, 2018, our outstanding share capital will consist of 37,833,921 ordinary shares (including ordinary shares in the form of ADSs), nominal value €0.25 per share (or 38,831,421 if the underwriters exercise their option to purchase additional ADSs and/or ordinary shares in the global offering in full).

### Reconciliation of the Shares Outstanding Prior to the Global Offering

Shares outstanding at December 31, 2015	23,958,904
Number of shares issued in connection with a private placement on February 29, 2016	2,395,890
Number of shares issued in connection with a private placement on October 12, 2016	1,695,000
Number of shares issued in connection with a rights issuance on November 2, 2016	3,116,643
Shares outstanding at December 31, 2016 and 2017	31,166,437
Number of shares issued in connection with the vesting of free shares on December 27, 2018	17,484
Shares outstanding at December 31, 2018	<u>31,183,921</u>

### History of Securities Issuances

From January 1, 2016 through December 31, 2018, the following events have changed the number and classes of our issued and outstanding shares:

- On February 29, 2016, we issued an aggregate of 2,395,890 shares to 3 purchasers in connection with a private placement, at a purchase price of €20.70 per share.
- On October 12, 2016, we issued an aggregate of 1,695,000 shares to 18 purchasers in connection with a private placement, at a purchase price of €20.00 per share.
- On November 2, 2016, we issued an aggregate of 3,116,643 shares in connection with a rights issuance, at a purchase price of €14.30 per share.
- On October 16, 2017, we issued convertible bonds, convertible into an aggregate of 6,081,081 shares, for aggregate gross proceeds of €180.0 million.

- From January 1, 2016 to December 31, 2018, we issued BSAAR share warrants to purchase an aggregate of 11,124 shares, at a weighted-average exercise price of €23.50 per share. None of these BSAAR share warrants have been exercised or cancelled or have expired.
- From January 1, 2016 to December 31, 2018, we issued BSA share warrants to purchase an aggregate of 36,690 shares, at a weighted-average exercise price of €19.97 per share. None of these BSA share warrants, have been exercised or cancelled or have expired.
- From January 1, 2016 to December 31, 2018, we issued stock options to purchase an aggregate of 322,125 shares, at a weighted-average exercise price of €17.62 per share. Of these stock options, none have been exercised, 2,500 have been cancelled and none have expired.
- From January 1, 2016 to December 31, 2018, we issued free shares to purchase an aggregate of 107,705 shares upon the performance of specified conditions. As of the date of this prospectus, 1,104 of these free shares have been cancelled and 17,484 of these free shares have vested.

### **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 an exhibit to the registration statement of which this prospectus forms a part.

#### ***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 give 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. See the section of this prospectus titled "Management—Compensation of Directors and Senior Management—Director Compensation" for a description of our compensation policy for our non-employee directors.

**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. The amount of our share capital plus the amount of our legal reserves which may not be distributed was equal to €1,035,981.50 at December 31, 2018.

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, 1<sup>st</sup> 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 (*Règlement 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 of this prospectus 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.

To better understand the voting rights of the ADSs, you should carefully read the section in this prospectus titled "Description of American Depositary Shares—Voting Rights."

*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 25<sup>th</sup> day preceding the date of the shareholders' meeting, and in any event no later than the 20<sup>th</sup> 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.; see the section of this prospectus titled "Limitations Affecting Shareholders of a French Company";
- 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 of this prospectus 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. 233-10 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.

Our current shareholders waived their preferential subscription rights with respect to the global offering at our combined general shareholders' meeting held on June 16, 2017.

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.

**Securities Exercisable for Ordinary Shares**

***Equity Incentives***

See the section of this prospectus titled "Management—Equity Incentives" for a description of securities granted by our board of directors to our directors, senior management and employees.



## 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.

	<u>FRANCE</u>	<u>DELAWARE</u>
Number of Directors	Under French law, a <i>société anonyme</i> 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. 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 will be null and void. The directors are appointed at the shareholders' general meetings.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the Chairman of the board of directors), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.
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.	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.

	<u>FRANCE</u>	<u>DELAWARE</u>
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 ( <i>mandataire ad hoc</i> ) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notice of General Meetings

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FRANCE

A meeting announcement is published in the French Journal of Mandatory Statutory Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least twenty-one day prior to the meeting. Subject to limited exceptions provided by French law, additional convening 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.

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DELAWARE

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.

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FRANCE

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DELAWARE

Proxy

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.

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

FRANCE

Under French law, shareholders' action by written consent is not permitted in a *société anonyme*.

DELAWARE

Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.

Preemptive Rights

Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a *pro rata* his/her share ownership unless such rights are waived by a two-thirds majority of the votes held by the shareholders present at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights have not been waived by the extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Since October 1, 2016, preferential subscription rights may only be exercised two business days prior to the day on which the subscription is opened until the second business day prior to its closing. Thus, the preferential subscription rights are transferable during the same period as their period of exercise. In accordance with French law, the period of exercise shall be no less than 5 business days.

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

FRANCE

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 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.

Repurchase of Shares

Under French law, a corporation may acquire its 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 the following purposes:

DELAWARE

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.

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.

- 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.

A simple exemption is provided when the acquisition is made under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 225-209 of the French Commercial Code and in accordance with the General Regulations of the Financial Markets Authority (AMF).

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.

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FRANCE

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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.

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DELAWARE

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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.



	<u>FRANCE</u>	<u>DELAWARE</u>
Voting Rights	<p>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 March 2014, double voting rights are automatically granted to the shares held in registered form for more than two years, unless provided otherwise in the bylaws.</p>	<p>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.</p>
Shareholder Vote on Certain Transactions	<p>Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires:</p> <ul style="list-style-type: none"><li>• the approval of the board of directors; and</li><li>• 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.</li></ul>	<p>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:</p> <ul style="list-style-type: none"><li>• the approval of the board of directors; and</li><li>• 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.</li></ul>

Dissent or Dissenters' Appraisal Rights

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FRANCE

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.

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DELAWARE

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

FRANCE

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*).

DELAWARE

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Shareholder Suits

French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's corporate interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders.

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.

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.

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.

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.

	<u>FRANCE</u>	<u>DELAWARE</u>
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 ( <i>registre du commerce et des sociétés</i> ) and only have bylaws ( <i>statuts</i> ) as organizational documents.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: <ul style="list-style-type: none"><li>• its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and</li><li>• 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.</li></ul>
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 ADSs have been approved for listing on the Nasdaq Global Select Market under the symbol "GNFT." 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. Upon the closing of the ADS offering, BNP Paribas Securities Services will also serve as transfer agent and registrar for our ADSs. The share register reflects only record owners of our ordinary shares. Holders of our ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

## LIMITATIONS AFFECTING SHAREHOLDERS OF A FRENCH COMPANY

### Ownership of ADSs or Shares by Non-French Residents

Neither the French Commercial Code nor our bylaws presently impose any restrictions on the right of non-French residents or non-French shareholders to own and vote shares. 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 such 10% threshold. Violation of this filing requirement may be sanctioned by five years of imprisonment and a fine of up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity.

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.

### Foreign 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.

### Availability of Preferential Subscription Rights

Our shareholders will have the preferential subscription rights described under "Description of Share Capital—Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares—Changes in Share Capital—Preferential Subscription Right." Under French law, shareholders have preferential rights to subscribe for cash issues of new shares or other securities giving rights to acquire additional shares on a pro rata basis. Holders of our securities in the United States (which may be in the form of shares or ADSs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, holders of our securities in the United States will be unable to exercise any preferential subscription rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities. We intend to evaluate at the time of any rights offering the costs and potential liabilities associated with registering the rights, as well as the indirect benefits to us of enabling the exercise by holders of shares and holders of ADSs in the United States of the subscription rights, and any other factors we consider appropriate at the time, and then to make a decision as to whether to register the rights. We cannot assure you that we will file a registration statement.

For holders of our ordinary shares in the form of ADSs, the depositary may make these rights or other distributions available to ADS holders. If the depositary does not make the rights available to ADS holders and determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case ADS holders will receive no value for them. The section of this prospectus titled "Description of American Depositary Shares—Dividends and Other Distributions" explains in detail the depositary's responsibility in connection with a rights offering. See also "Risk Factors—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 purchasers of ADSs in the ADS offering."

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

### American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, or ADSs. Each ADS will represent 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 deposited ordinary shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You 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 your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description 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, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

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. For directions on how to obtain copies of those documents, see the section of this prospectus titled "Where You Can Find More Information."

### 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.* After completion of the global offering, 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. See the section of this prospectus titled "Material United States Federal Income and French Tax Considerations." 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:**

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

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

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

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

Any charges incurred by the depositary or its agents for servicing the deposited securities

**For:**

- 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
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- 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
- Cable and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to U.S. dollars
- As necessary
- 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 depositary 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 Depository; Limits on Liability to Holders of ADSs***

The deposit agreement expressly limits our obligations and the obligations of the depository. It also limits our liability and the liability of the depository. We and the depository:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depository 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 depository 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 depository agree to indemnify each other under certain circumstances.

## **Requirements for Depository Actions**

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of ordinary shares, the depository 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 depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository 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 depository 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 depository 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 depository 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 depository 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 depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

## **Shareholder communications; inspection of register of holders of ADSs**

The depository 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 depository 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 depository 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 depository 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.

## SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to the ADS offering, while our ordinary shares have been traded on Euronext Paris since April 2014 and prior to that, on the Alternext since 2006, there has been no public market on a U.S. national securities exchange for our ADSs or ordinary shares in the United States. Future sales of ADSs in the U.S. public market after the ADS offering, and the availability of ADSs for future sale, could adversely affect the market price of the ADSs prevailing from time to time. As described below, a significant number of currently outstanding ordinary shares will not be available for sale shortly after the global offering due to contractual restrictions on transfers of ordinary shares and ADSs. However, sales of substantial amounts of our ADSs or our ordinary shares, or the perception that these sales could occur, could adversely affect prevailing market prices for the ADSs and could impair our future ability to raise equity capital.

Based on the number of ordinary shares outstanding on December 31, 2018, upon completion of the global offering, 37,833,921 ordinary shares (including ordinary shares in the form of ADSs) will be outstanding, assuming no outstanding warrants are exercised and assuming no exercise of the underwriters' option to purchase additional ADSs and/or ordinary shares. All of the ADSs sold in the ADS offering will be freely tradable without restrictions or further registration under the Securities Act, except for any ADSs sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The ordinary shares held by existing shareholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the United States on the Nasdaq Global Select Market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or 701 promulgated under the Securities Act.

Under the lock-up and market stand-off agreements described below and the provisions of Rules 144 and 701 under the Securities Act and French law, and assuming no exercise of the underwriters' option to purchase additional ADSs and/or ordinary shares, these restricted securities will be available for sale in the public market 90 days after the date of the underwriting agreement related to this global offering, provided that shares held by our affiliates will remain subject to volume, manner of sale and other resale limitations set forth in Rule 144 and subject to French law, both as described below.

### Rule 144

In general, a person who has beneficially owned restricted ordinary shares for at least six months would be entitled to sell their securities pursuant to Rule 144 under the Securities Act provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (2) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted ordinary shares for at least six months, but who are our affiliates at the time of, or at any time during the 90 days preceding a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1.0% of the number of ordinary shares then outstanding (including ordinary shares in the form of ADSs), which will equal approximately 380,000 ordinary shares immediately after the completion of the global offering based on the number of ordinary shares (including ordinary shares in the form of ADSs) outstanding as of December 31, 2018 and assuming no exercise of the underwriters' option to purchase additional ADSs and/or ordinary shares; and
- the average weekly trading volume of our ordinary shares in the form of ADSs on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;



provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

## **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, senior management or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares subject also to French law, as described below.

## **Lock-up Agreements**

We and our senior management and directors and their affiliated entities have agreed that, without the prior written consent of SVB Leerink LLC and Barclays Capital Inc., we and they will not, subject to customary exceptions, during the period ending 90 days after the date of this prospectus, directly or indirectly, sell, offer, contract or grant any option to sell, pledge or otherwise transfer or dispose of any ordinary shares, ADSs or any securities convertible into, exercisable or exchangeable for our ordinary shares or ADSs or publicly announce an intent to do any of the foregoing. SVB Leerink LLC and Barclays Capital Inc., on behalf of the underwriters, will have discretion in determining if and when to release any ordinary shares or ADSs subject to lock-up agreements.

We do not currently expect any release of ordinary shares or ADSs subject to lock-up agreements prior to the expiration of the applicable lock-up periods. Upon the expiration of the applicable lock-up periods, substantially all of the ordinary shares and ADSs subject to such lock-up restrictions will become eligible for sale, subject to the limitations described above.

## **French Law**

Under French law, and in particular under the General Regulation issued by the French Financial Markets Authority (*Règlement Général de l'AMF*), as well as under Market Abuse Regulation 596/2014 of 16 April 2014 (MAR), any person that holds inside information shall, until such information is made public, refrain from (1) carrying out any transactions relating to securities issued by the company, (2) recommending that another person engage in insider dealing or induce another person to engage in insider dealing, (3) unlawfully disclosing inside information outside of the normal exercise of an employment, a profession or duties. The use of inside information by cancelling or amending an order concerning a financial instrument to which the information relates where the order was placed before the person concerned possessed the inside information, shall also be considered to be insider dealing. These rules apply to all persons who hold inside information as a result of (1) their status as board member, executive officer, manager, employee of the company, third parties acting on behalf of the company and having access to privileged information as party of their professional relations with the company during the preparation or the completion of a particular transaction, such as investor services providers, lawyers or public relations agencies, (2) their holding of securities in the share capital of the company, and/or (3) their access to information because of their employment, profession or duties or their participation in the preparation of a financial transaction.

Under MAR and the General Regulation of the French Financial Markets Authority, it is also prohibited for a person to engage or attempt to engage in market manipulation.

Prohibited transactions include all transactions related to securities (stocks, bonds, securities convertible, options and warrants), and, in particular, the (1) transfer of securities, (2) exercise of options and warrants (including founder's share warrants) and exercise of any securities giving access to the capital, (3) transfer of free shares and (4) acquisition of securities.

## MATERIAL UNITED STATES FEDERAL INCOME AND FRENCH TAX CONSIDERATIONS

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 depository 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 and, unless otherwise noted, this discussion is the opinion of Linklaters LLP, our French tax counsel, insofar as it relates to matters of French tax law and legal conclusions with respect to those matters.

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 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 prospectus.

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 new 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 French wealth tax, 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 French wealth tax 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.

### ***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, 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.

## **Transfer Taxes**

Pursuant to Article 235 ter ZD of the *Code général des impôts* (French Tax Code, or 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. The Nasdaq Global Select Market is not currently acknowledged by the French AMF but this may change in the future. 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 used to be published annually, by the French Ministry of Economy by a ministerial decree until December 2014. It was not published by the French tax authorities, and could be amended at any time. As from such date, the list is published by the French tax authorities on an annual basis in their official guidelines. Pursuant to regulations BOI-ANNX-000467-20181217 issued on December 17, 2018, we are currently not included in such list. Please note that such list may be updated from time to time, or may not be published anymore in the future.

Following the global offering, purchases of our securities may be subject to such tax provided that its 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 French 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, or *acte* and provided that Article 235 ter ZD of the FTC is not applicable.

## **Tax on Sale or Other Disposition**

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 a non-cooperative State or territory 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 expands 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.)

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 a non-cooperative State or territory 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) corresponding to the standard corporate income tax rate set forth in Article 219-I of the FTC 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) 30% (to be aligned on the standard corporate income tax rate set forth in Article 219-I of the FTC for fiscal years beginning as from January 1, 2020) 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 a non-cooperative State or territory, 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 expands 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 30% (to be aligned on the standard corporate income tax rate set forth in Article 219-I of the FTC for fiscal years beginning as from January 1, 2020) or 75% withholding tax rate, but may be subject to the withholding tax at a reduced rate (as described below).

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); 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 30% (to be aligned on the standard corporate income tax rate set forth in Article 219-I of the FTC for fiscal years beginning as from January 1, 2020), or 75% if paid in a non-cooperative State or territory (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 30% 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 determined to be real estate assets) or rights, 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 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 fluctuate after the global offering. 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 we were characterized as a PFIC in our taxable year ending December 31, 2018 and do not believe we will be characterized as a PFIC for our taxable year ending 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 PROSPECTUS, 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.**

## ENFORCEMENT OF CIVIL LIABILITIES

We are a corporation organized under the laws of France. All of our directors are citizens and residents of countries other than the United States, and the majority of our assets are located outside of the United States. We have appointed an agent for service of process in the United States; however, it may be difficult for investors:

- to obtain jurisdiction over us or our non-U.S. resident officers and directors in U.S. courts in actions predicated on the civil liability provisions of the U.S. federal securities laws;
- to enforce in U.S. courts judgments obtained in such actions against us or our non-U.S. resident officers and directors;
- to bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us or our non-U.S. resident officers or directors; and
- to enforce in U.S. courts against us or our directors in non-U.S. courts, including French courts, judgments of U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws.

Nevertheless, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would be recognized and enforced in France provided that a French judge considers that this judgment meets the French legal requirements concerning the recognition and the enforcement of foreign judgments and is capable of being immediately enforced in the United States. A French court is therefore likely to grant the enforcement of a foreign judgment without a review of the merits of the underlying claim, only if (1) that judgment resulted from legal proceedings compatible with French standards of due process, (2) that judgment does not contravene international public order and public policy of France and (3) the jurisdiction of the U.S. federal or state court has been based on principles of French private international law. The French court would also require that the U.S. judgment is not tainted with fraud and is not incompatible with a judgment rendered by a French court in the same matter, or with an earlier judgment rendered by a foreign court in the same matter.

In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so that the victim does not suffer or benefit from the situation. Such system excludes damages such as, but not limited to, punitive and exemplary damages.

As a result, the enforcement, by U.S. investors, of any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities law against us or members of our board of directors, officers or certain experts named herein who are residents of France or countries other than the United States would be subject to the above conditions.

Finally, there may be doubt as to whether a French court would impose civil liability on us, the members of our board of directors, our officers or certain experts named herein in an original action predicated solely upon the U.S. federal securities laws brought in a court of competent jurisdiction in France against us or such members, officers or experts, respectively.

## UNDERWRITING

The global offering consists of a total of 6,650,000 ordinary shares, consisting of:

- an offering of a total of 6,150,000 ordinary shares in the form of ADSs in the United States and Europe, referred to herein as the ADS offering; and
- a concurrent private placement of a total of 500,000 ordinary shares in Europe (including France) and countries outside of the United States, referred to herein as the European private placement.

SVB Leerink LLC and Barclays Capital Inc. are acting as joint global coordinators for the global offering and joint bookrunners for the ADS offering. SVB Leerink LLC and Barclays Capital Inc. are also acting as representatives of each of the underwriters named below. Bryan, Garnier & Co. Limited and Natixis are acting as joint bookrunners with respect to the European private placement. Roth Capital Partners, LLC and H.C. Wainwright & Co., LLC are acting as co-managers of the ADS offering. The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively.

Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of ordinary shares and/or ADSs, as the case may be, set forth opposite its name below.

<u>Underwriter</u>	<u>Number of ADSs</u>	<u>Number of Ordinary Shares</u>
SVB Leerink LLC	2,398,500	195,000
Barclays Capital Inc.	2,214,000	180,000
Bryan, Garnier & Co. Limited	461,250	37,500
Natixis	461,250	37,500
Roth Capital Partners, LLC	369,000	30,000
H.C. Wainwright & Co., LLC	246,000	20,000
<b>Total</b>	<b>6,150,000</b>	<b>500,000</b>

If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

Any purchases of ADSs by the underwriters pursuant to the underwriting agreement are carried out by the underwriters agreeing, severally and not jointly, to subscribe for ordinary shares and deposit such ordinary shares with the Depositary, receiving in return the ADSs.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ordinary shares and ADSs representing ordinary shares that they subscribe for pursuant to the underwriting agreement, subject to prior issue, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the ordinary shares and ADSs and the ordinary shares underlying the ADSs, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Sales of our ordinary shares made outside of the United States may be made by the underwriters or by their affiliates.

**Commissions**

The representatives have advised us that the underwriters propose initially to offer the ordinary shares and ADSs to the public at the initial public offering price set forth on the cover page of this prospectus and any ordinary shares or ADSs sold to dealers at that price less a concession not in excess of €0.7560 per ordinary share and \$0.8534 per ADS. After the initial offering of the ordinary shares and ADSs, the public offering price, concession or any other term of the offering may be changed by the representatives.

The following table shows the per share and total public offering price, underwriting commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional ordinary shares and/or ADSs.

	Per ADS		Per Ordinary Share		Total	
	Without Option To Purchase Additional ADSs	With Option To Purchase Additional ADSs	Without Option To Purchase Additional Ordinary Shares	With Option To Purchase Additional Ordinary Shares	Without Option To Purchase Additional ADSs and/or Ordinary Shares	With Option To Purchase Additional ADSs and/or Ordinary Shares
Offering price	\$ 20.32	\$ 20.32	€ 18.00	€ 18.00	\$ 135,128,000	\$ 155,397,200
Underwriting commissions	\$ 1.4224	\$ 1.4224	€ 1.26	€ 1.26	\$ 9,459,093	\$ 10,877,937
Proceeds to us, before expenses	\$ 18.8976	\$ 18.8976	€ 16.74	€ 16.74	\$ 125,668,907	\$ 144,519,263

We estimate expenses payable by us in connection with the global offering, other than the underwriting commissions referred to above, will be approximately \$3.25 million. We also have agreed to reimburse the underwriters for up to \$35,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for the global offering.

**Option to Purchase Additional Ordinary Shares and/or ADSs**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 997,500 additional ordinary shares and/or ADSs at the public offering price, less the underwriting commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional ordinary shares and/or ADSs proportionate to that underwriter's initial amount reflected in the above table.

**No Sales of Similar Securities**

We, our senior management and directors and certain of our existing security holders have agreed not to sell or transfer any of our ordinary shares or securities convertible into or exchangeable or exercisable for our ordinary shares, which includes ADSs, for 90 days after the date of this prospectus without first obtaining the written consent of SVB Leerink LLC and Barclays Capital Inc. on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any of our ordinary shares;
- sell any option or contract to purchase any of our ordinary shares;
- purchase any option or contract to sell any of our ordinary shares;
- grant any option, right or warrant for the sale of any of our ordinary shares;
- otherwise dispose of or transfer any of our ordinary shares;

- request or demand that we file a registration statement related to any of our ordinary shares; or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any of our ordinary shares, whether any such swap, agreement or transaction is to be settled by delivery of ordinary shares or other securities, in cash or otherwise.

This lock-up provision applies to our ordinary shares and to securities convertible into or exchangeable or exercisable for our ordinary shares, which includes ADSs. It also applies to our ordinary shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

### **Exchange Listing**

Our ADSs have been approved for listing on The Nasdaq Global Select Market, under the symbol "GNFT." Our ordinary shares are listed on Euronext Paris under the symbol "GNFT."

### **Determination of Offering Price**

Before the global offering, while our ordinary shares are traded on Euronext Paris, there has been no public market for the ADSs or for our ordinary shares in the United States. Consequently, the offering price for our ADSs was determined through negotiations between us and the representatives of the underwriters, and by reference to the prevailing market prices of our ordinary shares on Euronext Paris after taking into account market conditions and other factors, but is not lower than a price that is 15% below the volume-weighted average price of our ordinary shares during a window of five to 30 consecutive trading days with the 30 trading days (as decided by our company) preceding the day on which the offering price was determined.

An active trading market for the ADSs may not develop. It is also possible that after the global offering, the ADSs will not trade in the public market at or above the initial public offering price.

### **Stamp Taxes**

If you purchase ordinary shares and/or ADSs offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### **Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the ordinary shares and ADSs is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing ordinary shares and ADSs. However, the representatives may engage in transactions that stabilize the price of the ADSs, such as bids or purchases to peg, fix or maintain that price.

In connection with the global offering, the underwriters may purchase and sell ordinary shares and ADSs in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of ordinary shares and ADSs than they are required to purchase in the global offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option described above. The underwriters may close out any covered short position by either exercising their option or purchasing ordinary shares and/or ADSs in the open market. In determining the source of ordinary shares and/or ADSs to close out the covered short position, the underwriters will consider, among other things, the price of ordinary shares and/or ADSs available for purchase in the open market as compared to the price at which they may purchase ordinary shares and/or ADSs through the option granted to them. "Naked" short sales are sales in excess of such

option. The underwriters must close out any naked short position by purchasing ordinary shares and/or ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares and/or ADSs in the open market after pricing that could adversely affect investors who purchase in the global offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares and/or ADSs made by the underwriters in the open market prior to the closing of the global offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased ordinary shares and/or ADSs sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of the ordinary shares and/or ADSs or preventing or retarding a decline in the market price of the ordinary shares and/or ADSs. As a result, the price of the ordinary shares and/or ADSs may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Select Market, Euronext Paris, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the ordinary shares and/or ADSs. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Electronic Distribution**

In connection with the global offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

### **Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **Selling Restrictions**

#### ***Notice to Investors***

Under the authority granted by our shareholders to conduct the global offering, the ordinary shares and ADSs that we are offering may only be purchased initially by industrial or commercial companies in the pharmaceutical/biotech sector or investment fund companies or fund management



companies or collective savings managing funds governed by French or foreign law or any other legal entity (including a trust) or natural person, investing in the pharmaceutical/biotech sector, that is qualified to invest in a private placement. In order to purchase ordinary shares or ADSs in the global offering, you will be required to execute and provide to the underwriters an investor letter representing that you satisfy the foregoing investor criteria.

***Notice to Prospective Investors in the European Economic Area***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, no offer of any securities which are the subject of the global offering contemplated by this prospectus may be made to the public in that Relevant Member State other than:

- A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- B. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or
- C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any securities or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any ADSs being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and each of our and the representatives' and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of securities in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of securities. Accordingly, any person making or intending to make an offer in that Relevant Member State of the securities which are the subject of the global offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the company nor the underwriters have authorized, nor do they authorize, the making of any offer of the securities in circumstances in which an obligation arises for the company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression "an offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in the Relevant

Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC as amended or superseded (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### ***MiFID II Product Governance***

Any person offering, selling or recommending the securities (a "distributor") should take into consideration the manufacturers' target market assessment; however, a distributor subject to Directive 2014/65/EU on markets in financial instruments, as amended is responsible for undertaking its own target market assessment in respect of the securities (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels.

### ***Notice to Prospective Investors in the United Kingdom***

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (1) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order"), and/or (2) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

### ***Notice to Prospective Investors in Canada***

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with the global offering.

***Notice to Prospective Investors in Australia***

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC") in relation to the global offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the global offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring the securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

***Notice to Prospective Investors in Hong Kong***

The securities have not been offered or sold, and will not be offered or sold, in Hong Kong by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

***Notice to Prospective Investors in Japan***

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

***Notice to Prospective Investors in Qatar***

The securities described in this prospectus have not been, and will not be, offered, sold or delivered, at any time, directly or indirectly in the State of Qatar in a manner that would constitute a public offering. This prospectus has not been, and will not be, registered with or approved by the Qatar Financial Markets Authority or Qatar Central Bank and may not be publicly distributed. This prospectus is intended for the original recipient only and must not be provided to any other person. This prospectus is not for general circulation in the State of Qatar and may not be reproduced or used for any other purpose.

***Notice to Prospective Investors in Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (2) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

***Notice to Prospective Investors in Switzerland***

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the global offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the global offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of the securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the securities.

***Notice to Prospective Investors in the Dubai International Financial Centre***

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus, you should consult an authorized financial advisor.

**EXPENSES RELATING TO THE GLOBAL OFFERING**

The following table sets forth the costs and expenses, other than underwriting commissions, payable in connection with the sale of ordinary shares and ADSs in the global offering. All amounts are estimated except the SEC registration fee, the Nasdaq initial listing fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee. Except as otherwise noted, all the expenses below will be paid by us.

<u>ITEM</u>	<u>AMOUNT</u>
SEC registration fee	\$ 18,349
FINRA filing fee	23,210
Nasdaq initial listing fee	150,000
Legal fees and expenses	1,300,000
Accounting fees and expenses	1,400,000
Printing expenses	130,000
Miscellaneous fees and expenses	228,441
Total	<u>\$ 3,250,000</u>

## **LEGAL MATTERS**

The validity of the ordinary shares and ADSs and certain other matters of French law will be passed upon for us by Linklaters LLP, including matters of French income tax law. Certain matters of U.S. federal law will be passed upon for us by Cooley LLP, Boston, Massachusetts. Legal counsel to the underwriters in connection with the global offering are Jones Day with respect to French law and Goodwin Procter LLP, Boston, Massachusetts, with respect to U.S. federal law.

## **EXPERTS**

The consolidated financial statements of Genfit S.A. at December 31, 2017 and 2018 and for the years then ended appearing in this registration statement have been audited by Ernst & Young et Autres, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The offices of Ernst & Young et Autres are located at 1-2 place des Saisons, 92400 Courbevoie, Paris La Défense 1, France.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form F-1 under the Securities Act with respect to the ordinary shares and ADSs offered in this prospectus. A related registration statement on Form F-6 has been filed with the Securities and Exchange Commission to register the ADSs. This prospectus, which forms a part of the registration statement, does not contain all of the information included in the registration statement. Certain information is omitted and you should refer to the registration statement and its exhibits for that information. With respect to references made in this prospectus to any contract or other document of GENFIT S.A., such references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document.

The SEC maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding registrants, such as, that file electronically with the SEC.

Upon completion of the ADS offering, we will be 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 above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We maintain a corporate website at [www.genfit.com](http://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 prospectus is not part of this prospectus.



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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 Company") as of December 31, 2017 and 2018, the related consolidated statements of operations, other comprehensive loss, cash flows and changes in equity for the years ended December 31, 2017 and 2018 and the related notes to the financial statements (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 Company at December 31, 2017 and 2018 and the results of its operations and its cash flows for the years then ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS").

### Restatement of 2017 financial statements

As discussed in Note 2.3 to the consolidated financial statements, the 2017 consolidated financial statements have been restated to correct misstatements in accordance with the provisions of IAS 8.

### Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board ("PCAOB") and are required to be independent with respect to the Company 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 Company 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 Company'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 Company's auditors since 1999.

Paris, France  
February 8, 2019

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

(amounts in thousands of euros)

	Notes	As of December 31,	
		2017 Restated*	2018
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	5	€ 636	€ 796
Property, plant and equipment	6	6,324	7,764
Non-current trade and other receivables	7	1,921	1,489
Other non-current financial assets	8	729	1,313
Total non-current assets		<u>9,611</u>	<u>11,362</u>
<b>Current assets</b>			
Inventories		4	4
Current trade and other receivables	7	7,955	8,794
Other current financial assets	8	31	—
Other current assets	9	1,761	2,078
Cash and cash equivalents	10	273,820	207,240
Total current assets		<u>283,572</u>	<u>218,116</u>
Total assets		<u>€ 293,183</u>	<u>€ 229,478</u>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
Share capital	11	€ 7,792	€ 7,796
Share premium		251,932	251,554
Accumulated deficit		(102,531)	(158,897)
Currency translation adjustment		(8)	6
Net loss		(55,728)	(79,521)
Total shareholders' equity		<u>101,457</u>	<u>20,939</u>
<b>Non-current liabilities</b>			
Non-current convertible loans	12	154,539	159,176
Other non-current loans and borrowings	12	6,978	7,255
Non-current deferred income and revenue		2	1
Non-current employee benefits	15	936	1,085
Deferred tax liabilities	21.2	2,165	1,773
Total non-current liabilities		<u>164,620</u>	<u>169,291</u>
<b>Current liabilities</b>			
Current convertible loans	12	1,329	1,312
Other current loans and borrowings	12	1,834	1,848
Current trade and other payables	13	23,580	35,974
Current deferred income and revenue		1	1
Current provisions	14	361	112
Total current liabilities		<u>27,106</u>	<u>39,248</u>
Total shareholders' equity and liabilities		<u>€ 293,183</u>	<u>€ 229,478</u>

\* See Note 2.3, "Correction of errors."

## CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Notes	Year Ended December 31,	
		2017	2018
<b>Revenues and other income</b>			
Revenue		€ 118	€ 69
Other income	17	6,737	7,425
Revenues and other income		6,856	7,494
<b>Operating expenses and other operating income (expenses)</b>			
Research and development expenses	18	(54,189)	(67,024)
General and administrative expenses	18	(9,421)	(9,793)
Other operating income (expense)	18	60	(162)
Operating loss		(56,695)	(69,484)
Financial income	20	642	728
Financial expenses	20	(3,096)	(11,118)
Financial loss		(2,453)	(10,391)
Net loss before tax		(59,148)	(79,875)
Income tax benefit	21	3,420	354
Net loss		€ (55,728)	€ (79,521)
Basic and diluted loss per share	22	€ (1.79)	€ (2.55)

\* See Note 2.3, "Correction of Errors."

**CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE LOSS****(amounts in thousands of euros)**

	Notes	Year Ended December 31,	
		2017	2018
Net loss		€ (55,728)	€ (79,521)
Actuarial gains and losses net of tax	15	(210)	(31)
Other comprehensive income (loss) that will never be reclassified to profit or loss		(210)	(31)
Exchange differences on translation of foreign operations		(29)	14
Other comprehensive income (loss) that are or may be reclassified to profit or loss		(29)	14
Total other comprehensive loss		€ (55,967)	€ (79,537)

\* See Note 2.3, "Correction of Errors."

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(amounts in thousands of euros)

	Year Ended	
	December 31,	
	2017	2018
	Restated*	
<b>Cash flows from operating activities</b>		
Net loss	€ (55,728)	€ (79,521)
<b>Reconciliation of net loss to net cash used in operating activities</b>		
Adjustments for:		
Amortization	1,226	1,819
Depreciation and impairment charges	186	(208)
Expenses related to share-based compensation	278	787
Net result on disposal of property, plant & equipment	8	(2)
Net finance expenses	2,296	10,971
Income tax expense (benefit)	(3,420)	(354)
Other non-cash items	17	—
Operating cash flows before change in working capital	(55,137)	(66,507)
Decrease in inventories	10	—
Increase in trade receivables and other assets	(2,106)	(724)
Increase in trade payables and other liabilities	7,364	11,056
Change in working capital	5,268	10,332
Income tax paid	13	93
Net cash flows used in operating activities	(49,856)	(56,081)
<b>Cash flows from investment activities</b>		
Acquisition of property, plant & equipment	(2,800)	(2,938)
Proceeds from disposal of property, plant & equipment	15	3
Acquisition of financial instruments and financial assets	(163)	(1,050)
Net cash flows used in investment activities	(2,948)	(3,986)
<b>Cash flows from financing activities</b>		
Proceeds from subscription / exercise of share warrants	37	37
Proceeds from new loans and borrowings net of issue costs	177,338	1,800
Repayments of loans and borrowings	(1,655)	(2,000)
Financial interests paid (including finance lease)	(1,372)	(6,351)
Net cash flows (used in) provided by financing activities	174,348	(6,514)
Increase (decrease) in cash and cash equivalents	121,544	(66,580)
Cash and cash equivalents at the beginning of the period	152,277	273,820
Cash and cash equivalents at the end of the period	<u>€ 273,820</u>	<u>€ 207,240</u>

\* See Note 2.3, "Correction of Errors."

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Amounts in thousands of euros, except for number of shares)

	Share Capital		Share Premium	Treasury Shares	Accumulated Deficit	Currency Translation Adjustment	Net Loss	Total Shareholders' Equity
	Number of Shares	Share Capital						
As of								
December 31, 2016	31,166,437	€ 7,792	€ 237,305	€ (127)	€ (68,527)	€ 21	€ (33,667)	€ 142,797
Net loss	—	—	—	—	—	—	(55,728)	(55,728)
Other comprehensive income (loss)	—	—	—	—	(210)	(29)	—	(239)
Total comprehensive income (loss)	—	—	—	—	(210)	(29)	(55,728)	(55,967)
Allocation of prior period profit (loss)	—	—	—	—	(33,667)	—	33,667	—
Equity component of OCEANE net of deferred taxes	—	—	14,312	—	—	—	—	14,312
Share-based compensation	—	—	278	—	—	—	—	278
Other movements	—	—	37	—	—	—	—	37
As of								
December 31, 2017* restated	31,166,437	7,792	251,932	(127)	(102,404)	(8)	(55,728)	101,457
Net loss	—	—	—	—	—	—	79,521	79,521
Other comprehensive income (loss)	—	—	—	—	(31)	14	—	(17)
Total comprehensive income (loss)	—	—	—	—	(31)	14	79,521	79,537
Allocation of prior period profit (loss)	—	—	—	—	(55,728)	—	55,728	—
Capital increase**	17,484	4	(1,201)	—	—	—	—	(1,201)
Share-based compensation	—	—	787	—	—	—	—	787
Treasury shares	—	—	—	(603)	—	—	—	(603)
Other movements	—	—	37	—	—	—	—	37
As of								
December 31, 2018	31,183,921	€ 7,796	€ 251,554	€ (730)	€ (158,167)	€ 6	€ (79,521)	€ 20,939

\* See Note 2.3, "Correction of Errors."

\*\* Expenses incurred as of December 31, 2018 in connection with the preparation of capital market transactions are deducted from equity.

## 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 biopharmaceutical company dedicated to the discovery and development of drugs and biomarkers in therapeutic areas of high unmet need due to the lack of effective treatments or diagnostic tools and/or due to the increasing number of patients worldwide. The Company concentrates its research and development (R&D) efforts to participate in the potential commercialization of treatment solutions and diagnostic tools to fight certain metabolic, inflammatory, autoimmune or fibrotic diseases affecting especially the liver (such as non-alcoholic steatohepatitis, or NASH) and more generally in gastroenterology.

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 as "GENFIT" or the "Group").

### 2. 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") as of December 31, 2018.

The consolidated financial statements as of and for the year ended December 31, 2018 were prepared under the responsibility of the Board of Directors that authorized for issue such statements on February 4, 2019.

The term IFRS includes International Financial Reporting Standards ("IFRS"), International Accounting Standards (the "IAS"), as well as the Interpretations issued by the Standards Interpretation Committee (the "SIC"), and the International Financial Reporting Interpretations Committee ("IFRIC"). The principal accounting methods used to prepare the Consolidated Financial Statements are described below.

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



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**2. BASIS OF PRESENTATION (Continued)**

**2.1. Changes in accounting policies and new standards or amendments**

<u>New or amended policies or standards</u>		<u>Effective date</u>	<u>Potential impact on consolidated financial statements</u>
<b>IFRS 15</b> Revenue from Contracts with Customers	IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces existing revenue recognition guidance, including IAS 18, Revenue.	Applicable for fiscal years open from January 1, 2018	The first application of IFRS 15 does not have an impact on the Group's consolidated financial statements.
<b>IFRS 9</b> Financial Instruments	IFRS 9, published in July 2014, replaces the existing guidance in IAS 39, Financial Instruments: Recognition and Measurement.	Applicable for fiscal years open from January 1, 2018	The first application of IFRS 9 does not have an impact on the Group's consolidated financial statements.
<b>Amendment to IFRS 2</b> Share-based payments	This amendment to IFRS 2 provides clarification on the valuation and modification of the plans.	Applicable for fiscal years open from January 1, 2018	These provisions do not have a significant impact on the Group's consolidated financial statements.
<b>IFRIC 22</b> Foreign currency transactions and advanced consideration	IFRIC 22 clarifies the accounting for transactions that include the receipt or payment of advance consideration in a foreign currency.	Applicable for fiscal years open from January 1, 2018	The application of this amendment to the Group's consolidated financial statements is not expected to have a significant impact.

**2.2. Standards, interpretations and amendments issued but not yet effective**

The paragraph below describes the standards and amendments to standards that are binding and apply starting from January 1, 2019 or later, and indicates GENFIT's position with respect to the future application of these texts.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****2. BASIS OF PRESENTATION (Continued)**

GENFIT has not applied any of these texts earlier than required.

<b>New or amended Standards Text already adopted in the EU</b>		<b>Effective date</b>	<b>Potential impact on consolidated financial statements</b>
<b>IFRS 16</b> Leases	IFRS 16 aligns the accounting of simple leases to that of finance leases.	Applicable for fiscal years open from January 1, 2019	The Group plans to adopt IFRS 16 using the modified retrospective method and to elect to apply the standard to contracts that were previously identified as leases applying IAS 17 and IFRIC 4. The Group also plans to use the exemptions proposed by the standard on lease contracts for which the lease term ends within 12 months as of the date of initial application and lease contracts for which the underlying asset is of low value. The Group is currently identifying the related contracts (the most significant ones relating to building lease contracts) and assessing the related impact on its consolidated financial statements.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 2. BASIS OF PRESENTATION (Continued)

Amendments to standards Text not yet adopted in the EU		Effective date	Potential impact on consolidated financial statements
<b>Improvements to IFRS Standards 2015 - 2017 Cycle</b>	This cycle concerns IFRS 3, IFRS 11, IAS 12, and IAS 23.	Applicable for fiscal years open from January 1, 2019	The application of this amendment to the Group's consolidated financial statements is not expected to have a significant impact.
<b>IFRIC 23</b> Uncertainty over income tax treatments	IFRIC 23 clarifies the interpretation to be applied to the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates, when there is an uncertainty over income tax treatments under IAS 12.	Applicable for fiscal years open from January 1, 2019	The application of this amendment to the Group's consolidated financial statements is not expected to have a significant impact.
<b>Amendments to IAS 19</b> <b>Employee Benefits</b>	This amendment to IAS 19 clarified the assumptions to use for the remeasurement and the effect on the requirements regarding the asset ceiling when a plan amendment, curtailment or settlement occurs.	Applicable for fiscal years open from January 1, 2019	The application of this amendment to the Group's consolidated financial statements is not expected to have a significant impact.

## 2.3 Correction of errors

In the context of the preparation of its 2018 consolidated financial statements, and in accordance with IAS 8, the Company restated the financial statements previously published for the 2017 fiscal year with respect to the accounting for the OCEANE issuance.

These changes do not affect the cash position or the operating results.

These changes were approved by the Board of Directors at its meeting on February 4, 2019.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 2. BASIS OF PRESENTATION (Continued)

The following table shows the impact on the statement of operations for the 2017 fiscal year, compared to previously published figures:

(in thousands of euros, except earnings per share data)	Year ended December 31, 2017—as published	Correction: proper effective interest rate of convertible loan	Correction: proper accounting under IAS 12	Year ended December 31, 2017—as corrected	See explanatory note below
<b>Revenues and other income</b>					
Revenue	€ 118			€ 118	
Other income	6,737			6,737	
Revenue and other income	6,856	—	—	6,856	
<b>Operating expenses and other operating income (expenses)</b>					
Research and development expenses	(54,189)			(54,189)	
General and administrative expenses	(9,421)			(9,421)	
Other operating income (expenses)	60			60	
Operating loss	(56,595)	—	—	(56,695)	
Financial income	642			642	
Financial expenses	(2,168)	(928)		(3,096)	A
Financial loss	(1,526)	(928)	—	(2,453)	
Net loss before tax	(58,220)	(928)	—	(59,148)	
Income tax (expense) benefit	(384)	—	3,804	3,420	B
Net loss	€ (58,604)	€ (928)	€ 3,804	€ (55,728)	

The corrections lead to a decrease in the net loss of €2,876, bringing it to €(55,728) compared to €(58,604) in the previously published accounts.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**2. BASIS OF PRESENTATION (Continued)**

The accounting changes are related to:

- A
- Correction of the effective interest rate taken into account for the calculation of financial expenses related to the OCEANE at the transaction date of October 16, 2017 for an amount of €928 (increase of financial expenses).
- B Recognition of:
- A deferred tax liability with respect to the equity component of the OCEANE €(19,960) for €5,648, as a decrease of equity on October 16, 2017 on initial recognition;
  - A deferred tax liability as of December 31, 2017 related to the tax deduction of the OCEANE issuance costs and the difference between the effective interest rate and the portion of deductible coupon (€120 net), as an increase of the financial expenses in net result (deferred tax expense); and
  - A deferred tax asset arising from recognizing deferred tax assets with respect to tax deductible net operating losses (NOLs) carried forward with respect to the deferred tax liabilities mentioned above, taking into account the French tax rule which limits application of such NOLs to 50% (above one million euros) against taxable profit, and the timing of reversal of these deferred tax liabilities, for an amount of €3,724 on initial recognition (deferred tax income), the use of NOLs for the period of €121 (deferred tax expense) and the reversal of the previously recognized deferred tax expense as of December 31, 2017 for €321 (decrease of deferred tax expense), resulting in an aggregate amount of €3,924 of reduction of deferred tax expense (or a net deferred tax income).

As a result, the net loss per share for the 2017 fiscal year decreased from €1.88 to €1.79.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**2. BASIS OF PRESENTATION (Continued)**

The following table shows the impact of the corrections of these errors in the consolidated statement of financial position at December 31, 2017:

Shareholders' Equity and Liabilities (in thousands of euros, except earnings per share data)	As of December 31, 2017—as published	Correction: proper effective interest rate of convertible loan	Correction: proper accounting under IAS 12	As of December 31, 2017—as corrected	See explanatory note below
<b>Shareholders' equity</b>					
Share capital	€ 7,792			€ 7,792	
Share premium	257,580		(5,648)	251,932	C
Accumulated deficit	(102,531)			(102,531)	
Currency translation adjustment	(8)			(8)	
Net loss	(58,604)	(928)	3,804	(55,728)	D
<b>Total shareholders' equity</b>	<b>104,229</b>	<b>(928)</b>	<b>(1,844)</b>	<b>101,457</b>	
<b>Non-current liabilities</b>					
Non-current convertible loans	153,611	928		154,539	E
Other non-current loans and borrowings	6,978			6,978	
Non-current deferred income and revenue	2			2	
Non-current employee benefits	936			936	
Deferred tax liabilities	321		1,844	2,165	F, G
<b>Total—Non-current liabilities</b>	<b>161,848</b>	<b>928</b>	<b>1,844</b>	<b>164,620</b>	
<b>Current liabilities</b>					
Current convertible loans	1,329			1,329	
Other current loans and borrowings	1,834			1,834	
Current trade and other payables	23,580			23,580	
Current deferred income and revenue	1			1	
Current provisions	361			361	
<b>Total—Current liabilities</b>	<b>27,106</b>	<b>—</b>	<b>—</b>	<b>27,106</b>	
<b>Total—Shareholders' equity and liabilities</b>	<b>€ 293,183</b>	<b>—</b>	<b>—</b>	<b>€ 293,183</b>	

The statement of financial position at December 31, 2017 was restated due to the following changes, in particular:

- C The equity component of the OCEANE (€19,960) determined in accordance with split accounting under IAS 32 was decreased by the deferred tax liability recognized under IAS 12 (€5,648).
- D The impact on income is the result of the elements explained in points A and B above.
- E The non-current part of the convertible loan (OCEANE) is increased by the financial expenses calculated with the proper application of the effective interest rate.
- F The correction of the initially recognized deferred tax liabilities under IAS 12 for €1,844.
- G Following these corrections, the deferred tax liabilities are €2,165.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 2. BASIS OF PRESENTATION (Continued)

The overall impact of these corrections is a €2,772 decrease in equity and an increase in non-current liabilities in the same amount.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### 3.1. 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 3.19.2, "Research tax credit", employee benefits (see Note 3.17, "Employee benefits"), share-based payments (see Note 19, "Share-based compensation"), accruals related to clinical trials (see Note 18, "Operating expenses") and convertible loans (see Note 3.14, "Loans and Borrowings").

#### 3.2. 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.

#### 3.3. Foreign currency

##### 3.3.1. 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.

##### 3.3.2. Foreign currency translation

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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The Group 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.

<u>Ratio : 1 US dollars (USD) = × euros (EUR)</u>	<u>Year ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Exchange rate at period end	0.83382	0.87336
Average exchange rate for the period	0.88704	0.84758

**3.4. 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 3 and 5 years.

**3.5. Property, plant and equipment**

Property, plant and equipment are initially recognized at cost. Cost includes expenditures that are directly attributable to the acquisition of the asset. Routine maintenance costs are expensed as incurred.

Subsequently, depreciation expense is recognized on a straight-line basis over the estimated useful lives of the assets. If components of property, plant and equipment have different useful lives, they are accounted for separately. Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted, if appropriate.

Estimated useful lives are as follows:

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)."

**3.6. Leases**

GENFIT is a lessee in a number of lease contracts (see Note 6, "Property, plant and equipment").

**3.6.1. Finance leases**

If, according to the terms of a lease, it appears that substantially all the risks and rewards incidental to ownership are transferred from the lessor to the lessee, the leasing contract is qualified as a finance lease. The associated leased assets are initially recognized as an asset at their fair value or present value of the minimum lease payments due under the contract, if this is lower, and are



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

subsequently depreciated or impaired, as necessary. The resulting financial liabilities are reported in the line items "Non-current loans and borrowings" and "Current loans and borrowings".

#### 3.6.2. Operating leases

A lease is classified as an operating lease if it does not transfer to the lessee substantially all the risks and rewards incidental to ownership.

Payments made under operating leases are expensed on a straight-line basis over the term of the lease.

Lease incentives received such as rent-free periods or uneven lease payments are spread on a straight-line basis over the term of the lease.

### 3.7. 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.

### 3.8. Financial instruments

IFRS 9, Financial Instruments, replaces IAS 39, Financial Instruments: Recognition and Measurement, for annual periods beginning on or after January 1, 2018, bringing together all three aspects of the accounting for financial instruments: (a) classification and measurement; (b) impairment; and (c) hedge accounting.

The first time application of IFRS 9 had no impact on the Group's financial statements.

Loans and borrowings are initially measured at fair value and subsequently recorded at amortized cost.

### 3.9. Inventories

The Company recognizes inventories of laboratory consumables in connection with its former co-research agreements.

These inventories are measured at the lower of cost and net realizable value. Cost is determined using the weighted average cost method.

### 3.10. 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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### 3.11. 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.

#### 3.12. Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits, together with short-term, 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 financial assets available for sale.

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).

#### 3.13. 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 shareholder's equity under treasury shares.

#### 3.14. 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 accounting of the Company's financial liabilities remains largely the same as it was under IAS 39. Similar to the requirements of IAS 39, IFRS 9 requires contingent liabilities to be treated as financial instruments measured at fair value, with the changes in fair value recognized in the statement of profit or loss.

The Group derecognizes financial liabilities when the contractual obligations are discharged or 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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The liability component is measured, at the date of issuance, at its fair value in accordance with IAS 39, *Financial Instruments: Recognition and Measurement* 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 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 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.

#### 3.15. 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.

#### 3.16. 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.

#### 3.17. Employee benefits

The Group's pension schemes and other post-employment benefits consist of defined benefit plans and defined contribution plans.

##### 3.17.1. 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 in 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 performed to determine the benefit obligations. The amount of future payments is determined on the basis of demographic and financial assumptions such as mortality, staff

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 immediately in the statements of other comprehensive loss.

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.

#### 3.17.2. 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.

#### 3.17.3. 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.

### 3.18. Revenues

Revenue recognized in 2017 and 2018 related primarily to the sublease of a part of the Group's corporate headquarters.

The Group has not yet entered into other contracts with customers that would fall within the scope of IFRS 15.

### 3.19. Other income

#### 3.19.1. 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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### 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 programs needs.

In accordance with IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, the advantage resulting from interest-free or low interest rates as compared to a market interest rate is considered and accounted for as a government grant. A financial liability is recognized for proceeds received from the advance less the grant, and interest expense is subsequently recorded under the effective interest rate method using a market interest rate.

The grant portion of conditional advances is treated as a grant related to income.

For advances granted by BPI France, repayment is required in the event of commercial success. In addition, if the Group decides to stop the research program, the conditional advance may be repayable. If a program is unsuccessful, a pre-determined amount may be repayable. The remaining amount, if any, is then considered as a grant and written off in the line item "Other income" in the statements of operations.

#### **3.19.2. 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 repaid in cash to the entity by the 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 7, "Trade and other receivables" and Note 17, "Revenue and other income"). The CIR for fiscal years 2010, 2011, 2012 and 2014 was under audit by the tax authorities and proposed reassessments were made, which the Group has contested using the legal remedies available to it (see Note 23, "Litigation and contingent liabilities").

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**3.20. Research and development costs**

Research expenses are recorded in the financial statements as expenses (see Note 18, "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.

Since some of these criteria were not fulfilled, the Group did not capitalize any development costs.

**3.21. Classification of operating expenses**

Research and development expenses include:

- employee-related costs;
- costs related to external employees seconded to the Company (clinical development and IT);
- lab supplies and facility costs;
- donations to The NASH Education Program<sup>TM</sup> endowment fund, in particular for the creation of patient registry;
- fees paid to scientific advisers and contracted research and development activities conducted by third parties; and
- intellectual property fees corresponding to the filing of the Group's patents.

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;
- legal, audit and accounting fees;
- press releases and communications firm fees;
- the cost of external employees seconded to the Company (security and reception);

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- other service costs (recruitment, etc.);
- grants to the endowment fund, The NASH Education Program<sup>TM</sup>, earmarked in particular to finance the International NASH Day; and
- intellectual property fees corresponding to the maintenance of the Group's patents.

#### 3.22. 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 account in determining fair value. Regarding the stock options and free shares, market conditions are taken into account in the evaluation of the fair value for the allocation plans that provide for it. 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.

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.

#### 3.23. Income tax

Income tax expense (or income) comprises current tax expense (or income) and deferred tax expense (or income), 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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

#### 3.24. 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).

#### 3.25. 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.

### 4. 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.

#### 4.1. Foreign exchange risk

As of the date of this document, the Group's exposure to exchange rate risk is moderate because the majority of its operations are denominated in euros, with the notable exception of the operations performed by GENFIT CORP in U.S. dollars.

In the future, and in particular with respect to its clinical trials, the Group may have to manage an increasing number of transactions either denominated in other foreign currencies or indirectly exposed to currency risk, which will increase its overall exposure to this risk.

The increase in the overall exposure of the Group 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 geographic location of clinical trials on drug or biomarker candidates;



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****4. FINANCIAL RISKS MANAGEMENT (Continued)**

- the ability, for its co-contracting parties to indirectly transfer foreign exchange risk to the Group; 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.

The following table shows the sensitivity of the Group's expenses in U.S. dollars to a variation of 10% of the U.S. dollar against the euro in 2017 and 2018:

Sensitivity of the Group's expenses to a variation of +/- 10% of the U.S. dollar against the euro (in thousands of euros or U.S. dollars, as applicable)	Year Ended December 31,	
	2017	2018
Expenses denominated in U.S. dollars	5,993	9,613
Equivalent in euros, on the basis of 1 euro = 1.1993 U.S. dollars in 2017 and 1.1456 U.S. dollars in 2018	4,997	8,396
Equivalent in euros, in the event of an increase of 10% of U.S. dollar vs euro	5,552	9,328
Equivalent in euros, in the event of a decrease of 10% of U.S. dollar vs euro	4,543	7,632

For the 2017 fiscal year, the impact of the operational exchange rate risk consisted of realized and unrealized foreign exchange rate losses of €765, offset in part by gains of €59, and in 2018, a realized and unrealized foreign exchange rate loss of €(127), offset in part by gains of €101. These gains and losses are not necessarily indicative of the future impact of exchange rate risk.

**4.2. Interest rate risk**

As of December 31, 2018, 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). Consequently, the Group is not significantly exposed to fluctuations in interest rates for its liabilities.

As of December 31, 2017 and 2018, the Group's financial liabilities totaled €164,680 and €169,593, respectively, net of the equity component of the convertible loan and debt issue costs. The Group's exposure to interest rate risk through its financial assets is also limited, 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.

**4.3. 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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**4. FINANCIAL RISKS MANAGEMENT (Continued)**

The Company has conducted a specific review of its liquidity risk and considers that it is able to meet its future maturities. At December 31, 2017 and 2018, the Group has €274,581 and €208,553, respectively, in cash and cash equivalents and other financial assets. The Group's net cash at December 31, 2017 and 2018, consisting of cash and cash equivalents, less the carrying value of the OCEANES and current and non-current financial liabilities, amounted to €109,141 and €37,647, respectively. 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.

**4.4. 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.

**5. 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 and 2018:

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

5. INTANGIBLE ASSETS (Continued)

Intangible assets—Variations (in thousands of euros)	As of January 1, 2018	Increase	Decrease	As of December 31, 2018
<b>Gross</b>				
Software	1,900	216	(67)	2,049
Patents	21	—	—	21
Other intangibles	—	313	—	313
<b>TOTAL—Gross</b>	<b>1,921</b>	<b>529</b>	<b>(67)</b>	<b>2,384</b>
<b>Accumulated depreciation and impairment</b>				
Software	(1,264)	(370)	67	(1,567)
Patents	(21)	—	—	(21)
Other intangibles	—	—	—	—
<b>TOTAL—Accumulated depreciation and impairment</b>	<b>(1,285)</b>	<b>(370)</b>	<b>67</b>	<b>(1,588)</b>
<b>TOTAL—Net</b>	<b>636</b>	<b>159</b>	<b>—</b>	<b>796</b>

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment (including assets held under finance lease contracts) consist of the following:

Property, plant & equipment— Variations (in thousands of euros)	As of January 1, 2017	Increase	Decrease	Reclassification	As of December 31, 2017
<b>Gross</b>					
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)	—
<b>TOTAL—Gross</b>	<b>8,940</b>	<b>4,287</b>	<b>(105)</b>	<b>—</b>	<b>13,123</b>
<b>Accumulated depreciation and impairment</b>					
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	—	—	—	—	—
<b>TOTAL—Depreciation and impairment</b>	<b>(5,930)</b>	<b>(949)</b>	<b>81</b>	<b>—</b>	<b>(6,798)</b>
<b>TOTAL—Net</b>	<b>3,010</b>	<b>3,338</b>	<b>(24)</b>	<b>—</b>	<b>6,324</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**6. PROPERTY, PLANT AND EQUIPMENT (Continued)**

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

Property, plant and equipment— Variations (in thousands of euros)	As of January 1, 2018	Increase	Decrease	Reclassification	As of December 31, 2018
<b>Gross</b>					
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)	—
<b>TOTAL—Gross</b>	<b>13,123</b>	<b>2,939</b>	<b>(288)</b>	<b>—</b>	<b>15,774</b>
<b>Accumulated depreciation and impairment</b>					
Buildings on non-freehold land	—	(1)	—	—	(1)
Scientific equipment	(5,063)	(1,142)	218	—	(5,988)
Fittings	(722)	(91)	43	—	(769)
Vehicles	(24)	(21)	—	—	(45)
Computer equipment	(703)	(216)	4	—	(915)
Furniture	(285)	(11)	4	—	(292)
In progress	—	—	—	—	—
<b>TOTAL—Depreciation and impairment</b>	<b>(6,798)</b>	<b>(1,481)</b>	<b>270</b>	<b>—</b>	<b>(8,010)</b>
<b>TOTAL—Net</b>	<b>6,324</b>	<b>1,459</b>	<b>(18)</b>	<b>—</b>	<b>7,764</b>

Assets under finance lease contracts relate to scientific equipment. Their net carrying value as of December 31, 2017 and 2018 amounted to €1,895 and €1,889, respectively.

Financial commitments—Operating leases

Lease payments for property rented under the Group's real estate operating leases for its offices in Loos, France; Paris, France; and Cambridge, Massachusetts, USA) and the payment schedule for minimum future lease payments under these leases are as follows:

Operating lease payments—group as lessee (in thousands of euros)	Year Ended December 31,	
	2017	2018
Minimum payments—for the period	1,072	1,153

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 6. PROPERTY, PLANT AND EQUIPMENT (Continued)

Operating lease commitments—group as lessee (in thousands of euros)	As of December 31,	
	2017	2018
Minimum payments—within 1 year	1,072	1,213
Minimum payments—after 1 year but no more than 5 years	3,832	3,262
Minimum payments—more than 5 years	293	316
<b>TOTAL</b>	<b>5,197</b>	<b>4,791</b>

In May 2018, the Company signed an agreement with an independent third party who owns the Company's headquarters, for a building extension of approximately 1,000 square meters for a maximum amount of €2.5 million. The expected completion date for the extension is end of the first quarter of 2019.

GENFIT has guaranteed its rental payment obligation under the lease agreement for the headquarters in Loos in the amount of €455 at December 31, 2017 and 2018.

Financial commitments—Capital leases

The payment schedule for minimum future lease payments under capital leases is as follows:

Finance lease (in thousands of euros)	As of December 31,	
	2017	2018
Minimum payments—Within 1 year	439	539
Minimum payments—After 1 year but not more than 5 years	1,489	1,404
Minimum payments—More than 5 years	—	—
<b>Total—Minimum payments</b>	<b>1,928</b>	<b>1,943</b>
Of which : Principal—Within 1 year	420	520
Of which : Principal—After 1 year but not more than 5 years	1,460	1,381
Of which : Principal—More than 5 years	—	—
<b>Total—Of which : Principal</b>	<b>1,880</b>	<b>1,900</b>
Of which : Interest—Within 1 year	18	19
Of which : Interest—After 1 year but not more than 5 years	29	23
Of which : Interest—More than 5 years	—	—
<b>Total—Of which : Interest</b>	<b>48</b>	<b>42</b>

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 7. TRADE AND OTHER RECEIVABLES

Trade and other receivables consisted of the following:

<u>Trade and other receivables—Total</u> <u>(in thousands of euros)</u>	As of December 31,	
	2017	2018
Trade receivables, net	61	25
Research tax credit	8,466	8,785
Social security costs receivables	3	10
VAT receivables	994	1,103
Grants receivables	13	—
Other receivables	340	361
<b>TOTAL</b>	<b>9,876</b>	<b>10,284</b>

<u>Trade and other receivables—Current</u> <u>(in thousands of euros)</u>	As of December 31,	
	2017	2018
Trade receivables, net	61	25
Research tax credit	6,545	7,295
Social security costs receivables	3	10
VAT receivables	994	1,103
Grants receivables	13	(1)
Other receivables	340	361
<b>TOTAL</b>	<b>7,955</b>	<b>8,794</b>

<u>Trade and other receivables—Non-current</u> <u>(in thousands of euros)</u>	As of December 31,	
	2017	2018
Trade receivables, net	—	—
Research tax credit	1,921	1,489
Social security costs receivables	—	—
VAT receivables	—	—
Grants receivables	—	—
Other receivables	—	—
<b>TOTAL</b>	<b>1,921</b>	<b>1,489</b>

At December 31, 2017 and 2018, trade receivables neither past due nor impaired amounted to €49 and €7, respectively. At December 31, 2017 and 2018, past due trade receivables amounted to €12 and €18, respectively. At December 31, 2017 and 2018, the part of trade receivables classified as doubtful accounts amounted to €73 and €4, respectively. During the 2018 period, a majority of the trade receivables were classified as non-recoverable, in the amount of €57.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 7. TRADE AND OTHER RECEIVABLES (Continued)

Research tax credit

The research tax credit receivable as of December 31, 2018 included:

- 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 23, "Litigation and contingent liabilities".
- The amount received following the judgment in favor of the Company at the Montreuil court (€432) has been deducted.

The estimated amount of €7,295 for the research tax credit receivable for the year 2018 (€6,545 for the year 2017) is in addition to the amounts described above. At December 31, 2018, other receivables mainly included VAT receivables for €1,103, receivables from suppliers for €235 and the CICE receivable for €122.

## 8. OTHER FINANCIAL ASSETS

Other financial assets consisted of the following:

<u>Financial assets—Total</u> <u>(in thousands of euros)</u>	<u>As of</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Loans	219	259
Deposits and guarantees	274	284
Liquidity contract net	267	770
<b>TOTAL</b>	<b>760</b>	<b>1,313</b>

<u>Financial assets—Current</u> <u>(in thousands of euros)</u>	<u>As of</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Deposits and guarantees	31	—
<b>TOTAL</b>	<b>31</b>	<b>—</b>

<u>Financial assets—Non current</u> <u>(in thousands of euros)</u>	<u>As of</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Loans	219	259
Deposits and guarantees	243	284
Liquidity contract	267	770
<b>TOTAL</b>	<b>729</b>	<b>1,313</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****8. OTHER FINANCIAL ASSETS (Continued)**

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.

During the period, Genfit made an additional contribution of €1,000 to the liquidity agreement with CM-CIC Market Solutions. As of December 31, 2018, the liquidity agreement had a cash balance of €770. CM-CIC Market Solutions holds on behalf of Genfit, 27,911 shares, recorded as a deduction from equity.

**9. OTHER ASSETS**

Other assets of €1,761 and €2,078 at December 31, 2017 and 2018, respectively, consisted of prepaid expenses related to current operating expenses. This follows the increase in operating expenses in 2018.

**10. 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 a low risk of changes in value.

<b>Cash and cash equivalents (in thousands of euros)</b>	<b>As of December 31,</b>	
	<b>2017</b>	<b>2018</b>
Short-term deposits	244,279	201,522
Cash on hand and bank accounts	29,541	5,718
<b>TOTAL</b>	<b>273,820</b>	<b>207,240</b>

<b>Short-term deposits (in thousands of euros)</b>	<b>As of December 31,</b>	
	<b>2017</b>	<b>2018</b>
UCITS	38,052	29,189
Term accounts	138,967	124,316
Negotiable medium-term notes	4,150	—
Interest-bearing current accounts	63,110	48,017
<b>TOTAL</b>	<b>244,279</b>	<b>201,522</b>

**11. 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).



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 11. EQUITY (Continued)

At December 31, 2018, 2,300,214 shares have been held for more than two years and entitle their holders to double voting rights (7.38% 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 €180,000. 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.

### 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 €180,000. 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 7.3%. 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 and 2018, the Group recorded a liability of €155,868 and €160,489, respectively, related to the OCEANEs net of the equity portion and debt issue costs. Of this amount, €1,329 and €1,312, respectively, was classified as current and €154,539 and €159,176, respectively, was classified as non-current.

The conversion of all of the convertible bonds would result in a dilution of 19.5% (expressed as a percentage of share capital).

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 12. LOANS AND BORROWINGS (Continued)

## 12.2. Breakdown of other loans and borrowings

Other loans and borrowings consisted of the following:

<b>Other loans &amp; borrowings—Total</b> <b>(in thousands of euros)</b>	<b>As of</b> <b>December 31,</b>	
	<b>2017</b>	<b>2018</b>
Refundable and conditional advances	3,407	3,229
Bank loans	3,488	3,964
Obligations under finance leases	1,890	1,900
Accrued interests	3	3
Other financial loans and borrowings	24	7
<b>TOTAL</b>	<b>8,812</b>	<b>9,104</b>

<b>Other loans and borrowings—Current</b> <b>(in thousands of euros)</b>	<b>As of</b> <b>December 31,</b>	
	<b>2017</b>	<b>2018</b>
Refundable and conditional advances	178	—
Bank loans	1,209	1,319
Obligations under finance leases	420	520
Accrued interests	3	3
Other financial loans and borrowings	24	7
<b>TOTAL</b>	<b>1,834</b>	<b>1,848</b>

<b>Other loans and borrowings—Non current</b> <b>(in thousands of euros)</b>	<b>As of</b> <b>December 31,</b>	
	<b>2017</b>	<b>2018</b>
Refundable and conditional advances	3,229	3,229
Bank loans	2,279	2,645
Obligations under finance leases	1,469	1,381
Accrued interests	—	—
Other financial loans and borrowings	—	—
<b>TOTAL</b>	<b>6,978</b>	<b>7,255</b>

All financial liabilities are denominated in euros.

## 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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

12. LOANS AND BORROWINGS (Continued)

Note 3.19.1, "Government grants". The following table summarizes advances outstanding at December 31, 2017.

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 <i>Development of a global strategy for the prevention and management of type 2 diabetes</i>	12/23/2008	3,229	3,229	—	—	3,229
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 <i>Research of pharmaceutical entities in plant extracts for the treatment of inflammatory diseases</i>	11/24/2010	200	160	(108)	(2)	51
<b>TOTAL</b>						<b>3,407</b>

The following table summarizes advances outstanding at December 31, 2018.

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 <i>Development of a global strategy for the prevention and management of type 2 diabetes</i>	12/23/2008	3,229	3,229	—	—	3,229
<b>TOTAL</b>		<b>3,229</b>	<b>3,229</b>	<b>—</b>	<b>—</b>	<b>3,229</b>

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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****12. LOANS AND BORROWINGS (Continued)**Main terms of the contracts

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**12. LOANS AND BORROWINGS (Continued)**
**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:

(amounts in thousands of euros)	Loan date	Facility size	Interest rate	Available as of December 31, 2017	Installments	Outstanding as of December 31, 2017
CIC	July 2017	€ 1,000	0.69%	€ 500	60 monthly	€ 451
Crédit du Nord	June 2017	600	0.36%	—	48 monthly	525
BNP Paribas	April 2017	800	0.87%	800	60 monthly	—
CIC	December 2016	264.6	0.69%	—	60 monthly	217
BNP Paribas	October 2016	1,050	0.80%	—	20 quarterly	945
Banque Neuflyze OBC	June 2016	500	1.10%	—	12 quarterly	252
BNP Paribas	June 2016	500	0.80%	—	20 quarterly	377
Crédit du Nord	April 2016	500	0.72%	—	60 monthly	335
CIC	March 2015	500	0.85%	—	16 quarterly	158
BNP Paribas	December 2014	500	2.00%	—	20 quarterly	205
Other						23
<b>Total bank loans</b>						<b>3,488</b>

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

(amounts in thousands of euros)	Loan date	Facility size	Interest rate	Available as of December 31, 2018	Installments	Outstanding as of December 31, 2018
CIC	July 2017	€ 1,000	0.69%	€ —	60 monthly	€ 753
Crédit du Nord	June 2017	600	0.36%	—	48 monthly	376
BNP Paribas	April 2017	800	0.87%	—	60 monthly	695
CIC	December 2016	265	0.69%	—	60 monthly	164
BNP Paribas	October 2016	1,050	0.80%	—	20 quarterly	735
Banque Neuflyze OBC	June 2016	500	1.10%	—	12 quarterly	84
BNP Paribas	June 2016	500	0.80%	—	20 quarterly	277
Crédit du Nord	April 2016	500	0.72%	—	60 monthly	236
CIC	March 2015	500	0.85%	—	16 quarterly	32
BNP Paribas	December 2014	500	2.00%	—	20 quarterly	103
Crédit du Nord	November 2018	500	0.46%	—	48 monthly	490
Other	—	—	—	—	—	19
<b>Total bank loans</b>						<b>3,964</b>

**12.3. Development agreements with participation feature**

In June 2010, BPI France granted the Company a development agreement with participation feature amounting to €2,300 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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**12. LOANS AND BORROWINGS (Continued)**

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.

**12.4. Maturities of financial liabilities**

Maturity of financial liabilities (in thousands of euros)	As of December 31, 2018	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
<b>TOTAL—Refundable and conditional advances</b>	<b>3,229</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>3,229</b>
Convertible loans	160,489	1,312	—	—	159,176	—	—
Bank loans	3,964	1,319	1,105	942	544	54	—
Obligations under finance leases	1,900	520	525	523	291	42	—
Accrued interests	3	3	—	—	—	—	—
Other financial loans and borrowings	7	7	—	—	—	—	—
<b>TOTAL—Other loans and borrowings</b>	<b>166,364</b>	<b>3,161</b>	<b>1,631</b>	<b>1,465</b>	<b>160,012</b>	<b>96</b>	<b>—</b>
<b>TOTAL</b>	<b>169,593</b>	<b>3,161</b>	<b>1,631</b>	<b>1,465</b>	<b>160,012</b>	<b>96</b>	<b>3,229</b>

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 €180,000 is due in less than 4 years.

**13. TRADE AND OTHER PAYABLES**

Trade and other payables consisted of the following:

Trade and other payables—Total (all current) (in thousands of euros)	As of December 31,	
	2017	2018
Trade payables	19,053	32,649
Social security costs payables	4,217	2,949
Employee profit sharing	17	17
VAT payables	19	1
Taxes payables	241	286
Other payables	34	71
<b>TOTAL</b>	<b>23,580</b>	<b>35,974</b>

**14. PROVISIONS**

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****14. PROVISIONS (Continued)**

The accruals recorded are mainly related to the research tax credit and the salary tax for 2017. See Note 23, "Litigation and contingent liabilities".

**15. 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 and 2018 amounted to €543 and €765, respectively.

French law also requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement, which are accounted for as a defined benefit plan. Benefits do not vest prior to retirement. The Group is paying this defined benefit plan. It 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 and 2018, pension provisions recorded were €936 and €1,085, respectively.

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

Population	Permanent staff
Retirement age	65
Terms of retirement	Initiated by the employee
Life expectancy	On the basis of the INSEE table(1)
Probability of continued presence in the company at retirement age	On the basis of the DARES table(1)

(1) INSEE is the French National Institute of Statistics; DARES is the French Bureau of Studies and Statistics

Rate	As of December 31,	
	2017	2018
Salary growth rate in 2019	5.8%	5.8%
Salary growth rate beyond 2019	3.0%	3.0%
Discount rate	1.5%	1.53%

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**15. 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 of euros)	
<b>Defined benefit obligation as of January 1, 2017</b>	<b>849</b>
Current service cost	76
Interest cost on benefit obligation	13
Actuarial losses on obligation	210
Past service costs	(211)
<b>Defined benefit obligation as of December 31, 2017</b>	<b>936</b>
Current service cost	104
Interest cost on benefit obligation	14
Actuarial losses on obligation	31
Past service costs	—
<b>Defined benefit obligation as of December 31, 2018</b>	<b>1,085</b>

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

**16. 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 and 2018:

(in thousands of euros)	As of December 31, 2017						
	Carrying value				Fair value		
	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
<b>Assets</b>							
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	—	—
<b>TOTAL—Assets</b>	<b>274,375</b>	<b>273,820</b>	<b>555</b>	<b>—</b>	<b>273,820</b>	<b>555</b>	<b>—</b>
<b>Liabilities</b>							
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	—
<b>TOTAL—Liabilities</b>	<b>183,766</b>	<b>—</b>	<b>—</b>	<b>183,766</b>	<b>—</b>	<b>180,359</b>	<b>3,407</b>



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**16. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)**

(in thousands of euros)	As of December 31, 2018						
	Carrying value				Fair value		
	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
<b>Assets</b>							
Loans	259	—	259	—	—	259	—
Deposits and guarantees	284	—	284	—	—	284	—
Trade receivables	25	—	25	—	—	25	—
Cash and cash equivalents	207,240	207,240	—	—	207,240	—	—
<b>TOTAL—Assets</b>	<b>207,808</b>	<b>207,240</b>	<b>568</b>	<b>—</b>	<b>207,240</b>	<b>568</b>	<b>—</b>
<b>Liabilities</b>							
Conditional advances	3,229	—	—	3,229	—	—	3,229
Convertible loans	160,489	—	—	160,489	—	160,489	—
Bank loans	3,964	—	—	3,964	—	3,964	—
Obligations under finance leases	1,900	—	—	1,900	—	1,900	—
Accrued interests	3	—	—	3	—	3	—
Other financial loans and borrowings	7	—	—	7	—	7	—
Trade payables	32,649	—	—	32,649	—	32,649	—
Other payables	71	—	—	71	—	71	—
<b>TOTAL—Liabilities</b>	<b>202,313</b>	<b>—</b>	<b>—</b>	<b>202,313</b>	<b>—</b>	<b>199,084</b>	<b>3,229</b>

**17. OTHER INCOME**

Other income consisted of the following:

Other income (in thousands of euros)	Year Ended December 31,	
	2017	2018
CIR research tax credit	6,545	7,295
CICE tax credit; other	171	130
Government grants and subsidies	21	—
<b>TOTAL</b>	<b>6,737</b>	<b>7,425</b>

As described in section—Note 23, "Litigation and contingent liabilities", the research tax credits for the fiscal years 2010, 2011, 2012 and 2014 were subject to a tax audit and proposed reassessments were made which the Group has contested using the legal remedies available to it.

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.

In 2017 and 2018, this tax credit was used to finance the increase in headcount and to purchase scientific equipment.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**18. OPERATING EXPENSE**

Year Ended December 31, 2017

Operating expenses and other operating income (expenses) (in thousands of euros)	Total	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 property, plant & 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)
<b>TOTAL</b>	<b>€ (63,550)</b>	<b>€ (2,229)</b>	<b>€ (35,095)</b>	<b>€ (13,406)</b>	<b>€ (11,280)</b>	<b>€ (1,532)</b>	<b>€ (8)</b>

Year Ended December 31, 2018

Operating expenses and other operating income (expenses) (in thousands of euros)	Total	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 property, plant & equipment
Research and development expenses	€ (67,024)	€ (1,724)	€ (47,659)	€ (9,431)	€ (6,502)	€ (1,707)	€ —
General and administrative expenses	(9,793)	(130)	(2)	(4,194)	(5,738)	272	—
Other operating income and (expenses)	(162)	—	—	—	(164)	—	2
<b>TOTAL</b>	<b>€ (76,979)</b>	<b>€ (1,855)</b>	<b>€ (47,662)</b>	<b>€ (13,625)</b>	<b>€ (12,403)</b>	<b>€ (1,435)</b>	<b>€ 2</b>

Research and development expenses 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 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/

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****18. OPERATING EXPENSE (Continued)**

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 nitazoxanide.

The increase in employee expenses 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.

**18.1. Employee expenses**

Employee expenses and number of employees were as follows:

<b>Employee expenses (in thousands of euros)</b>	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2018</b>
Wages and salaries	(9,267)	(9,012)
Social security costs	(3,996)	(3,722)
Changes in pension provision	135	(104)
Share-based compensation	(278)	(787)
<b>TOTAL</b>	<b>(13,406)</b>	<b>(13,625)</b>
Average number of employees	123	135
Average age of employees	38 years 4 months	38 years 11 months
<b>Number of employees</b>		
Research and development	92	100
Administration and management	33	48
<b>TOTAL</b>	<b>125</b>	<b>148</b>

**19. 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 2018 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").

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation granted to board members and consultants in 2014, 2015 and 2017 corresponds to share warrants ("*Bons de Souscriptions d'Actions*" or "BSA").

For the measurement of this share-based compensation, the Group has determined that under IFRS its consultants were not equivalent to employees.

Under these programs, holders of vested instruments are entitled to subscribe to shares of the Company at a pre-determined exercise price. All of the plans are equity settled.

The table below presents the share-based compensation for each of the programs.

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

Share-based compensation—Annual expense	Year Ended December 31,		Total expense calculated	Total expense remaining
	2017	2018		
<b>BSA 2015-A</b>	—	—	<b>335</b>	—
Of which : expense related to non-executive officers	—	—	178	—
Of which : expense related to consultants	—	—	157	—
<b>BSA 2015-B</b>	—	—	<b>315</b>	—
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)

**19. SHARE-BASED COMPENSATION (Continued)**

Share-based compensation—Annual expense	Year Ended December 31,		Total expense calculated	Total expense remaining
	2017	2018		
<b>BSAAR 2016-A</b>	—	—	—	—
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	—	—	—
<b>BSAAR 2016-B</b>	—	—	—	—
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	—	—	—
<b>AGA D 2016-1</b>	<b>38</b>	<b>127</b>	<b>166</b>	—
Of which : expense related to executive officers	7	25	32	—
Of which : expense related to employees	31	101	133	—
<b>AGA D 2016-2</b>	<b>17</b>	<b>17</b>	<b>51</b>	<b>16</b>
Of which : expense related to executive officers	3	3	9	3
Of which : expense related to employees	14	14	42	13
<b>AGA S 2016-1</b>	<b>44</b>	<b>151</b>	<b>197</b>	—
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	44	151	197	—
<b>AGA S 2016-2</b>	<b>22</b>	<b>22</b>	<b>65</b>	<b>21</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	22	22	65	21
<b>SO 2016-1</b>	<b>83</b>	<b>83</b>	<b>249</b>	<b>79</b>
Of which : expense related to executive officers	13	13	40	13
Of which : expense related to employees	70	70	210	67
<b>SO 2016-2</b>	<b>38</b>	<b>38</b>	<b>113</b>	<b>36</b>
Of which : expense related to executive officers	6	6	18	6
Of which : expense related to employees	32	32	95	30
<b>SO US 2016-1</b>	<b>12</b>	<b>12</b>	<b>36</b>	<b>11</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	12	12	36	11
<b>SO US 2016-2</b>	<b>5</b>	<b>5</b>	<b>16</b>	<b>5</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	5	5	16	5

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**19. SHARE-BASED COMPENSATION (Continued)**

Share-based compensation—Annual expense	Year Ended December 31,		Total expense calculated	Total expense remaining
	2017	2018		
<b>BSA 2017-A</b>	<b>6</b>	<b>63</b>	<b>69</b>	<b>—</b>
Of which : expense related to non-executive officers	4	43	47	—
Of which : expense related to employees	2	20	22	—
<b>BSA 2017-B</b>	<b>3</b>	<b>66</b>	<b>70</b>	<b>—</b>
Of which : expense related to non-executive officers	2	46	48	—
Of which : expense related to employees	1	21	22	—
<b>AGA D 2017-1</b>	<b>—</b>	<b>17</b>	<b>35</b>	<b>17</b>
Of which : expense related to executive officers	0	2	4	2
Of which : expense related to employees	1	15	31	15
<b>AGA D 2017-2</b>	<b>—</b>	<b>29</b>	<b>89</b>	<b>58</b>
Of which : expense related to executive officers	0	3	11	7
Of which : expense related to employees	2	26	79	51
<b>AGA S 2017-1</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	—	—	—
<b>AGA S 2017-2</b>	<b>—</b>	<b>24</b>	<b>73</b>	<b>48</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	2	24	73	48
<b>SO 2017-1</b>	<b>2</b>	<b>28</b>	<b>57</b>	<b>28</b>
Of which : expense related to executive officers	0	5	10	5
Of which : expense related to employees	2	23	47	23
<b>SO 2017-2</b>	<b>3</b>	<b>48</b>	<b>146</b>	<b>95</b>
Of which : expense related to executive officers	1	8	26	17
Of which : expense related to employees	3	39	121	79
<b>SO US 2017-1</b>	<b>—</b>	<b>3</b>	<b>6</b>	<b>3</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	3	6	3
<b>SO US 2017-2</b>	<b>—</b>	<b>5</b>	<b>16</b>	<b>11</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	5	16	11

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation—Annual expense	Year Ended December 31,		Total expense calculated	Total expense remaining
	2017	2018		
<b>AGA D 2018</b>	—	<b>10</b>	<b>202</b>	<b>191</b>
Of which : expense related to executive officers	—	2	95	93
Of which : expense related to employees	—	9	107	98
<b>AGA S 2018</b>	—	<b>12</b>	<b>237</b>	<b>225</b>
Of which : expense related to executive officers	—	0	0	0
Of which : expense related to employees	—	12	237	225
<b>SO 2018</b>	—	<b>24</b>	<b>517</b>	<b>493</b>
Of which : expense related to executive officers	—	3	182	179
Of which : expense related to employees	—	21	335	314
<b>SO US 2018</b>	—	<b>3</b>	<b>55</b>	<b>52</b>
Of which : expense related to executive officers	—	—	—	—
Of which : expense related to employees	—	3	55	52
<b>TOTAL</b>	<b>278</b>	<b>787</b>	<b>5,530</b>	<b>1,390</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**19. SHARE-BASED COMPENSATION (Continued)**

**19.1. Share warrants (*bons de souscription d'actions* or BSA)**

The key terms and conditions related to each program are detailed in the following tables:

Share-based compensation Share warrants (BSA)	BSA 2014-A		BSA 2014-B	
	Officers(1)	Consultants	Officers(1)	Consultants
Date of the Shareholders meeting			04/02/2014	
Date of the Executive board meeting			07/24/2014	
Total number of BSA granted	23,385	23,380	23,385	23,380
Total number of BSA subscribed	23,385	23,380	23,385	23,380
Total number of BSA voided	23,385	23,380	—	—
Total number of BSA exercised	—	—	—	—
Total number of BSA remaining	—	—	23,385	23,380
Total number of shares to which the BSA give right	—	—	24,087	24,081
Share entitlement per option	1 warrant / 1.03 shares			
Issue price	0.01 €			
Exercise price(2)	23.50 €			
Subscription period	From 08/01/2014 to 09/15/2017		From 01/02/2015 to 02/15/2015	
Exercise period	From 11/01/2014 to 09/30/2018		From 03/01/2015 to 02/28/2019	
Methods of exercise	Exercisable per tranches of a minimum number of BSA equal to 2,000 or a multiple of 2,000, except outstanding balance			
Valuation method used	Black Scholes			
Expected dividends	0%			
Expected volatility	74.9%			
Risk-free interest rate	0.40%			
Expected life	4 years			
Estimated fair value—valued by expert opinion(3)	13.02 €			
<b>Estimation of fair value as of December 31, 2014</b>				
Period used for the estimation of the underlying share	As of 08/01/2014	From 08/01/2014 To 11/01/2014	As of 08/01/2014	From 08/01/2014 To 12/31/2014
Price of the underlying share	27.46 €	37.79 €	27.46 €	37.79 €
Estimated fair value—according to IFRS 2	15.61 €	24.84 €	15.61 €	24.85 €
<b>Estimation of fair value as of December 31, 2015</b>				
Period used for the estimation of the underlying share	—	—	As of 08/01/2014	From 01/01/2015 To 03/01/2015
Price of the underlying share	—	—	27.46 €	54.84 €
Estimated fair value—according to IFRS 2	—	—	15.61 €	40.09 €

(1) Independent members of the Supervisory board.

(2) Exercise price of the BSA 2014 is equal to the average, weighted by the volumes, of the closing prices of the share over five consecutive trading days from July 7, 2014 to July 11, 2014, decreased by a discount of 5.00%.

(3) Valuation of the financial instrument by independent expert opinion at the time of allocation.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**19. SHARE-BASED COMPENSATION (Continued)**

Share-based compensation Share warrants (BSA)	BSA 2015-A		BSA 2015-B	
	Officers(1)	Consultants	Officers(1)	Consultants
Date of the Shareholders meeting			04/02/2014	
Date of the Executive board meeting			01/09/2015	
Total number of BSA subscribed	7,015	11,690	7,015	11,690
Total number of BSA granted	7,015	5,845	7,015	5,845
Total number of BSA voided	—	—	—	—
Total number of BSA exercised	—	—	—	—
Total number of BSA remaining	7,015	5,845	7,015	5,845
Total number of shares to which the BSA give right	7,225	6,020	7,225	6,020
Share entitlement per option			1 warrant / 1.03 shares	
Issue price			0.01 €	
Exercise price(2)			35.95 €	
Subscription period	From 01/20/2015 to 02/25/2015		From 07/01/2015 to 09/15/2015	
Exercise period	From 06/01/2015 to 05/31/2019		From 12/01/2015 to 11/30/2019	
Methods of exercise	Exercisable per tranches of a minimum number of BSA equal to 2,000 or a multiple of 2,000, except outstanding balance			
Valuation method used	Black Scholes			
Expected dividends	0%			
Expected volatility	74.9%			
Risk-free interest rate	0.40%			
Expected life	4 years			
Estimated fair value—valued by expert opinion(3)	14.64 €			
<b>Estimation of fair value as of June 30, 2015</b>				
Period used for the estimation of the underlying share	As of 01/09/2015	From 01/09/2015 To 06/01/2015	As of 01/09/2015	From 01/09/2015 To 06/30/2015
Price of the underlying share	43.12 €	44.84 €	43.12 €	44.20 €
Estimated fair value—according to IFRS 2	25.33 €	26.89 €	25.33 €	26.31 €
<b>Estimation of fair value as of December 31, 2015</b>				
Period used for the estimation of the underlying share	—	—	As of 01/09/2015	From 07/01/2015 To 12/01/2015
Price of the underlying share	—	—	43.12 €	38.09 €
Estimated fair value—according to IFRS 2	—	—	25.33 €	20.80 €

(1) Independent members of the Supervisory board.

(2) Exercise price of the BSA 2015 is equal to the average, weighted by the volumes, of the closing prices of the share over five consecutive trading days from December 3, 2014 to December 9, 2014, decreased by a discount of 4.98%.

(3) Valuation of the financial instrument by independent expert opinion at the time of allocation.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**19. SHARE-BASED COMPENSATION (Continued)**

	BSA 2017-A		BSA 2017-B	
	Officers(1)	Consultants	Officers(1)	Consultants
<b>Share-based compensation Share warrants (BSA)</b>				
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of BSA subscribed	12,500	5,845	12,500	5,845
Total number of BSA granted	12,500	5,845	12,500	5,845
Total number of BSA voided	—	—	—	—
Total number of BSA exercised	—	—	—	—
Total number of BSA remaining	12,500	5,845	12,500	5,845
Total number of shares to which the BSA give right	12,500	5,845	12,500	5,845
Share entitlement per option			1 warrant / 1 share	
Issue price			2.00 €	
Exercise price(2)			19.97 €	
Subscription period	From 12/11/2017 to 12/26/2017		From 07/01/2018 to 07/15/2018	
Exercise period	From 07/01/2018 to 06/30/2022		From 07/16/2018 to 07/15/2022	
Methods of exercise	Exercisable per tranches of a minimum number of BSA equal to 2,000 or a multiple of 2,000, except outstanding balance			
Valuation method used			Black Scholes	
Expected dividends			0.0%	
Expected volatility	36.4%		35.7%	
Risk-free interest rate			0.00%	
Expected life			0.6 years	
Estimated fair value—valued by expert opinion(3)	3.78 €		3.81 €	
<b>Estimation of fair value as of December 31, 2017</b>				
Period used for the estimation of the underlying share			As of 12/11/2017	
Price of the underlying share			22.50 €	
Estimated fair value—according to IFRS 2	3.78 €		3.81 €	

(1) Independent members of the Board of Directors.

(2) Exercise price of the BSA 2017 is equal to the average, weighted by the volumes, of the closing prices of the share over five consecutive trading days from October 20, 2017 to October 26, 2017, decreased by a discount of 5%.

(3) Valuation of the financial instrument by independent expert opinion at the time of allocation.

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)

**19. SHARE-BASED COMPENSATION (Continued)**
**19.2. Redeemable warrants (*bons de souscription et/ou d'acquisition d'actions remboursables* or BSAAR)**

The key terms and conditions related to each program are detailed in the following tables:

Share-based compensation Redeemable share subscription warrants (BSAAR)	BSAAR 2014-A		BSAAR 2014-B		BSAAR 2014-C	
	Members of the Executive Board	Employees	Members of the Executive Board	Employees	Members of the Executive Board	Employees
Date of the Shareholders meeting			04/02/2014			
Date of the Executive board Meeting			09/15/2014			
Total number of BSAAR granted	18,711	17,248	18,711	17,248	18,711	17,248
Total number of BSAAR subscribed	5,901	9,299	17,822	5,416	18,711	5,568
Total number of BSAAR voided	5,901	8,466	—	1,083	—	833
Total number of BSAAR exercised	—	833	—	—	—	400
Total number of BSAAR remaining	—	—	17,822	4,333	18,711	4,335
Total number of shares to which the BSAAR give right	—	—	18,357	4,463	19,272	4,465
Share entitlement per option			1 warrant / 1.03 shares			
Issue price			5.61 €			
Exercise price(1)			23.50 €			
Subscription period	From 09/19/2014 to 10/15/2014		From 05/07/2015 to 05/29/2015		From 07/06/2015 to 07/31/2015	
Exercise period	From 09/15/2015 to 09/15/2018		From 09/15/2015 to 05/04/2019		From 09/15/2015 to 07/01/2019	
Methods of exercise	Exercisable by fraction of a number of BSAAR equal to 1/3 of the number held by each beneficiary					
Valuation method used	Black Scholes					
Expected dividends	0%					
Expected volatility	74.9%					
Risk-free interest rate	0.40%					
Expected life	4 years					
Estimated fair value—valued by expert opinion(2)	5.61 €					
<b>Estimation of fair value as of December 31, 2014</b>						
Period used for the estimation of the underlying share	From 10/10/2014 To 10/14/2014	From 10/10/2014 To 10/14/2014	As of 09/15/2014	As of 09/19/2014	As of 09/15/2014	As of 09/19/2014
Price of the underlying share	34.63 €	34.63 €	46.85 €	43.95 €	46.85 €	43.95 €
Estimated fair value—according to IFRS 2	8.44 €	8.44 €	11.29 €	10.61 €	11.29 €	10.61 €
<b>Estimation of fair value as of June 30, 2015</b>						
Period used for the estimation of the underlying share	From 10/10/2014 To 10/14/2014	From 10/10/2014 To 10/14/2014	As of 09/15/2014	As of 09/19/2014	As of 09/15/2014	As of 09/19/2014
Price of the underlying share	34.63 €	34.63 €	46.85 €	43.95 €	46.85 €	43.95 €
Estimated fair value—according to IFRS 2	8.44 €	8.44 €	11.29 €	10.61 €	11.29 €	10.61 €
<b>Estimation of fair value as of December 31, 2015</b>						
Period used for the estimation of the underlying share	From 10/10/2014 To 10/14/2014	From 10/10/2014 To 10/14/2014	As of 09/15/2014	As of 09/19/2014	As of 09/15/2014	As of 09/19/2014
Price of the underlying share	34.63 €	34.63 €	46.85 €	43.95 €	46.85 €	43.95 €
Estimated fair value—according to IFRS 2	8.44 €	8.44 €	11.29 €	10.61 €	11.29 €	10.61 €

(1) Exercise price of the BSAAR 2014 is equal to the average, weighted by the volumes, of the closing prices of the share over five consecutive trading days from August 13, 2014 to August 19, 2014, decreased by a discount of 13.60%.

(2) Valuation of the financial instrument by independent expert opinion at the time of allocation.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation Redeemable share subscription warrants (BSAAR)	BSAAR 2016-A	BSAAR 2016-B
	Employees	Employees
Date of the Shareholders meeting		02/24/2015
Date of the Executive board meeting		07/22/2016
Total number of BSAAR granted	7,200	3,600
Total number of BSAAR subscribed	7,200	3,600
Total number of BSAAR voided	—	—
Total number of BSAAR exercised	—	—
Total number of BSAAR remaining	7,200	3,600
Total number of shares to which the BSAAR give right	7,416	3,708
Share entitlement per option	1 warrant / 1.03 shares	
Issue price	4.60 €	
Exercise price(1)	23.50 €	
Subscription period	From 07/25/2016 to 07/27/2016	
Exercise period	From 01/01/2018 to 07/27/2020	From 08/01/2019 to 07/27/2020
Methods of exercise	Exercisable by fraction of a number of BSAAR equal to 1/3 of the number held by each beneficiary	
Valuation method used	Black Scholes	
Expected dividends	0%	
Expected volatility	75.4%	
Risk-free interest rate	0.00%	
Expected life	4 years	
Estimated fair value—valued by expert opinion(2)	4.60 €	

(1) Exercise price of the BSAAR 2016 is equal to the average, weighted by the volumes, of the closing prices of the share over five consecutive trading days from July 15, 2014 to July 21, 2016, decreased by a discount of 6.67%.

(2) Valuation of the financial instrument by independent expert opinion at the time of allocation.

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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

19.3. 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)	AGA D 2016-1		AGA S 2016-1	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting	06/21/2016			
Date of the Executive board meeting	12/15/2016			
Total number of AGA granted	5,242	4,879	—	10,419
Total number of AGA subscribed	5,242	4,879	—	10,399
Total number of AGA voided	—	778	—	900
Total number of AGA definitively vested	4,480	3,505	—	9,499
Total number of AGA remaining	762	596	—	—
Acquisition period	From 12/15/2016 to 12/15/2018 or 12/15/2019			
Valuation method used	Monte Carlo			
Price of the share at the time of allocation	20.79 €			
Expected dividends	0%			
Expected volatility	63.0%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Members of the Executive Board.

Share-based compensation Free shares (AGA)	AGA D 2016-2		AGA S 2016-2	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting	06/21/2016			
Date of the Executive board meeting	12/15/2016			
Total number of AGA granted	2,621	2,439	—	5,209
Total number of AGA subscribed	2,621	2,439	—	5,129
Total number of AGA voided	—	389	—	380
Total number of AGA definitively vested	—	—	—	—
Total number of AGA remaining	2,621	2,050	—	4,749
Acquisition period	From 12/15/2016 to 12/15/2019			
Valuation method used	Monte Carlo			
Price of the share at the time of allocation	20.79 €			
Expected dividends	0%			
Expected volatility	63.0%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Members of the Executive Board.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation Free shares (AGA)	AGA D 2017-1		AGA S 2017-1	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of AGA granted	2,000	14,646	—	11,443
Total number of AGA subscribed	2,000	14,646	—	10,822
Total number of AGA voided	—	1,806	—	649
Total number of AGA definitively vested	—	—	—	—
Total number of AGA remaining	2,000	12,840	—	10,173
Acquisition period	From 12/06/2017 to 12/31/2020			
Valuation method used	Monte Carlo			
Price of the share at the time of allocation	21.95 €			
Expected dividends	0%			
Expected volatility	53.7%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Chief executive officer

Share-based compensation Free shares (AGA)	AGA D 2017-2		AGA S 2017-2	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of AGA granted	1,000	7,321	—	5,718
Total number of AGA subscribed	1,000	7,321	—	5,407
Total number of AGA voided	—	903	—	324
Total number of AGA definitively vested	—	—	—	—
Total number of AGA remaining	1,000	6,418	—	5,083
Acquisition period	From 12/06/2017 to 12/31/2020			
Valuation method used	Monte Carlo			
Price of the share at the time of allocation	21.95 €			
Expected dividends	0%			
Expected volatility	53.7%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Chief executive officer

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation Free shares (AGA)	AGA 2018		AGA 2018	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting	06/16/2017			
Date of the decision and delegation of the Board of Directors to the CEO	11/21/2017			
Date of the Executive board meeting	12/06/2017			
Total number of AGA granted	3,000	16,149	—	17,923
Total number of AGA subscribed	3,000	16,149	—	16,651
Total number of AGA voided	—	—	—	366
Total number of AGA definitively vested	—	—	—	—
Total number of AGA remaining	3,000	16,149	—	16,285
Acquisition period	From 12/06/2017 to 12/31/2020			
Valuation method used	Monte Carlo			
Price of the share at the time of allocation	20.02 €			
Expected dividends	0%			
Expected volatility	38.0%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(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 Note 19.5, "Performance conditions".

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

19.4. 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 Stock-options (SO)	SO 2016-1		SO US 2016-1	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting	06/21/2016			
Date of the Executive board meeting	12/15/2016			
Total number of SO granted	20,001	21,916	—	7,000
Total number of SO subscribed	20,001	21,916	—	7,000
Total number of SO voided	—	1,667	—	7,000
Total number of SO definitively vested	17,093	17,305	—	—
Total number of SO remaining	2,908	2,944	—	—
Total number of SO exercised	—	—	—	—
Exercise price	15.79 €		21.12 €	
Vesting period	From 12/15/2016 to 12/15/2019			
Exercise period	From 12/16/2019 to 12/16/2026			
Valuation method used	Monte Carlo			
Fair Value	10.30 €		8.52 €	
Price of the share at the time of allocation	20.79 €			
Expected dividends	0%			
Expected volatility	63.0%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Members of the Executive Board.

Share-based compensation Stock-options (SO)	SO 2016-2		SO US 2016-2	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting	06/21/2016			
Date of the Executive board meeting	12/15/2016			
Total number of SO granted	9,999	10,959	—	3,500
Total number of SO subscribed	9,999	10,959	—	3,500
Total number of SO voided	—	833	—	3,500
Total number of SO definitively vested	—	—	—	—
Total number of SO remaining	9,999	10,126	—	—
Total number of SO exercised	—	—	—	—
Exercise price	15.79 €		21.12 €	
Vesting period	From 12/15/2016 to 12/15/2019			
Exercise period	From 12/16/2019 to 12/16/2026			
Valuation method used	Monte Carlo			
Fair Value	10.30 €		8.52 €	
Price of the share at the time of allocation	20.79 €			
Expected dividends	0%			
Expected volatility	63.0%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Members of the Executive Board.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**19. SHARE-BASED COMPENSATION (Continued)**

Share-based compensation Stock-options (SO)	SO 2017-1		SO US 2017-1	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of SO granted	11,333	52,831	—	8,666
Total number of SO subscribed	11,333	52,831	—	8,666
Total number of SO voided	—	—	—	8,666
Total number of SO definitively vested	—	—	—	—
Total number of SO remaining	11,333	52,831	—	—
Total number of SO exercised	—	—	—	—
Exercise price	17.91 €		22.54 €	
Vesting period	From 12/06/2017 to 12/31/2020			
Exercise period	From 01/01/2021 to 12/31/2027			
Valuation method used	Monte Carlo			
Fair Value	9.32 €			
Price of the share at the time of allocation	21.95 €			
Expected dividends	0%			
Expected volatility	53.7%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Chief executive officer

Share-based compensation Stock-options (SO)	SO 2017-2		SO US 2017-2	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of SO granted	5,667	26,419	—	4,334
Total number of SO subscribed	5,667	26,419	—	4,334
Total number of SO voided	—	—	—	4,334
Total number of SO definitively vested	—	—	—	—
Total number of SO remaining	5,667	26,419	—	—
Total number of SO exercised	—	—	—	—
Exercise price	17.91 €		22.54 €	
Vesting period	From 12/06/2017 to 12/31/2020			
Exercise period	From 01/01/2021 to 12/31/2027			
Valuation method used	Monte Carlo			
Fair Value	9.32 €			
Price of the share at the time of allocation	21.95 €			
Expected dividends	0%			
Expected volatility	53.7%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Chief executive officer

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 19. SHARE-BASED COMPENSATION (Continued)

Share-based compensation Stock-options (SO)	SO 2018		SO US 2018	
	Officers(1)	Employees	Officers(1)	Employees
Date of the Shareholders meeting			06/16/2017	
Date of the decision and delegation of the Board of Directors to the CEO			11/21/2017	
Date of the Executive board meeting			12/06/2017	
Total number of SO granted	17,000	105,000	—	17,500
Total number of SO subscribed	17,000	105,000	—	17,500
Total number of SO voided	—	—	—	—
Total number of SO definitively vested	—	—	—	—
Total number of SO remaining	17,000	105,000	—	17,500
Total number of SO exercised	—	—	—	—
Exercise price	16.00 €		21.65 €	
Vesting period	From 12/06/2017 to 12/31/2020			
Exercise period	From 01/01/2021 to 12/31/2027			
Valuation method used	Monte Carlo			
Fair value	9.32 €		6.90 €	
Price of the share at the time of allocation			22.12 €	
Expected dividends	0%			
Expected volatility	44.1%			
Risk-free interest rate	0.0%			
Turnover rate	15.00%			

(1) Chief executive officer

Volatility assumptions in the above tables are determined by reference to the Company's historical share price over a 3-year period prior to the grant date, adjusted for extreme and unusual variations, if any.

The final allocation of free shares is subject to continued employment with the Group and performance conditions. These performance conditions are described in Note 19.5, "Performance conditions".

**19.5. Performance conditions**

The SO and SO US stock option plans as well as certain free share plans (AGA "D") implemented in 2016, 2017 and 2018 are subject to internal performance conditions related to the progress of the Group's research and development programs, and to external performance conditions related to the evolution of the Company's stock price.

The other free share plans (AGA "S") are subject only to internal performance conditions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

19. SHARE-BASED COMPENSATION (Continued)

19.5.1. Performance conditions of the 2016-1 and 2016-2 plans

Plans	Assessment 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	<p>66<sup>2</sup>/3% of the instruments will be exercisable or definitively allocated, regardless of the variation of the stock market price, in the following events:</p> <p>(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</p> <p>(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:</p> <ul style="list-style-type: none"> <li>• a clinical trial with elafibranor within a NASH subpopulation; or</li> <li>• a clinical trial with respect to fibrosis within the TGFTX4/repositioning program.</li> </ul> <p style="text-align: center;">Nature of external conditions</p> <hr/> <p>33<sup>1</sup>/3% of the instruments will be exercisable or definitively allocated in proportion to the evolution of the stock market price of the Company, as follows:</p> <p>(i) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0;</p> <p>(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] × 1/3 of number of instruments;</p> <p>(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.</p>
AGA S 2016-1	12/15/2018 and/or 12/15/2019	<p style="text-align: center;">Nature of internal conditions</p> <hr/> <p>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.</p>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****19. SHARE-BASED COMPENSATION (Continued)**

<u>Plans</u>	<u>Evaluation date for performance conditions</u>	<u>Nature of internal conditions</u>
SO 2016-2 SO US 2016-2 AGA D 2016-2	12/15/2019	<p>66<sup>2</sup>/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:</p> <p>(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</p> <p>(ii) if the launch of at least two new clinical trials among the following are authorized by the EMA or the FDA, either:</p> <ul style="list-style-type: none"> <li>• Phase 3 clinical trials of or which aim to record a new product (TGFTX4) or a new indication for elafibranor (PBC); or</li> <li>• Clinical trials with a product in Phase 2 (Elafibranor) within a NASH subpopulation; or</li> </ul> <p>(iii) if at least on licensing agreement, on one or another of Genfit's products in one or several territories, is entered into by the Company</p>
		<u>Nature of external conditions</u>
		<p>33<sup>1</sup>/3% of the instruments will be exercisable or definitively allocated in proportion to the evolution of the stock market price, as follows:</p> <p>(i) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0</p> <p>(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 × <sup>1</sup>/3 of number of instruments ;</p> <p>(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.</p>
		<u>Nature of internal conditions</u>
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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 19. SHARE-BASED COMPENSATION (Continued)

## 19.5.2. Performance conditions of the 2017-1 and 2017-2 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	<p>66<sup>2</sup>/3% of the instruments will be definitively allocated, regardless of the variation of the stock market price, in the following events:</p> <p>(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</p> <p>(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:</p> <ul style="list-style-type: none"> <li>• a clinical trial with elafibranor within a NASH subpopulation; or</li> <li>• a clinical trial with respect to fibrosis with NTZ.</li> </ul> <p style="text-align: center;">Nature of external conditions</p> <p>33<sup>1</sup>/3% of the instruments will be exercisable or definitively allocated in proportion to the evolution of the stock market price of the Company, as follows:</p> <p>(i) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0;</p> <p>(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:  <math>[(\text{Final Price} / \text{Initial Price}) - 1] \times \frac{1}{3}</math> of number of instruments;</p> <p>(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.</p>
AGA S 2017-1	12/31/2019	<p style="text-align: center;">Nature of internal conditions</p> <p>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.</p>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****19. SHARE-BASED COMPENSATION (Continued)**

<b>Plans</b>	<b>Evaluation date for performance conditions</b>	<b>Nature of internal conditions</b>
SO 2017-2 SO US 2017-2 AGA D 2017-2	12/31/2020	<p>66<sup>2</sup>/<sub>3</sub>% 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:</p> <p>(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</p> <p>(ii) if the launch of at least one clinical trial among the following is authorized by the EMA or the FDA, either:</p> <ul style="list-style-type: none"> <li>• Phase 3 clinical trials of or which aim to record a new product (NTZ program) or a new indication for Elafibranor (PBC);</li> <li>• Clinical trials with a product in Phase 2 (Elafibranor) within a NASH subpopulation; or</li> </ul> <p>(iii) if at least on licensing agreement, on one or another of Genfit's products in one or several territories, is entered into by the Company.</p> <hr/> <p style="text-align: center;"><b>Nature of external conditions</b></p> <hr/> <p>33<sup>1</sup>/<sub>3</sub>% of the instruments will be exercisable or definitively allocated in proportion to the evolution of the stock market price, as follows:</p> <p>(i) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0</p> <p>(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 × <sup>1</sup>/<sub>3</sub> of number of instruments;</p> <p>(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.</p>
AGA S 2017-2	12/31/2020	<p>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.</p>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****19. SHARE-BASED COMPENSATION (Continued)**

<u>Plans</u>	<u>Evaluation date for performance conditions</u>	<u>Nature of internal conditions</u>
SO 2018 SO US 2018 AGA D 2018	12/31/2020	<p>66<sup>2</sup>/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:</p> <p>(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</p> <p>(ii) if authorization to launch at least one new clinical trial among the following trials is obtained:</p> <ul style="list-style-type: none"> <li>• Phase 3 or Phase 2/3 clinical trial evaluating a new product (NTZ);</li> <li>• Phase 3 or Phase 2/3 clinical trial evaluating elafibranor in PBC</li> <li>• Phase 3 clinical trial evaluating elafibranor in a NASH subpopulation; or</li> </ul> <p>(iii) if at least on licensing agreement, on one or another of Genfit's products in one or several territories, is entered into by the Company</p>
		<p style="text-align: center;"><u>Nature of external conditions</u></p> <hr/> <p>33<sup>1</sup>/3% of the Stock Options will be exercisable in proportion to the variation of the Company's stock market price as per the following breakdown:</p> <p>(i) if the Final Price is strictly lower than the Initial Price, the number of the Stock Options exercisable is equal to 0;</p> <p>(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:</p> <p>[(Final Price / Initial Price)-1]/2 × 1/3 of number of Stock Options;</p> <p>(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.</p>
AGA S 2018	12/31/2020	<p style="text-align: center;"><u>Nature of internal conditions</u></p> <hr/> <p>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.</p>

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 20. FINANCIAL INCOME AND EXPENSES

Financial income and expenses (in thousands of euros)	Year Ended December 31,	
	2017	2018
<b>Financial income</b>		
Interest income	389	202
Foreign exchange gain	59	101
Other financial income	195	425
<b>TOTAL—Financial income</b>	<b>642</b>	<b>728</b>
<b>Financial expenses</b>		
Interest expenses for loans and borrowings	(2,309)	(10,955)
Interest expenses for financial leases	(10)	(21)
Foreign exchange losses	(764)	(127)
Other financial expenses	(13)	(14)
<b>TOTAL—Financial expenses</b>	<b>(3,096)</b>	<b>(11,118)</b>
<b>FINANCIAL GAIN (LOSS)</b>	<b>(2,453)</b>	<b>(10,391)</b>

The increase in financial expenses is mainly due to the interest payments on the OCEANEs which were issued in October 2017.

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 discounting of the bond debt at an effective interest rate of 7.29%. 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.

In 2017 the foreign exchange result is mainly explained by a loss related to a currency forward in USD. (There was an unfavourable USD versus EUR variation).

## 21. INCOME TAX

## 21.1. Losses available for offsetting against future taxable income

At December 31, 2017 and 2018, the tax loss carryforwards for the Company amounted to €226,708 and €305,530, respectively.

Such carryforwards can be offset against future taxable profit within a limit of €1,000 per year plus 50% of the profit exceeding this limit. Remaining unused losses will continue to be carried forward indefinitely.

## 21.2. 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 carryforwards: €226,708 and €305,530, respectively;



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****21. INCOME TAX (Continued)**

- 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. See Note 2.3, "Correction of errors"; and
  - related to post-employment benefits: €936 and €1,085, respectively, or an impact on deferred tax assets of €262 and €304, respectively.

Other 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 carryforwards.

**22. EARNINGS (LOSS) PER SHARE**

The components of the earnings (loss) per share computation are as follows:

<u>Earnings per share</u>	<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Loss for the period (in thousands of euros)	(55,728)	(79,521)
Weighted average number of ordinary shares for the period	31,166,437	31,167,203
Loss per share (in €)	(1.79)	(2.55)

Potentially dilutive instruments were excluded from the calculation of the diluted weighted average number of shares as their effect was anti-dilutive.

**23. LITIGATION AND CONTINGENT LIABILITIES**Dispute over research tax credit calculation*Context*

During 2014, the Company was under a tax audit at the end of which the tax authorities questioned part of the Research Tax Credit (CIR) received by the Company for 2010. The tax audit continued for the 2011 and 2012 CIR returns.

*Subject matter of the dispute*

The dispute with the French tax authorities pertained mainly to collaborative research alliances with companies 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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**23. LITIGATION AND CONTINGENT LIABILITIES (Continued)**

*Status of the tax audit*

The Company received proposed tax adjustments in December 2014 (for the 2010 CIR) and in December 2015 (for the 2011 and 2012 CIR), to which the Company presented its observations in written letters in February 2015 and February 2016.

Following the administrative appeal and the departmental meeting (*interlocution départementale*) held in June 2016 and October 2016 respectively, the tax authorities partially accepted the Company's arguments.

As a result, the final tax adjustments on the CIRs totaled €566 for 2010, €623 for 2011 and €285 for 2012, and an additional €5 for late filing.

On January 27, 2017, the Company received the formal tax assessment notice for €1,478 from the tax authorities, which were paid as follows:

- a cash payment for an amount of €338;
- a request for write-off with the amount withheld on its CIR receivable for 2014 (€1,141), which was accepted up to €693 in August 2017;
- a request for a partial write-off with the amount due on its CIR receivable for 2016, which was accepted for €447 in August 2017.

The Company filed two claims, on February 15, 2017 and October 6, 2017, contesting the aforementioned adjustments (the initial €1,478 and the potential tax adjustment on the CIR for 2014 of €447).

On April 5, 2018, the Administrative Court of Montreuil substantially accepted the Company's claim regarding the tax qualification of its collaborative research. On July 25, 2018, the Ministry of Action and Public Accounts appealed the April 5, 2018 judgment.

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 reimbursed by €432.

The Company was informed on October 28, 2018 that the Ministry of Action and Public Accounts appealed the aforementioned June 28, 2018 judgment.

*Potential liability*

The Company, in accordance with IFRS standards, measured its potential tax liability should the tax authorities' interpretation prevail with respect to the CIR for the years under tax audit and subsequent years. The recording and disclosure of this potential tax liability in these consolidated financial statements does not, under any circumstances, constitute an acknowledgement of the tax authorities' arguments in this matter. Based on analyses conducted by independent third party tax experts, the Company believes that the potential tax liability is approximately €1,809 out of the aggregate €20,695 in CIRs reported in the 2010 to 2015 financial statements.

Independent of the payments made pursuant to the tax authorities' requests in the assessment notice, the amount of the potential tax liability of €1,809 mentioned above remains unchanged considering the appeal formed by the Ministry. There is no provision for this amount considering that the risk was assessed as possible rather than probable.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 23. LITIGATION AND CONTINGENT LIABILITIES (Continued)

#### *Provision*

In addition, the Company has accrued €106 for contracts, other than joint research alliances, which could be considered as sub-contracting for third parties that are themselves eligible for the research tax credit, and for other adjustments related to the type of tangible assets considered eligible for the CIR.

#### Dispute regarding social security contributions and other payments

Following an URSSAF (French social security administration) audit which began in September 2016 with respect to the 2013, 2014 and 2015 fiscal years, the Company received in November 2016 a social security contribution reassessment for €5 which the Company contested in the amount of €4 before the *Tribunal des Affaires Sociales* (Social Affairs Court). The Court is expected to rule on this case in March 2019.

### 24. RELATED PARTIES

Biotech Avenir SAS and The NASH Education Program<sup>TM</sup>, 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 Education Program<sup>TM</sup> are located at the same address as the Company. These domiciliations are provided without charge.

Biotech Avenir SAS is a holding company incorporated in 2001 by the Company's founders. Most of its share capital is currently held by the four co-founders of the Company and approximately thirteen Company employees.

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

At December 31, 2018, Biotech Avenir SAS held 6.06% of the share capital of the Company.

The Company did not carry out any transactions with Biotech Avenir in 2017 nor in 2018.

In addition to the cash contributed by the Company to the liquidity agreement put in place with CM-CIC Securities, Biotech Avenir SAS contributed shares of the Company to the liquidity agreement. Biotech Avenir SAS withdrew from this liquidity agreement as of December 1, 2017 in order to comply with the latest recommendations of the *Autorité des Marchés Financiers*.

The NASH Education Program<sup>TM</sup> 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 and 2018 between the Group and The NASH Education Program<sup>TM</sup> and the Group's obligations with respect to The NASH Education Program<sup>TM</sup> are described in Note 26, "Commitments".

### 25. 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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(amounts in thousands of euros, except for numbers of shares and per share amounts)****25. COMPENSATION OF CORPORATE OFFICERS (Continued)**

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.

<b>Compensation paid to Officers (in thousands of euros)</b>	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2018</b>
Short-term employee benefits (gross plus employer's social contributions paid)	1,476	1,569
Post-employment pension and medical benefits	199	—
Share-based payment transactions	51	104
Director fees for service to Genfit Corp.	37	30
<b>TOTAL</b>	<b>1,763</b>	<b>1,703</b>

The changes in provision for pension liabilities relate to rates described in Note 15, "Employee benefits" and the fact that the Chairman and CEO exercised his pension rights in September 2017 retaining his position as Chairman and CEO.

The Chairman and CEO is entitled to a severance payment falling within the scope of article L.225-42-1 of the French commercial code, equal to six months' salary, calculated on the basis of the last 12 months' salary (excluding payments under the Group's incentive plan) and increased by additional compensation of one months' salary per year of service with the Company (calculated on the same basis). This severance payment is capped at 2 years gross compensation (excluding exceptional payments under the incentive plans) paid with respect to the last fiscal year and subject to performance conditions. This commitment (gross amount and employer charges) at December 31, 2018 amounted to €1,438.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 25. COMPENSATION OF CORPORATE OFFICERS (Continued)

The directors' fees and other compensation due and paid to the non executive directors are as follows:

Attendance fees and other forms of remuneration payable to each of the non executive officer (in euros)	Amounts due*	Amounts paid*	Amounts due*	Amounts paid*
	During the year ended December 31,			
	2017(4)		2018	
<b>Jean-François MOUNEY(1)</b>				
Attendance fees	—	—	—	—
Other remuneration (outside compensation as CEO)	—	—	—	—
<b>Total</b>	—	—	—	—
<b>Xavier GUILLE DES BUTTES</b>				
Attendance fees	30,218	24,688	53,330	41,311
Other remuneration	—	—	—	—
<b>Total</b>	<b>30,218</b>	<b>24,688</b>	<b>53,330</b>	<b>41,311</b>
<b>Charles WOLER(2)</b>				
Attendance fees	5,925	5,925	—	—
Other remuneration	—	—	—	—
<b>Total</b>	<b>5,925</b>	<b>5,925</b>	—	—
<b>Frédéric DESDOUITS</b>				
Attendance fees	13,627	11,258	21,174	17,113
Other remuneration	—	—	—	—
<b>Total</b>	<b>13,627</b>	<b>11,258</b>	<b>21,174</b>	<b>17,113</b>
<b>BIOTECH AVENIR</b>				
Represented by Florence Séjourné				
Attendance fees	—	—	—	—
Other remuneration	—	—	—	—
<b>Total</b>	—	—	—	—
<b>Philippe MOONS</b>				
Attendance fees	18,763	14,023	29,704	22,345
Other remuneration	—	—	—	—
<b>Total</b>	<b>18,763</b>	<b>14,023</b>	<b>29,704</b>	<b>22,345</b>
<b>Anne-Hélène MONSELLATO(3)</b>				
Attendance fees	14,813	10,468	37,075	24,307
Other remuneration	—	—	—	—
<b>Total</b>	<b>14,813</b>	<b>10,468</b>	<b>37,075</b>	<b>24,307</b>
<b>Catherine LARUE(3)</b>				
Attendance fees	11,258	8,098	21,256	17,985
Other remuneration	—	—	—	—
<b>Total</b>	<b>11,258</b>	<b>8,098</b>	<b>21,256</b>	<b>17,985</b>
<b>TOTAL</b>	<b>94,602</b>	<b>74,458</b>	<b>162,539</b>	<b>123,061</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**25. COMPENSATION OF CORPORATE OFFICERS (Continued)**

	2017(4)	2018
<b>IFRS 2 valuation of options granted during the financial year</b>	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.

**26. 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 third party vendors for clinical and commercial supply manufacturing, commercial and precommercial activities, research and development activities and other services and products for operating purposes. The Group's agreements generally provide for termination with specified periods of advance notice. Such agreements are generally cancelable contracts and not included in the description of the Group's contractual obligations and commitments.

Deposits and guarantees

The Company has guaranteed its rental payment obligation under the lease agreement for the headquarters in Loos, France in the amount of €455 at December 31, 2018.

Lease commitments

In 2016, CM-CIC Bail and the Company entered into a master agreement for leases with an option to purchase scientific equipment for a maximum amount of €2,000.

This contract was amended several times, with Amendment No. 3 increasing the amount of this agreement to €2,150, valid until June 30, 2019.

In addition, in 2016, NatioCreditMur (BNP Paribas) and the Company entered into a master lease agreement of €1,050, which was extended by amendments in 2017 and 2018 until June 30, 2019.

Through December 31, 2018, the Company had drawn on €2,637 under these leasing agreements.

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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### 26. COMMITMENTS (Continued)

The Company ensures, with regard to these programs, that the collaboration or subcontracting agreements that it is required to enter into, systematically stipulate that the results of the research are the Company's property. This is particularly the case for research consortia, in which the Group is associated with university laboratories and other biotechnology companies. It therefore holds all the intellectual property rights over its portfolio of proprietary programs and products.

On the other hand, the agreements signed in the framework of the Company's historical co-research alliances with partners in the pharmaceutical industry provided that the intellectual property rights of the drug candidates developed under these alliances belonged to the partners. These agreements also provided that the Company had intellectual property rights over the innovative technologies discovered on this occasion, even if it had to grant a royalty free and non-exclusive license to the industrial partner for the purpose of developing drug candidates discovered under the co-research programs.

To date, Sanofi remains the only industrial partner likely to still have exploitation rights on a drug candidate developed as part of its historical co-research alliance with the Company and therefore able to use on a royalty-free basis, but not exclusively, technologies developed by the Company under this program. The other historic partners have informed the Company of their decision not to exploit or stop exploiting the results of joint research. Nevertheless, to date, Sanofi has not communicated to the Company its desire to continue the development of this program despite the last research phase shared with the Company's teams having ended in May 2015.

#### 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<sup>TM</sup>. The NASH Education Program<sup>TM</sup> 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 and 2018, the Company granted to The NASH Education Program<sup>TM</sup> endowment fund a donation of €1,808 and €959, respectively, so that The NASH Education Program<sup>TM</sup> 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.

For the year 2019, our board of directors approved a grant of an amount of €200 to the Nash Education Program.

### 27. EVENTS AFTER THE REPORTING PERIOD

On January 2, 2019, GENFIT signed a licensing agreement with LabCorp, a company specialized in drug development. The agreement will expand access to Genfit's NASH liver diagnostic test for the clinical research market.

# GENFIT S.A.

6,650,000 Ordinary Shares  
(including Ordinary Shares in the form of American Depositary Shares)



## PROSPECTUS

March 26, 2019

**SVB Leerink**

**Barclays**

**Bryan, Garnier & Co.**

**Natixis**

**Roth Capital Partners**

**H.C. Wainwright & Co.**

Through and including April 20, 2019 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in the global offering, may be required to deliver a prospectus. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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