

#### **GENFIT SA**

A French corporate (Société Anonyme) governed by a Board of Directors with share capital of €9,714,654.25 Registered office: Parc Eurasanté, 885, avenue Eugène Avinée, 59120 Loos, France 424 341 907 R.C.S. Lille Métropole

#### AMENDMENT TO THE UNIVERSAL REGISTRATION DOCUMENT



This amendment to the universal registration document was filed on 22 December 2020 with the *Autorité des marchés financiers* (the "**AMF**") in its capacity as the competent authority under Regulation (EU) 2017/1129 (the "**Prospectus Regulation**"), without prior approval, in accordance with Article 9 of the Prospectus Regulation.

The universal registration document may be used for the purposes of an offer of securities to the public or the admission of securities to trading on a regulated market if it is accompanied by a securities note and, if applicable, a summary, and all amendments made to the universal registration document. These documents are then approved as a whole by the AMF in accordance with the Prospectus Regulation.

This amendment (the "Amendment") supplements and should be read in conjunction with the universal registration document filed with the AMF on 27 May 2020 under number D.20-0503 (the "Universal Registration Document").

A reconciliation table is provided in this Amendment in order to facilitate locating updated or modified information as well as information incorporated by reference.

The Universal Registration Document and its Amendment are available on the Company's website (www.genfit.com) and the website of the AMF (www.amf-france.org).

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#### GENERAL STATEMENT

Unless specified otherwise in this Amendment, the terms "GENFIT", the "Company", the "Group", "we" and "us" refers to the group of companies constituted by GENFIT SA and its two subsidiaries. "GENFIT", the GENFIT logo and the other marks filed or registered by GENFIT S.A., such as "NIS4", "RESOLVE-IT" and "ELATIVE" appearing in this Amendment are the property of GENFIT S.A. or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in the Amendment are listed without the TM or ® 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 rights thereto. All other trademarks, trade names and service marks appearing in this Amendment 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.

#### Forward-looking information

This Amendment contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Amendment, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. It may in some instances be possible to identify information of this nature on the basis of the use of the future or conditional tense or the use of terms with a forward-looking meaning, such as "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning. Such information appears in various Sections of this Amendment and contains indications as to the intentions, estimates and objectives of the Group relating inter alia to the market in which it operates and its strategy, growth, revenues, financial position, cash position and forecasts. Such information is not historical data and should not be construed as a guarantee that the events and data in question will occur or prove to be accurate. Such information is based on data, assumptions and estimates which the Company considers to be reasonable. Such information may change or be modified as a result of contingencies attributable to inter alia the economic, financial, competitive and regulatory environment, which could lead to results significantly different from those described, referred to or anticipated in such forward-looking statements.

#### Information about markets

This Amendment contains information about the markets described in Chapter 1 (*Overview of the Group and its Activities*) of the Universal Registration Document and Section 2 (*Overview of the Group and its Activities*) of this Amendment, information about the markets in which the Group is active and information about its competitive position. Such information comes *inter alia* from research carried out by external sources. Publicly available information which the Company deems reliable has not been verified by an independent expert, and the Company cannot guarantee that a third party using differing methods to collect, analyse or calculate data relating to such markets would obtain the same results. In addition, the competitors of the Group may define the markets in question differently.

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In this Amendment, the following acronyms, terms and expressions have the following meanings:

Adjustments to OCEANEs:	the	(i) the Modification of the Conversion Ratio; (ii) the extension of the maturity date of the OCEANEs from 16 October 2022 until 16 October 2025; (iii) the deferral of the start date of the early redemption period in accordance with the terms and conditions of the OCEANEs to 23 November 2023; and (iv) the amendment of the conversion ratio adjustment clause in case of tender offer targeting the shares of the Company, in order to take into account the extension of the maturity date of the OCEANEs.
ALP:		alkaline phosphatase.
Bondholders:		holders of the OCEANEs.
Bondholders' Meeting:		the general meeting of the Bondholders to be held on 25 January 2021.
CRO		contract research organization.
DIRECCTE		the French Direction régionale des entreprises, de la concurrence, de la consommation, du travail et de l'emploi
ELATIVE:		the international Phase 3 clinical trial of the most advanced drug candidate of the Company, namely elafibranor (a dual agonist of the PPAR alpha and PPAR delta nuclear receptors), as a potential treatment for PBC.
EMA:		the European Medicines Agency in Europe.
FDA:		the Food & Drug Administration in the United States.
IVD:		In Vitro Diagnostic tests.
LDT:		a Laboratory Developed Test.
LTE:		a long-term extension.
Modification of Conversion Ratio:	the	the modification of the initial conversion ratio from one (1) OCEANE for one (1) new or existing share to one (1) OCEANE for five and a half (5.5) new or existing shares.
NAFLD:		a non-alcoholic fatty liver disease.
NASH:		non-alcoholic steatohepatitis, a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. NASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for a liver transplant. The prevalence of NASH is rapidly increasing as a result of the growing obesity and diabetes epidemics and is believed to affect as many as 12% of the population in the US and 6% of the population worldwide. Because of its asymptomatic nature, NASH is often undiagnosed and can only be confirmed through an invasive biopsy.
NDA:		a New Drug Application.

New Shares	no more than 17,522,016 new shares to be issued by the Company pursuant to the potential conversion of all OCEANEs post-Partial Buyback on the basis of a conversion ratio of one (1) OCEANE for five and a half (5.5) new shares.
NIS4:	the non-invasive, blood-based diagnostic technology of the Company developed to identify patients with non-alcoholic steatohepatitis (NASH) and significant to advanced fibrosis (F>2), which is also referred to as atrisk NASH.
NTZ:	nitazoxanide.
OCEANEs:	6,081,081 bonds convertible into new shares and/or exchangeable for existing shares with nominal value of €29.60 each issued by the Company on 16 October 2017 and due (as of the date of this Amendment) 16 October 2022, having a total nominal amount of €179,999,997.60.
Partial Buyback:	the partial buyback of 47.6% of the total nominal amount of the outstanding OCEANEs for $\notin$ 47.48 million.
Partial Buyback Settlement Date:	the delivery and settlement date for the OCEANEs covered by the Partial Buyback scheduled for no later than 29 January 2021.
R&D:	research and development.
Repurchase Agreements:	the bond repurchase agreements entered into by the Company and certain Bondholders.
Repurchase Price:	the repurchase price per OCEANE, namely $\notin 16.40$ . This price includes the coupon accruing until the Partial Buyback Settlement Date ( $\notin 0.30$ ).
RESOLVE-IT:	the international Phase 3 clinical trial of the most advanced drug candidate of the Company, namely elafibranor (a dual agonist of the PPAR alpha and PPAR delta nuclear receptors), as a potential treatment for NASH.
Shareholders:	the shareholders of the Company.
Shareholders' Meeting:	the extraordinary general meeting to be convened on 13 January 2021, on first notice, and (as the case may be), on 25 January 2021 on second notice.
<b>Total Repurchase Price:</b>	€47.48 million.
Transaction:	(i) the Partial Buyback and (ii) the amendment of the terms and conditions of the outstanding OCEANEs (post-Buyback).
OCEANEs:	6,081,081 bonds convertible into new shares and/or exchangeable for existing shares with nominal value of $\notin$ 29.60 each issued by the Company on 16 October 2017 and due (as of the date of this Amendment) 16 October 2022, having a total nominal amount of $\notin$ 179,999,997.60.
<b>Total Repurchase Price:</b>	€47.48 million.
UDCA:	ursodeoxycholic acid.
ULN:	Upper Limit of Normal.

#### **1 OVERVIEW OF THE GROUP AND ITS ACTIVITIES**

## **1.1** Section 1.2 (*General description of our activities*) of the Universal Registration Document is deleted and replaced by the following:

The Company is a late-stage biopharmaceutical group dedicated to improving the lives of patients with metabolic and liver diseases. The Group is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. As part of the Company's comprehensive approach to clinical management of patients with liver disease, the Company is also developing a new diagnostic technology, which could enable easier identification of patients at risk from NASH, who for a long time show no symptoms despite the progression of their disease.

We advance therapeutic and diagnostic solutions to make them available to patients. With this goal in mind, we have developed multiple platforms in our areas of therapeutic expertise and set up close collaborations with academic experts and specialist companies whose expertise complements our own.

Our R&D is founded on several areas of excellence:

- clinical expertise in our major therapeutic areas, with a detailed knowledge of the diseases;
- in-depth scientific understanding of gene regulation and of biological mechanisms;
- broad technological know-how in the study and control of biological mechanisms, with a focus on translational research between animal models and human diseases.

In addition, we possess the expertise necessary to coordinate and manage regulatory pre-clinical toxicology, pharmacokinetic, and ADME (Absorption, Distribution, Metabolism, and Excretion) studies as well as to manage the development and production of active pharmaceutical ingredients and drug products, throughout the entire drug development process. The strong skills that we have acquired in these areas enable us to guarantee an optimal transfer of our know-how to our specialized partners at all stages of development, so that they can carry out our studies and production while maintaining a high level of scientific integrity.

As explained in greater detail in Section 1.4.2 of this Amendment, the preliminary interim results obtained from the RESOLVE-IT trial in May 2020 did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without a worsening of fibrosis. These results led us, after a detailed review of the whole dataset, to initiate the trial termination process for RESOLVE-IT at the end of July, and in September the termination process for several related trials, including our study in paediatric NASH and our Phase 2 trial on liver fat. Similarly, and for the same reasons, we have decided to discontinue our combination program with elafibranor in NASH.

We are however continuing our efforts in NASH through our diagnostic technology known as NIS4<sup>TM</sup>.

NASH is a liver disease that affects millions of people and can in the long-term lead to potentially lifethreatening complications like cirrhosis, hepatic impairment, liver cancer and may ultimately require a liver transplant. It is the second leading cause of liver transplant in the U.S. after hepatitis C and is expected to become the leading cause in the near future. NASH represents a pressing public health challenge, even more so as the disease is largely under-diagnosed due to the lack of non-invasive diagnostic tools with enough accuracy to identify patients with significant to advanced fibrosis who are most at risk for NASH progression.

NASH is a silent disease. Patients often have no liver-specific symptoms until the first signs of liver failure. Currently, liver biopsy is the standard for diagnosis, which is an invasive and costly procedure. In addition to these limitations, variability in the standard of NASH clinical care and competing physician priorities all contribute to under-diagnosis. This is why we have developed NIS4<sup>TM</sup>, a novel, standalone diagnostic technology based on the development of a novel algorithm that discovery of integrates a score the integrating

the outputs of four NASH-associated biomarkers (alpha2-macroglobulin (A2M), miR-34a-5p, YKL-40, and HbA1c) into a single score, which can be used to inform clinical decision-making. We and our partners want patients and physicians to be able to access NIS4<sup>TM</sup> technology. We believe that in doing so, we and our partners have the potential to address the urgent need for a non-invasive, cost-effective, accessible and validated test to identify patients with NASH and significant to advanced fibrosis who should be considered for intervention while decreasing the reliance on liver biopsy.

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

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

Finally, the Company continues to explore the possibility of obtaining regulatory approval to release an IVD test integrating NIS4<sup>TM</sup> technology in the United States and European markets the Company.

We are also evaluating elafibranor as a potential treatment for PBC in a global ELATIVE Phase 3 international trial. The PBC programme is independent from elafibranor in NASH, as PBC is an auto-immune liver disease with no relation to the metabolic origins of NASH. PBC is a chronic condition 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. The initial symptoms of PBC are general fatigue and pruritus (or itchy skin). PBC is diagnosed based on blood tests. Left untreated, PBC typically leads to cirrhosis, liver failure and the need for a liver transplant.

PBC is a disease with a global prevalence of approximately 40 cases per 100,000 people. However, that prevalence is increasing; in the United States, the prevalence of PBC increased from 21.7 to 39.2 cases per 100,000 people from 2006 to 2014.

There is currently no cure for PBC, although there are medications that work to slow its progression. For many years ursodiol, a drug containing UDCA, was the only drug approved by the FDA for the treatment of PBC. Although ursodiol is the first-line treatment, 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 2016, the FDA approved obeticholic acid (marketed as Ocaliva) 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. Concerns remain over pruritus and serious liver injury or liver death caused by administration of Ocaliva, which led the FDA to add a Boxed Warning to the Ocaliva label. 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 involve safety risks. The market for a second line therapy could potentially be worth \$1 billion, according to some estimates.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Based on market research by IQVIA, a life sciences and pharmaceutical sector consultancy.

Positive results from our Phase 2 clinical trial of elafibranor in PBC, which were presented in April 2019 at the International Liver Congress 2019 organised by EASL (European Association for the Study of the Liver), formed a strong rationale to launch the ELATIVE Phase 3 trial for the evaluation of elafibranor in this indication. Elafibranor met the primary endpoint of our Phase 2 clinical trial, which was the relative change from baseline at week 12 in ALP. Compared to placebo, treatment with 80 mg and 120 mg elafibranor resulted in mean decrease from baseline of -52% and -44%, respectively, each with high statistical significance. With respect to the composite endpoint used for registration of the second line treatment, the 80 mg and 120 mg elafibranor treatment groups achieved with high statistical significance mean response rates of 67% and 79%, as compared to 6.7% for the placebo group. We also observed a beneficial trend on pruritus – a major symptom of PBC – but this remains to be confirmed in the ongoing ELATIVE Phase 3 trial. The first patient first visit in the ELATIVE trial took place on 24 September 2020.

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

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

The primary endpoint is the response to treatment at week 52 defined as defined by biochemical parameters: ALP < 1.67 x ULN and total bilirubin  $\leq$  ULN and ALP decrease  $\geq 15\%$ . Secondary endpoints include response to treatment based on ALP normalisation at week 52 and change in pruritus from baseline through week 52 on PBC Worst Itch NRS score. The preliminary results of the ELATIVE Phase 3 trial are expected at the beginning of 2023.

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

We are also developing NTZ, in particular for the treatment of liver fibrosis and other liver diseases. 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<sup>2</sup>. Annual direct and indirect costs for the care of cirrhosis exceed \$12 billion<sup>3</sup> in the United States alone, and there is an urgent need for anti-fibrotic drugs to prevent progression towards liver decompensation and the associated morbidities.

Our research programme designed to discover novel anti-fibrotic molecules with a particular focus on liver fibrosis made possible the identification of NTZ based on the use of a phenotypic screening approach combined with the use of a compound library composed of FDA-approved drugs. Following this screening, we identified NTZ, which is currently commercialised and prescribed in the United States and in several other countries as an anti-parasitic, which we believe can be repurposed for the treatment of fibrosis. After it demonstrated promising anti-fibrotic activity in our pre-clinical pathological models and in human fibroblasts from several human organs, we announced in December 2018 that an investigator-initiated Phase 2 proof-of-concept clinical trial to evaluate the safety and tolerability of NTZ in patients with NASH-induced stage 2 or 3 fibrosis had been

<sup>&</sup>lt;sup>2</sup> Tsochatzis, E.A., Bosch, J., and Burroughs, A.K. (2014), 'Liver cirrhosis', Lancet, 383 (9930), 1749-61

<sup>&</sup>lt;sup>3</sup> Ge, P.S. and Runyon, B.A. (2016), 'Treatment of Patients with Cirrhosis', N Engl J Med, 375 (8), 767-77

launched by Dr. Stephen Harrison, a clinical investigator that works with the Company. The results of this trial are expected in the first quarter of 2021.

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

Our research on the potential of NTZ is being carried out in parallel with the ongoing clinical trial conducted independently by Dr. Stephen Harrison in an investigator-led study.

We have retained worldwide rights to all of our programs, with some of them licensed to our partners LabCorp/Covance on the one hand and Terns Pharmaceuticals on the other hand.

The current Chairman of our Board of Directors, Jean-François Mouney, co-founded the Company in 1999. Pascal Prigent, our current CEO, was appointed on 16 September 2019.

We are led by an executive team and board of directors with extensive experience gleaned at leading biotech companies, large pharmaceutical companies and academic institutions.

The chairman of our Scientific Advisory Board, Professor Bart Staels, is a co-founder of the Company and a world-renowned expert in nuclear receptors. Our Scientific Advisory Board is comprised of internationally recognised key opinion leaders in the field of metabolic and inflammatory diseases, with a particular focus on the liver and gastroenterology.

As of 30 June 2020, the Group had approximately 200 employees at its various sites in Lille and Paris (France) and in Cambridge (Massachusetts, USA). As a consequence of the disappointing results of the RESOLVE-IT trial, the Company has however implemented an extensive cost-savings programme, including an employment protection plan (*plan de sauvegarde de l'emploi*) in France, which is being implemented on the date of this Amendment. The employment protection plan was submitted for information and consultation purposes to the Company's Employment and Economic Council and has been agreed with the relevant union representative and approved by the DIRECCTE. All in all, the Group aims to reduce the total headcount of its staff from approximately 200 on 30 June 2020 to 125.

The Company's shares are listed on the regulated market Euronext in Paris (Compartment B - ISIN: FR0004163111) and have since March 2019 been listed as American Depositary Shares, each representing one ordinary share, on the Nasdaq Global Select Market in the United States under the common symbol "GNFT".

## 1.2 The paragraph entitled "A note about the evolving COVID-19 pandemic and its potential consequences on our business" in Section 1.2 (General description of our activities) of the Universal Registration Document is deleted and replaced by the following paragraph:

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

appropriate measures implemented in consultation with the CRO, the ELATIVE Phase 3 clinical trial was able to launch in the autumn of 2020. The deployment of NIS4 in the field of clinical research has continued. The guidance provided in this Amendment may be subject to further adjustments which, by nature, cannot be precisely anticipated. Please see also Section 2.19 of this Amendment modifying the risk factor entitled "*The continuation and, as the case may be, the worsening of the COVID-19 pandemic, could adversely impact our business, including our pre-clinical studies and clinical trials, the supply of the active ingredient and therapeutic units of elafibranor, the preparation for commercialisation of our product candidates and the potential granting of regulatory approval required for their market launch."* 

## **1.3** Section 1.3.1 (*Our Strategy*) of the Universal Registration Document is deleted and replaced by the following:

"Our objective is to become a leader in the development and commercialisation of innovative therapies and diagnostic solutions targeting metabolic and liver-related diseases.

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

Consequently, the Company will now focus on two major programs that both address a significant unmet medical need, represent a significant business opportunity and have a favourable risk profile: the development of its molecule elafibranor as a second line treatment in PBC, and the development of a diagnostic franchise based on its NIS4 technology.

In this context we intend:

#### • to progress with the Phase 3 clinical development of elafibranor for the treatment of PBC

Ocaliva, marketed by Intercept, is currently the only option for second line therapy after UDCA. Its market represents approximately \$300 million annually with double digit growth in 2020. According to market research conducted by IQVIA, experts in life sciences and the pharmaceutical industry, the second line PBC market could reach \$1 billion in the coming years. According to reports, competitive intensity is low, given that in second intention, there is only one approved product. In terms of clinical development, elafibranor is today the only product which is enrolling participants for the ELATIVE Phase 3 clinical trial in which patients will be randomised on a 2:1 ratio, with 100 patients receiving 80 mg elafibranor and 50 patients receiving placebo. The Phase 3 trial of a third molecule developed by another company was terminated early after security concerns arose. That trial should (re-)launch at the beginning of 2021. The commercial opportunities in this indication are therefore significant.

Furthermore, elafibranor obtained promising results in the Phase 2 trial evaluating efficacy and safety in PBC. After twelve weeks, efficacy observed with elafibranor on the composite endpoint was well above what has been required to obtain marketing authorization for this condition. In addition, a positive trend (which remains to be confirmed in the ELATIVE Phase 3 trial) was observed on pruritus, reinforcing elafibranor's potential for differentiation in this indication. Lastly, the extensive data from the RESOLVE-IT trial and the period of total exposure to the product – counted in thousands of years of exposure/thousands of patients for elafibranor – have to date demonstrated a good safety profile.

Lastly, uncertainty with respect to commercial development is much lower in PBC than in NASH due to:

- easier patient identification;
- a well-defined patient population-to-treat;

- drug price that is significantly higher than in NASH and is accepted by payers; and
- a specialty launch such as in PBC is less resource-intensive than a mass market approach.

The preliminary results of the ELATIVE Phase 3 trial are expected at the beginning of 2023.

#### • progress our NASH diagnostic programme and commercialise our NIS4 technology

Market research has shown that there is a significant challenge with NASH patient identification. Patients are often asymptomatic, and those with NASH do not necessarily require treatment. There is a need to identify those for whom treatment is appropriate. Biopsies are considered the imperfect gold standard used for regulatory approval in the clinical trial context, but are not adapted to the practicalities of real life, in that patients are reluctant to undergo biopsy, which is expensive and resource-intensive, and there also being an insufficient number of pathologists to execute the procedure for all at-risk patients.

For the market potential of NASH to be realised, there is a need for a non-invasive solution that could be easily deployed at a large scale. Since the barrier is determining whether a given patient should be treated (as opposed to being simply diagnosed with NASH), the Company has focussed its NASH diagnostic program on identifying patients with a NAFLD Activity Score (NAS) of at least 4 or a fibrosis score of at least 2.

The NIS4 programme achieved two major milestones in August and September 2020:

- Publication in The Lancet (Gastroenterology & Hepatology) of pivotal data describing the validation process and performance of NIS4. The data showcased the robust and consistent performance of NIS4 in identifying patients with at-risk NASH. In addition, NIS4 technology also delivered high overall performance in critical sub-populations (i.e. diabetic vs. non-diabetic, men vs. women) as compared to the results provided by other non-invasive tests evaluated in the same individuals. This scientific publication is critical, as it demonstrates not only that NIS4 is a simple and scalable solution but also that it is a high performance solution which looks at both components of NASH and can help identify and therefore manage patients who are at risk.
- The signature of an exclusive license agreement with LabCorp to commercialise a novel diagnostic test for NASH powered by the Company's NIS4 technology. This agreement should enable a large-scale commercial launch of our technology, an important progression from prior collaboration with partners targeting the clinical research environment. NIS4 technology should now become broadly available and start addressing the diagnostic needs of millions of individuals at risk of progressing to the late-stage complications of NASH. Launch is anticipated in 2021, and the Company is looking forward to seeing its partner LabCorp successfully commercialise the solution. Although the market is expected to accelerate with the availability of the first NASH drugs, market research also suggests that there is already an unmet need. Therefore, launching a diagnostic test makes sense despite recent setbacks in NASH therapeutics. Millions of patients, including pre-diabetic, diabetic, overweight or obese patients or patients with other risk factors:
  - still need a NASH diagnosis, so that healthcare professionals will know whether such patients are at risk and to monitor such patients closely; and
  - o can be empowered to make healthier personal choices regarding diet and exercise;

- to advance other drug candidates in our pipeline. In the context of our development programme focussing on fibrotic diseases, we have launched a strategy seeking to reposition NTZ. This programme involved in December 2018 the launch of an investigator-initiated Phase 2 proof-of-concept trial in the United States, to evaluate NTZ for the treatment of NASH patients with significant or severe fibrosis. We believe NTZ could be developed as an anti-fibrotic monotherapy but also as combination therapy; and
- to leverage business development opportunities in our main therapeutic areas and remain open to opportunities that could create value for the Company, whether through forging new strategic partnerships or new scientific collaborations.

#### Structure and cost-savings plan

To execute its strategy, the Company is planning to modify its structure and has initiated a restructuring and cost-savings plan seeking to reduce its employee headcount and cash-burn.

There are very limited synergies between these two main programmes in terms of business models, clients, partnership opportunities and lastly financing or regulatory environment.

For these reasons, the Company has decided to establish two separate entities:

- the Diagnostics entity would be primarily focussed on diagnostics but plans to leverage the Company's accumulated knowledge and network, to carry forward tools that have the potential to create value for the Company. For example, artificial intelligence applied to diagnostics or clinical trials, as well as extensive data gathered over the years, could be leveraged to develop value-added patient services; and
- the other entity focussed on drug candidates' development would initially be focussed on accelerating the execution of the PBC program but would also ultimately be the vehicle to develop either new molecules or additional indications for elafibranor, such as Primary Sclerosing Cholangitis or PSC.

In order to support its new strategy, the Company also announced a workforce reduction plan that would reduce the total headcount from over 200 prior to the end of the first half 2020 to fewer than 125. To such end a employment protection plan (*plan de sauvegarde de l'emploi*) is currently being implemented. As at the date hereof, it was submitted for information and consultation purposes to the Company's Employment and Economic Council, agreed with the relevant union representative and approved by DIRECCTE.

The Company has also undertaken a reduction of operating expenses, including eliminating all non-essential expenses. The Company's intends to achieve an approximately 50% reduction in operating cash-burn between now and 2022. Prior to the RESOLVE-IT Phase 3 trial results announcement, the Company was operating at an annual cash-burn of approximately  $\in$ 110 million and expects to reduce cash-burn in 2022 to approximately  $\in$ 45 million annually. 2021 will be a transitional year in terms of operating cash-burn, which is expected to be in the region of  $\in$ 75 million (excluding the Partial Buyback at a total cost of  $\in$ 47.48 million), corresponding mainly to the residual costs and expenses associated with the termination of the RESOLVE-IT trial and the costs associated with the workforce reduction plan."

#### 1.4 Section 1.4 (*Our Programmes*) of the Universal Registration Document is amended as follows:

1.4.1 The introductory table in Section 1.4 (*Our Programmes*) on page 15 of the Universal Registration Document is deleted and replaced by the following table:

Program	Indication	Mechanism of Action	Development Stage	
<u>Elafibranor</u>	PBC	PPAR α/δ		Phase 3 ELATIVE™ High level data readout 1Q2023
Nitazoxanide	Fibrosis	Undisclosed		Phase 2 - Investigator-led study POC data readout: 1Q2021

#### **Therapeutics Programs**

#### Diagnostic Program



## 1.4.2 Sections 1.4.1 (*Elafibranor for the treatment of NASH*) and 1.4.2 (*Elafibranor Development Program in NASH*) of the Universal Registration Document are deleted and replaced by the following:

#### "RESOLVE-IT Phase 3 trial in NASH

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

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

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

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

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

Statistical significance was not achieved in the other key secondary endpoint related to metabolic parameters, which were: triglycerides, non-HDL cholesterol, HDL cholesterol, LDL cholesterol, HOMA-IR in non-diabetic patients, and HbA1c in diabetic patients.

The favourable safety and tolerability profile of elafibranor observed in our previously conducted trials was similar to what has been observed in the interim results of RESOLVE-IT, which is encouraging for the ongoing Phase 3 trial evaluating elafibranor in PBC (see below).

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

On July 22, 2020, following the detailed review of the full RESOLVE-IT interim efficacy dataset, the Company determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the United States and Europe. The Company announced that it would engage with the RESOLVE-IT investigators to expedite the trial termination process – which is ongoing at the time of this Amendment and due to last for several months – and that it would also meet with regulatory agencies to share key learnings, including results from the second reading of liver biopsies that will help better understand inter-reader variability and its impact. The Company also indicated that it is now focusing its efforts on developing its two major programs: elafibranor development in PBC, and the commercial growth of NIS4 technology, for NASH diagnostics."

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

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

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

In September and following its decision to terminate all development of elafibranor in NASH, the Company decided to initiate the termination process of the PK/PD trial in paediatric NASH, as well as the Phase 2 study on hepatic lipid composition.

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

#### Other Phase 1 trials

The Company also announced in March 2020, in the context of the COVID-19 pandemic, that all ongoing or upcoming phase 1 trials – which included pharmacokinetic, food effect and bioequivalence studies – had been put on hold. These studies were necessary to support a potential elafibranor NDA submission.

Since then, and as a result of its decision to end development of elafibranor in NASH, the following decisions have been made regarding these trials, given that some of them will be required for a new drug application for elafibranor in PBC:

- pharmaco-kinetic and drug interaction studies have resumed;

- the bioequivalence study has restarted; and
- the food interaction study will start in 2021."

## 1.4.3 Section 1.4.3 (*NIS4 for the diagnosis of liver fibrosis*) of the Universal Registration Document is renumbered 1.4.2 and supplemented by the following:

"During the first half of the year, the NIS4 technology to support a diagnostic solution continued to be deployed in the clinical research field through Covance. While interest in NIS4 technology is high, the Company announced in late March that there may be some limits in NIS4 powered test utilization due to delays potentially experienced by some sponsors as the result of the COVID-19 pandemic.

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

In September 2020 the Company and LabCorp (NYSE:LH), a global life sciences leader specialising in health improvement and patient treatment decision support, announced the signature of a five-year exclusive license agreement for the Company's NIS4 technology, which seeks to enable easier identification of patients with atrisk NASH. Under the license agreement, LabCorp will commercialise a blood-based molecular test based on NIS4 technology in the United States and Canada, thereby making it more widely accessible to health professionals.

NASH is widely under-diagnosed disease, on account of its asymptomatic nature and the limitations currently inherent to diagnostic approaches. Liver biopsy, which is an invasive procedure, is the current clinical gold standard for officially diagnosing NASH and identifying the stage of fibrosis reached. The NIS4 technology, which was recently the subject of an article in *The Lancet Gastroenterology and Hepatology*,<sup>4</sup> is based on an innovative multi-biomarker algorithm developed to identify patients with at-risk NASH, defined as the established presence of NASH with the following characteristics: an NAFLD (*non-alcoholic fatty liver disease*) score of  $\geq 4$ , and "significant" to "advanced" fibrosis with a score of  $F \geq 2$ .

Patients who present with at-risk NASH have an advanced form of the disease and are at greater risk of progression to serious complications, including liver cancer, cirrhosis and the need for a liver transplant in the absence of treatment. A simple test score obtained from four independent biomarkers (miR-34a-5p, alpha-2-macroglobuline, YKL-40 and HbA1c) will enable health professionals to determine the best course of clinical management.

The partnership with LabCorp aims to make this test available to a large number of specialist and generalist physicians in the United States and Canada. LabCorp will use its vast experience in the commercialisation of innovative diagnostic tools to make health professionals more aware of NASH and non-invasive ways of diagnosing NASH. The collaboration between the Company and LabCorp began at the start of 2019, when LabCorp launched through Covance, its drug development subsidiary, deployment of the NIS4 technology for clinical trials being conducted by its biopharmaceutical clients.

In November 2020, the Company announced that data relating to the NIS4 technology and the final results of the RESOLVE-IT Phase 3 clinical trial could be consulted on five posters in the context of the *Liver Meeting* 

<sup>&</sup>lt;sup>4</sup> Available on the following link: https://www.thelancet.com/journals/langas/article/PIIS2468-1253(20)30252-1/fulltext

*Digital Experience*, the annual conference of the *American Association for the Study of Liver Diseases*, which was held virtually on 13, 14 and 15 November 2020.

The Company also continues to explore the possibility of obtaining regulatory approval to release an IVD test integrating NIS4 technology on the US and European markets."

## 1.4.4 Section 1.4.4 (*Elafibranor for the treatment of PBC*) of the Universal Registration Document is renumbered 1.4.3 and supplemented by the following:

"Due to the COVID-19 pandemic, the Company also announced in March 2020 that the start of the ELATIVE Phase 3 study in patients with PBC had been delayed.

In September 2020, the Company announced the completion of the first patient first visit in the ELATIVE Phase 3 trial. Appropriate measures have been implemented, including virtual appointments, biological evaluations performed by local laboratories and delivery of the drug candidate to the patients' home, to ensure the safety of participants in the study. As of the date of this Amendment, enrolment is continuing, and new clinical research centres have been opened."

## 1.4.5 Section 1.4.5 (*Nitazoxanide Development Programme in Liver Fibrosis*) of the Universal Registration Document is renumbered 1.4.4 and supplemented by the following:

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

### 1.4.6 Section 1.4.6 (*TGFTX1 Programme for the Treatment of Auto-Immune Diseases*) in the Universal Registration Document is deleted.

## 1.5 Section 1.6 (*Competitive environment*) of the Universal Registration Document is amended as follows:

1.5.1 The paragraph entitled "*Treatment*" in the sub-section entitled "*NASH*" within Section 1.6 (*Competitive environment*) of the Universal Registration Document is deleted.

## 1.5.2 The following sub-section entitled "*Fibrosis*" is inserted into Section 1.6 (*Competitive environment*) of the Universal Registration Document:

"Fibrosis, the build-up of tissue scarring, is a condition which can affect a number of organs: the liver, lungs, intestines, etc. No drug has to date obtained regulatory approval as an exclusively anti-fibrotic drug, irrespective of the organ in question.

The competitive environment is characterised by several research programmes being conducted in parallel by a number of actors. Some of these programmes are focusing on the pre-fibrotic phases of the condition and involve a more preventive approach which seeks to prevent patients from progressing to more serious forms of the condition. Other programmes focus to a greater degree on the more advanced stages of the condition, such as (in the case of the liver) compensated or decompensated cirrhosis. The benefit of an approach focusing on the more advanced stages of the condition is that accelerated regulatory approval procedures are often available and this approach may lead to higher prices. The commercial opportunity is therefore potentially significant but will depend on the future clinical efficacy results for NTZ in this indication.

Competition will ultimately be determined by the number of drugs available as a monotherapy and also by the therapeutic approaches adopted by experts in the context of combination therapies."

#### 1.6 Section 1.8 (*Organisation*) of the Universal Registration Document is amended as follows:

## 1.6.1 The Section 1.8.1 (*Legal structure*) of the Universal Registration Document is deleted and replaced by the following:

"The new strategy of the Company aims to create, in 2021, two separate operating entities, in order to ensure more independent management and growth:

- one entity will be dedicated to the development of specialty indications, starting with the execution of the ELATIVE Phase 3 programme in PBC; and
- the second entity would house NASH solutions, including all programs related to the identification, evaluation and monitoring of patients with NASH. This independent structure would facilitate future partnerships for NIS4<sup>™</sup>.

The goal being to best highlight each of the activities to benefit the Group's overall valuation.."

## 1.6.2 Section 1.8.3 (*Other entities*) in the Universal Registration Document is deleted and replaced by the following:

"In 2016 the Company set up The NASH Education Program, an endowment fund governed by the Law of 4 August 2008 and subsequent legislation. The objective behind this fund was in particular to create in line with the scientific and medical activities of the Company an independent entity dedicated to the generation and dissemination of knowledge around NASH and its causes and consequences, with a view to educating and informing both physicians and patients. In 2019, the fund was renamed The NASH Epidemiology Institute and the programmes developed by The NASH Education Program were transferred in their entirety to the Company. In parallel, the rights and assets associated with International NASH Day were transferred to a coalition of patient associations chaired by the Global Liver Institute.

The Company was the sole founder of the endowment fund.

It is administered by a Board of Directors comprised of:

- Jean-François MOUNEY, Chairman;
- Xavier GUILLE DES BUTTES, Vice-Chairman;
- Nathalie HUITOREL, Treasurer; and
- Pascal PRIGENT, Secretary.

We donated 45,000 Euros in 2019 (and 959,000 Euros in 2018) to The NASH Epidemiology Institute.

Following the termination of elafibranor's development in NASH, the Company plans in the near future to liquidate this fund. The Company will provide information in its 2020 Annual Report on the allocation of the funds remaining in *The NASH Epidemiology Institute*."

#### 2 RISK FACTORS

Investors are invited to consider all the information contained in the Universal Registration Document and this Amendment before deciding to purchase or subscribe for the shares of the Company. This includes in particular the risk factors described in Chapter 2 of the Universal Registration Document and in this Section. The occurrence of such risks is likely to have (and in some cases has had) a material adverse effect on the Group and its business, financial position, results, growth or prospects, and such risks are material when making an investment decision.

When drawing up this Amendment and following its decision to terminate the RESOLVE-IT Phase 3 clinical trial (as well as other programmes and studies relating to NASH in particular) and to give priority to programmes focussing on the development of elafibranor in PBC and of NIS4, the Company undertook a review of the risk factors described in Chapter 2 of the Universal Registration Document. The Company also factored into such review the impact of the continuing COVID-19 pandemic, which is still largely underway as of the publication date of this Amendment.

The Company draws the attention of investors to the fact that, in accordance with Article 16 of the Prospectus Regulation and the recommendations of the European Securities and Markets Authority, only the most material risk factors specific to the Group are described. The list in this Section is therefore not exhaustive and other risk factors of a generic nature, or risk factors which are currently unknown or are considered as of the date of this Amendment to be unlikely to have a material adverse effect on the Group and its business, prospects, financial position, results and development, may exist or may arise.

#### 2.1 Risk classification

The risk classification used in the Universal Registration Document has been reviewed. Consequently, the table in Section 2.1 (*Summary of main risks*) on pages 66 to 71 of the Universal Registration Document is deleted and replaced with the following table. The order of the risk factors in Section 2.2 (*Risk factors and risk management*) of the Universal Registration Document has been modified accordingly.

The table below sets out the main risks identified by us in the context of eight categories: (1) risks related to the development of and obtaining regulatory approval for our product candidates; (2) risks related to the development of and obtaining regulatory approval for our diagnostic technology, (3) risks related to the commercialisation of our products; (4) risks related to dependence on third parties, (5) risks related to our organisation and operations; (6) risks related to legal and compliance matters and intellectual property; (7) risks related to our financial position and capital needs; and (8) risk related to the consequences of the current Covid-19 pandemic. The table specifies for each one of such risks the probability of the occurrence thereof as of the filing date of this Amendment, as well as its adverse impact on the Company, in light of the risk management procedures and measures put in place by the Company. Probability of occurrence is assessed at one of three levels ("low", "moderate" or "high"), and the magnitude of the negative impact of each risk at one of four levels ("low", "moderate", "high" or "critical").

New Section number	Risk factors	Probability	Adverse impact	Former Section number
2.2.1	Risks related to the development of and obtaining regulatory approval for our product candidates			2.2.1.1
2.2.1.1	We cannot be certain that elafibranor or any of our other product candidates will, subject to meeting	High	Critical	2.2.1.1.1

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	clinical milestones and, as the case may be, regulatory milestones, receive regulatory approval necessary for their marketing and which will be requested in the medium run, and without regulatory approval, we will not be able to market our product candidates.			
2.2.1.2	We and our partner Terns Pharmaceuticals in some territories and for some indications are developing our lead product candidate, elafibranor, for the treatment of PBC, a condition for which only two treatments have been approved and are currently marketed and they do not fulfil the medical needs of all patients. As a result, our development approach and that of our partner involve new endpoints and methodologies. The outcome of our clinical trials may not be favourable or, even if favourable, regulatory authorities may not find the results of the clinical trials of our current or future partners to be sufficient for marketing approval.	High	Critical	2.2.1.1.2
2.2.1.3	We have obtained "breakthrough therapy" designation from the FDA for elafibranor in the treatment of PBC and we may seek to avail ourselves of such mechanisms to expedite the development or approval of our elafibranor for another indication or in combination in the future or in order to accelerate the development or approval of our other drug candidates, but such mechanisms may not actually lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that elafibranor will receive marketing approval for this indication.	High	Critical	2.2.1.1.3
2.2.1.4	Even though we have obtained "orphan drug" designation for elafibranor for the treatment of PBC from the FDA and the EMA, we may not be able to obtain or maintain the benefits associated with "orphan drug" status. We may also seek the same designation for elafibranor in a different indication or for any of our other drug candidates, but we may not be able to obtain it or maintain the benefits associated.	High	High	2.2.1.1.4
2.2.1.5	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	High	High	2.2.1.1.5

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.			
2.2.1.6	Delays in the commencement, enrolment and completion of clinical trials, starting with our ELATIVE Phase 3 clinical trial evaluating elafibranor in PBC (a rare disease), could result in increased costs to us and delay, limit or jeopardize our ability and that of Terns Pharmaceuticals, our partner in some territories and for some indications and that of future partners to obtain regulatory approval for elafibranor and our other drug candidates.	High	Critical	2.2.1.1.7
2.2.1.7	Clinical failure can occur at any stage of clinical development, as previously occurred with our RESOLVE-IT Phase 3 clinical trial evaluating elafibranor in NASH. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate that we or our current or future partners advance through clinical trials may not have favourable results in later clinical trials or receive regulatory approval.	High	Critical	2.2.1.1.8
2.2.1.8	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.	High	Critical	2.2.1.1.9
2.2.1.9	Due to our limited resources and access to fundings, that could affect our strategic decisions with respect to the development of certain product candidates and have an impact on the development or timing of our business prospects.	High	Critical	2.2.1.1.10
2.2.1.10	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.	High	Critical	2.2.1.1.11

New Section number	Risk factors	Probability	Adverse impact	Former Section number
2.2.2	Risks related to the development of and obtaining regulatory approval for our diagnostic technology			2.2.1.2
2.2.2.1	We or our potential future partners may not receive the necessary regulatory approvals to market NIS4, our proprietary diagnostic technology for use in treating NASH patients.	High	Critical	2.2.1.2.1
2.2.2.2	We intend for NIS4 to be marketed to treat NASH patients and as such, NIS4 remains a product in development subject to the hazards of diagnostic product development, and there is no assurance that we will be able to achieve commercialisation of an IVD test incorporating our technology on this market.	High	Critical	2.2.1.2.2
2.2.3	Risks related to the commercialisation of our products			2.2.2
2.2.3.1	Even if we successfully complete clinical trials and development of our product candidates, those candidates may not be commercialised successfully for other reasons.	High	Critical	2.2.2.1
2.2.3.2	Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare third-party payors, and as a result our revenues generated from their sales may be limited.	High	Critical	2.2.2.2
2.2.3.3	If we, or our current or future partners are unable to establish sales, marketing and distribution capabilities for elafibranor or our product candidates, we may not be successful in commercialising those product candidates if and when they are approved.	High	Critical	2.2.2.3
2.2.3.4	We have entered into, and may continue to seek and form, strategic alliances or enter into licensing or co- marketing arrangements to commercialise our approved drugs or NIS4 diagnostic products, and we may not realize the benefits of such arrangements.	High	Critical	2.2.2.4
2.2.3.5	All of our product candidates for which we or our current or future partners obtain marketing approval will be subject to ongoing regulation and could be subject to post-marketing restrictions or withdrawal from the market. Furthermore, we or our current or future partners may be subject to substantial penalties if we fail to comply with regulatory requirements or	Moderate	Critical	2.2.2.5

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	experience unanticipated problems with our products following approval.			
2.2.3.6	Government restrictions on pricing and reimbursement, as well as other healthcare third-party payor cost-containment initiatives, may negatively impact our ability or that of our current or future partners to generate revenues even if we or they obtain regulatory approval to market a product.	High	Critical	2.2.2.6
2.2.3.7	Failures to reimburse tests using NIS4 diagnostic technology, if commercialised for NASH patients' clinical care, or changes in reimbursement rates by healthcare third-party payors and variances in reimbursement rates could materially and adversely affect our revenues and could result in significant fluctuations in our revenues.	High	Critical	2.2.2.7
2.2.3.8	Our future growth depends, in part, on our current or future partners' ability to penetrate international markets, where we or they would be subject to additional regulatory burdens and other risks and uncertainties.	High	Critical	2.2.2.8
2.2.3.9	Adverse market and economic conditions may exacerbate certain risks associated with commercialising our product candidates.	High	Critical	2.2.2.9
2.2.4	Risks related to dependence on third parties			2.2.3
2.2.4.1	We depend on third-party contractors for a substantial portion of our operations, in particular, on clinical research organisations for our clinical trials and on clinical manufacturing organisations for the manufacturing of our active ingredients and therapeutic units, and may not be able to control their work as effectively as if we performed these functions ourselves.	High	Critical	2.2.3.1
2.2.4.2	We rely entirely on third-party contractors for the manufacturing of our drug candidates and the future manufacturing of the IVD test kit using our NIS4 diagnostic technology for NASH patients' clinical care, including one manufacturer for the active ingredient in elafibranor and another manufacturer for the therapeutic units of elafibranor used in our clinical trials. Our business could be harmed if those third- party contractors fail to provide us with sufficient	High	Critical	2.2.3.2

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	quantities of drug product, or fail to do so at acceptable quality levels or prices.			
2.2.4.3	We have entered, with Terns Pharmaceuticals for elafibranor and LabCorp/Covance for NIS4, and may in the future enter into, collaboration agreements with third parties for the development and eventual commercialisation of our product candidates, which may affect our ability to generate revenues.	High	Critical	2.2.3.3
2.2.4.4	We depend on LabCorp/Covance for the development of NIS4 for the clinical research market.	High	High	2.2.3.4
2.2.4.5	We depend on Terns Pharmaceuticals for the development and commercialisation of elafibranor on the Greater China territory in PBC.	High	High	2.2.3.5
2.2.4.6	The manufacturing facilities of our third-party manufacturers of drug candidates as well as the central testing laboratories of LabCorp/Covance. If these third-party manufacturers or laboratories fail to comply with applicable regulations or maintain these approvals, our business will be materially harmed.	Moderate	Critical	2.2.3.6
2.2.4.7	Our production costs may be higher than we currently estimate.	Moderate	High	2.2.3.7
2.2.5	Risks related to our organisation and operations			2.2.4
2.2.5.1	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.	High	Critical	2.2.4.1
2.2.5.2	We may encounter difficulties in managing our development, which could disrupt our operations.	High	Critical	2.2.4.2
2.2.5.3	We depend on qualified management personnel and our business could be harmed if we lose key personnel and cannot attract new personnel.	High	Critical	2.2.4.3
2.2.5.4	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.	Moderate	High	2.2.4.4
2.2.5.5	We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions and alliances.	High	Critical	2.2.4.5

New Section number	Risk factors	Probability	Adverse impact	Former Section number
2.2.5.6	Our internal information technology systems and those of our current or future partners or those of our third-party contractors or consultants, may fail or suffer security breaches, any of which could result in a material disruption of our product development and commercialisation programs.	Moderate	Critical	2.2.4.6
2.2.5.7	Use of social media may materially and negatively impact our reputation.	Moderate	High	2.2.4.7
2.2.5.8	We are exposed to a number of regulatory and commercial risks related to the United Kingdom leaving the European Union if the United Kingdom and the European Union are not able to come to an agreement regarding the modalities of the withdrawal of the United Kingdom.	High	High	2.2.4.8
2.2.6	Risks related to legal and compliance matters and intellectual property			2.2.5 and 2.2.6
2.2.6.1	We are subject to transparency, ethics and healthcare laws and regulations that may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.	Moderate	Critical	2.2.6.1
2.2.6.2	We are subject to laws and regulations related to data privacy, both in the United States and the European Union, the breach of which might have a significant negative impact on our activities.	Moderate	Critical	2.2.6.2
2.2.6.3	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.	Moderate	Critical	2.2.6.3
2.2.6.4	Product liability and other lawsuits could divert our resources, result in substantial liabilities, reduce the commercial potential of our product candidates and harm our reputation.	Moderate	Critical	2.2.6.4
2.2.6.5	If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of that patent protection is not sufficiently broad, our competitors could develop and commercialise products similar or identical to ours, and our ability or that of a current or future partner to	Low	Critical	2.2.5.1

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	commercialise our product candidates successfully may be adversely affected.			
2.2.6.6	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.	Low	Critical	2.2.5.2
2.2.6.7	Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.	Low	Critical	2.2.5.3
2.2.6.8	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 commercialising our product candidates.	Low	High	2.2.5.4
2.2.6.9	Developments in patent law could have a negative impact on our business.	Low	High	2.2.5.5
2.2.6.10	If we do not obtain protection under the Hatch- Waxman Amendments and similar non-U.S. legislation (in particular in Europe) for extending the term of patents covering each of our product candidates, our business may be materially harmed.	Low	High	2.2.5.6
2.2.6.11	If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.	Low	High	2.2.5.7
2.2.6.12	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.	Low	High	2.2.5.8
2.2.6.13	Third parties may assert ownership or commercial rights to inventions we develop.	Low	Critical	2.2.5.9
2.2.6.14	Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.	Low	High	2.2.5.10
2.2.6.15	A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming	Low	Low	2.2.5.11

New Section number	Risk factors	Probability	Adverse impact	Former Section number
	and costly, and an unfavourable outcome could harm our business.			
2.2.6.16	If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest or the markets of interest of our current or potential future partners.	Low	Low	2.2.5.12
2.2.7	Risks related to our financial position and capital needs			2.2.7
2.2.7.1	Currently, we have no products approved for commercial sale, and to date we have not generated any recurring revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.	High	Critical	2.2.7.1
2.2.7.2	Our ability to be profitable in the future will depend on our ability and that of our current or future partners to obtain marketing approval for and commercialise our product candidates, particularly our lead product candidate, elafibranor, and IVD test using our NIS4 diagnostic technology for the clinical care of NASH patients.	High	Critical	2.2.7.2
2.2.7.3	We will require substantial additional funding to develop and commercialise our products, if approved, which may not, in particular in our current situation, be available to us or our current or future partners on acceptable terms, or at all, and, if not so available, may require us or them to delay, limit, reduce or cease our operations.	High	Critical	2.2.7.3
2.2.7.4	If the Transaction is not completed, we will not be in position to reimburse our debt and will have to contemplate alternative solutions in order to protect its interests. Our stock price may never reach a price at which the conversion of our OCEANEs (respectively, 29.60 Euros prior to the Transaction and 5.38 Euros after the Transaction) becomes economically viable and the redemption in cash of our OCEANEs could therefore be compromised.	High	Critical	2.2.7.4
2.2.7.5	Our stock price is particularly volatile and this situation may continue.	High	Critical	2.2.7.7
2.2.7.6	The ownership interests of the shareholders of our Company may be diluted.	High	Critical	2.2.7.8

New Section number	Risk factors	Probability	Adverse impact	Former Section number
2.2.7.7	Our business is going to be exposed to greater foreign exchange risk.	High	High	2.2.7.6
2.2.7.8	We are currently the subject of securities class action litigation with respect to the information furnished on elabibranor in the NASH treatment at the time of our initial public offering on Nasdaq and may become subject to additional litigation, which could harm our business, financial condition and reputation.	High	High	2.2.7.9
2.2.7.9	Our failure to maintain certain tax benefits applicable to French biopharmaceutical companies may adversely affect our results of operations.	Moderate	Critical	2.2.7.5
2.2.8	The continuation and, as the case may be, the worsening of the COVID-19 pandemic, could adversely impact our business, including our pre- clinical studies and clinical trials, the supply of the active ingredient and therapeutic units of elafibranor, the preparation for commercialisation of our product candidates and the potential granting of regulatory approval required for their market launch.	High	Critical	2.2.8

2.2 The risk factor in the Universal Registration Document entitled "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." is deleted and replaced by the following (previously Section 2.2.1.1.1 and now Section 2.2.1.1):

"We cannot be certain that elafibranor or any of our other product candidates will, subject to meeting clinical milestones and, as the case may be, regulatory milestone, receive regulatory approval, and without regulatory approval, we will not be able to market our product candidates.

Our business currently depends substantially on the successful development and commercialisation of elafibranor. Our ability to generate (direct or indirect) revenue related to product sales will depend on the successful development and regulatory approval of elafibranor in the indications we are developing. This ability to generate revenue is also dependent on the future of the development and marketing of an IVD test using our NIS4 diagnostic technology.

We have been developing elafibranor in several clinical trials, including for the treatment of PBC in a Phase 2 trial, the promising results of which led us to decide to pursue its development in a pivotal (ELATIVE) Phase 3 clinical trial for such indication. The first patient for such trial was enrolled in September 2020.

In parallel, we are also developing our NIS4 diagnostic technology to identify patients with NASH and fibrosis who may be appropriate candidates for drug therapy in a context where these patients are difficult to identify based on the currently available diagnostic methods. A successful development of NIS4 as a diagnostic

technology used in NASH patients' clinical care could have a significant impact on the development and marketing of product candidates currently under development for the treatment of NASH, including elafibranor.

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

The trial began in the first quarter of 2016 and was expected to enrol approximately 2,000 patients. Due to the significant public health risks which NASH represents, the original plan was to use conclusive interim results within the meaning of the endpoints on approximately the first 1,000 randomized patients in the trial after 72 weeks of treatment in order to file an NDA with the FDA for accelerated approval under Subpart H and an application for so-called conditional marketing authorisation with the EMA.

The disappointing results of the interim analysis published in May mean we cannot seek accelerated marketing approval under Subpart H from the FDA and conditional approval from the EMA. On the date of this Amendment we had already decided to terminate the RESOLVE-IT clinical trial. These events clearly illustrate the risks inherent to clinical development and in particular the fact that encouraging results in Phase 1 or Phase 2 constitute no guarantee of subsequent positive results. Even if we had decided to continue the trial, including after consultation with the regulatory authorities, the successful pursuit of more traditional marketing authorisations with the FDA or the EMA would remain very uncertain.

We currently have no drug candidates approved for sale and we cannot guarantee that we or any of our current or future partners will ever have marketable products. The development of drug candidates and NIS4 and issues relating to their approval and marketing are subject to extensive regulation by the FDA in the United States, the European Union and the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country

We (or a future partner of ours) will not be permitted to market our drug candidates in the United States or Europe until we receive approval of a New Drug Application, or NDA, from the FDA or an MA from the European Commission (based on the positive opinion of the EMA), as applicable. We have not submitted at this time any marketing applications for any of our drug candidates and neither has Terns Pharmaceuticals, our development partner for elafibranor in some territories and for some therapeutic indications, for its products. NDAs and MAs must include extensive pre-clinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs and MAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a NDA or a MA 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 an 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 labelling or require expensive and time-consuming clinical trials or reporting as conditions of approval.

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

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

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

2.3 The risk factor in the Universal Registration Document entitled "We and our partner Terns Pharmaceuticals in some territories and for some indications are developing our lead product candidate, elafibranor, for the treatment of NASH, a condition for which no drug has yet been commercialised and for which there is little clinical experience. In PBC, the other major indication for which we and our partner Terns Pharmaceuticals are developing elafibranor, only two treatments have been approved and are currently marketed and they do not fulfil the medical needs of all patients. As a result, our development approach and that of our partner involve new endpoints and methodologies. The outcome of our clinical trials may not be favourable or, even if favourable, regulatory authorities may not find the results of the clinical trials of our current and future partners to be sufficient for marketing approval." is deleted and replaced by the following (previously Section 2.2.1.1.2 and now Section 2.2.1.2):

"We and our partner Terns Pharmaceuticals in some territories and for some indications are developing our lead product candidate, elafibranor, for the treatment of PBC, a condition for which only two treatments have been approved and are currently marketed and they do not fulfil the medical needs of all patients. As a result, our development approach and that of our partner involve new endpoints and methodologies. The outcome of our clinical trials may not be favourable or, even if favourable, regulatory authorities may not find the results of the clinical trials of our current and future partners to be sufficient for marketing approval."

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

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

Similarly, the EMA may give a positive opinion for conditional marketing authorisation 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 authorisation. Conditional marketing authorisations 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.

It may be expensive and time consuming to conduct and complete additional pre-clinical 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 pre-clinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we, our partner Terns Pharmaceuticals, or a future partner receives regulatory approval of elafibranor for the treatment of PBC, the labelling for our product candidates in the United States, Europe or other countries in which we, our partner Terns Pharmaceuticals, or a future partner have received or seek approval may include limitations that could impact the commercial success of our products.

## 2.4 The risk factor in the Universal Registration Document entitled "We are currently considering the development of some of our drug candidates in combination with other treatments, which exposes us to additional risks." is deleted.

After ceasing our research into the use of elafibranor in NASH in combination with other treatments, pursuant to our suspension of the development of elafibranor in NASH, the risk factor described in Section 2.2.1.1.6 of the Universal Registration Document ("We are currently considering the development of some of our drug candidates in combination with other treatments, which exposes us to additional risks") specific to such developmental focus is no longer relevant.

2.5 The risk factor in the Universal Registration Document entitled "Delays in the commencement, enrolment and completion of clinical trials could result in increased costs to us and delay or limit our ability and that of Terns Pharmaceuticals, our partner in some territories and for some indications and that of a future partners to obtain regulatory approval for elafibranor and our other drug candidates." is deleted and replaced by the following (previously Section 2.2.1.1.7 and now Section 2.2.1.6):

"Delays in the commencement, enrolment and completion of clinical trials, starting with our ELATIVE Phase 3 clinical trial evaluating elafibranor in PBC (a rare disease), could result in increased costs to us and delay, limit or jeopardize our ability and that of Terns Pharmaceuticals, our partner in some territories and for some indications and that of future partners to obtain regulatory approval for elafibranor and our other drug candidates.

Delays in the commencement, enrolment and completion of our clinical trials or those of our partner Terns Pharmaceuticals or any future partner could increase our product development costs or limit the regulatory approval of our drug candidates. We currently have underway a number of trials, including our pivotal (ELATIVE) Phase 3 clinical study of elafibranor in PBC, for which the first patient was enrolled in September 2020. We may also be required to conduct additional clinical trials of elafibranor or our other drug candidates. In the past, we have experienced some delays in enrolment in our clinical trials and our RESOLVE-IT clinical trial in particular. We continue to work towards expanding our overall elafibranor development program with additional trials and studies, including in product combinations and we plan on conducting additional development activities with elafibranor in other diseases. Terns Pharmaceuticals, our partner for the development of elafibranor in certain territories and for some indications will also launch new trials recruiting specific patient populations. The results from these trials may not be available when we expect, or we or our partner may be required to conduct additional clinical trials or pre-clinical studies not currently planned to receive approval for elafibranor as a treatment for the relevant indication. In addition, our clinical programs and those of our partner are subject to a number of variables and contingencies, such as the results of other trials, patient enrolments or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies in elafibranor or our other product candidates will begin on time or will be completed on schedule, if at all.

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

- inability to demonstrate sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- inability to validate test methods to support quality testing of the drug substance and drug product;
- inability to determine dosing and clinical trial design;
- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to enter into collaborations relating to the development and commercialisation of our drug candidates;
- inability to reach agreements on acceptable terms with subcontractors (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, the 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, the 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 partners 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 pre-clinical studies or clinical trials;
- difficulty identifying, recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrolment criteria for our trial, the rarity of the disease or condition, the rarity of the characteristics of the population being studied, the nature of the protocol, the risks of procedures that may be required as part of the trial, such as a liver biopsy, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial, and competition from other clinical trial programs for the same indications as our product candidates;
- global health pandemics such as COVID-19 or natural disasters; and
- inability to retain enrolled patients after a clinical trial is underway.

For example, our RESOLVE-IT trial was a large and complex Phase 3 clinical trial, in a disease without any approved therapies and the diagnosis of which generally involves invasive procedures such as liver biopsies, specific factors which have in the past led us to delay our analysis of interim results.

Furthermore, if one of our competitors' products is approved by the FDA or another regulatory body for the treatment of PBC before elafibranor is approved, we may experience difficulties enrolling patients in our clinical trials and retaining patients in any of our existing clinical trials.

As we engage in other large and complicated trials and trials in advanced disease populations, including our planned Phase 3 pivot trial evaluating elafibranor in PBC and a Phase 2 trial evaluating NTZ in liver fibrosis, we may experience a number of complications that may negatively affect our plans or our development programs. Our Phase 3 pivotal trial evaluating elafibranor in PBC in particular is made complex by the small number of patients and the fact that one of our competitor's product is the only one to have recently received market approval in this indication, which may compromise our ability to retain or recruit patients or finalize the trial on time. Potential discussions with the FDA, the EMA or other regulatory authorities outside the United States or Europe regarding the scope or design of our clinical trials may also happen at any time.

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

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

2.6 The risk factor in the Universal Registration Document entitled "Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate that we or our current or future partners advance through clinical trials may not have favourable results in later clinical trials or receive regulatory approval." is amended as follows (previously Section 2.2.1.1.8 and now Section 2.2.1.7):

The title of risk factor is deleted and replaced by the following:

"Clinical failure can occur at any stage of clinical development, as previously occurred with our RESOLVE-IT Phase 3 clinical trial evaluating elafibranor in NASH. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate that we or our current or future partners advance through clinical trials may not have favourable results in later clinical trials or receive regulatory approval."

The first paragraph of the risk factor is deleted and replaced by the following:

"Clinical failure can occur at any stage of our clinical development or those of our current partner or a future partner. Clinical trials may produce negative or inconclusive results, and we or our current partner or a future partner may decide, or regulators may require us, to conduct additional clinical trials or pre-clinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favourably as we or our partners do, which may delay, limit or prevent regulatory approval. Success in pre-clinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us or our current partner, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development in particular in PBC, even after seeing promising results in earlier clinical trials."

2.7 The risk factor in the Universal Registration Document entitled "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." is deleted and replaced by the following (previously Section 2.2.1.1.10 and now Section 2.2.1.9):

#### "Due to our limited resources and access to fundings, that could affect our strategic decisions with respect to the development of certain product candidates and have an impact on 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. This risk is particularly increased in the context of our specific undertaking to reduce our operating expenses, including eliminating all non-essential expenses. In fact, the Company's intends to achieve an approximately 50% reduction in operating cash-burn by 2022. Prior to the RESOLVE-IT Phase 3 clinical trial results announcement, the Company was operating at an annual cash-burn of approximately 110 million Euros and expects to reduce cash-burn in 2022 to approximately 45 million Euros annually. 2021 will be a transitional year in terms of operating cash-burn, which should be in the region of 75 million Euros (excluding the Partial Buyback at a total cost of 47.48 million Euros), corresponding mainly to the remaining costs and expenses associated with the closing of the RESOLVE-IT clinical trial and the costs associated with the employment protection plan. As such, we are currently primarily

focused on the development of elafibranor for the treatment of PBC, and the parallel development of NIS4 for identifying patients with NASH and fibrosis who may be appropriate candidates for drug therapy. Due to the foregoing, 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."

2.8 The risk factor in the Universal Registration Document entitled "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." is amended as follows (previously Section 2.2.1.11) and now Section 2.2.1.10):

The first paragraph of the risk factor is deleted and replaced by the following:

"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, our current partner or a future partner may need to either restrict their use of such product to a smaller population or abandon our development of elafibranor for PBC and other potential indications."

2.9 The risk factor in the Universal Registration Document entitled "Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare third-party payors, and as a result our revenues generated from their sales may be limited." is deleted and replaced by the following (previously Section 2.2.2.2 and now Section 2.2.3.2):

"The commercial success of elafibranor as a treatment for PBC, of an IVD test using our NIS4 diagnostic technology or of any one of our other product candidates, if approved and cleared, will depend upon their acceptance among the medical community, including physicians, healthcare third-party payors and patients. Given that currently a limited number of products is approved for the treatment of PBC, we do not know the degree to which elafibranor would be accepted as a therapy, if approved. There are, however, a number of products being developed by other companies for the treatment of PBC, 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 an IVD test using our NIS4 diagnostic technology 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 an IVD test using our NIS4 is used, a physician may still require additional testing (e.g. liver biopsy) to confirm diagnosis. The degree of market acceptance of elafibranor, NIS4 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 PBC or an alternative to liver biopsy for the diagnosis of NASH;
- limitations in the approved clinical indications or patient populations for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- limitations or warnings, including boxed warnings, contained in our drug candidates' FDA- or EMAapproved labelling;

- in the case of elafibranor, our ability and that of our partner, Terns Pharmaceuticals or of a potential future partner to access the under-diagnosed NASH market or the PBC market;
- for NIS4, our ability, that of our partner, Covance/LabCorp or of a potential future partner to access the clinical research market and, if applicable, develop an IVD test for NASH patients' clinical care;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of coverage and adequate reimbursement from managed care plans and other healthcare third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies or diagnostic solutions at similar or lower cost, including generics and over-the-counter products;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug or diagnostic candidates are designated under physician diagnostic and treatment guidelines for the treatment of the indications for which we, our partner, Terns Pharmaceuticals or a potential future partner have received regulatory approval;
- adverse publicity about our product candidates or favourable 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 third-party 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 healthcare third-party payors on the benefits of our product candidates may require significant resources and may never be successful."

# 2.10 The risk factor in the Universal Registration Document entitled "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." is amended as follows (previously Section 2.2.3.1 and now Section 2.2.4.1):

The title of the risk factor is deleted and replaced by the following:

"We depend on third-party contractors for a substantial portion of our operations, in particular, on clinical research organisations for our clinical trials and on clinical manufacturing organisations for the manufacturing of our active ingredients and therapeutic units, and may not be able to control their work as effectively as if we performed these functions ourselves."

The first paragraph of the risk factor is deleted and replaced by the following:

"Under our supervision, we outsource substantial portions of our operations to third-party service providers, including pre-clinical studies and clinical trials, collection and analysis of data and manufacturing of our drug candidates and the realization of certain analyses pertaining to NIS4 on the clinical research market. In

particular, we subcontract the design and/or conduct of our clinical trials to CROs, as well as the manufacturing of our active ingredients and therapeutic units to contract manufacturing organizations, or CMOs, especially with regard to our (ELATIVE) Phase 3 clinical trial evaluating elafibranor in PBC. We also contract with external investigators and other specialized services providers, for example with respect to certain statistical analyses, to perform services such as carrying out and supervising, and collecting, analysing and formatting of data for our trials. Although we are involved in the design of the protocols for these studies and in monitoring them, we do not control all the stages of their performance and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations. In particular, a contractor's failure to comply with protocols or regulatory constraints, or repeated delays by a contractor, could compromise the development of our products or result in liability for us. Such events could also inflate the product development costs borne by us."

2.11 The risk factor in the Universal Registration Document entitled "We have entered, and may in the future enter into, collaboration agreements with third parties for the development and eventual commercialisation of our product candidates, which may affect our ability to generate revenues." is amended as follows (previously Section 2.2.3.3 and now Section 2.2.4.3):

The title of the risk factor is deleted and replaced by the following:

"We have entered, with Terns Pharmaceuticals for elafibranor and Labcorp/Covance for NIS4, and may in the future enter into, collaboration agreements with third parties for the development and eventual commercialisation of our product candidates, which may affect our ability to generate revenues."

2.12 The risk factor in the Universal Registration Document entitled "We depend on Terns Pharmaceuticals for the development and commercialisation of elafibranor on the Greater China territory in NASH and PBC." is amended as follows (previously Section 2.2.3.5 and now Section 2.2.4.5):

The title of the risk factor is deleted and replaced by the following:

## *"We depend on Terns Pharmaceuticals for the development and commercialisation of elafibranor on the Greater China territory in PBC."*

The first paragraph of the risk factor is deleted and replaced by the following:

"Our only drug candidate licensed to date is elafibranor, whose development and commercialization rights in Greater China in PBC, and secondarily, in NASH, have been licensed to Terns Pharmaceuticals in June 2019 prior to the termination of the RESOLVE-IT clinical trial"

2.13 The risk factor in the Universal Registration Document entitled "We rely entirely on third-party contractors for the manufacturing of our drug candidates and the future manufacturing of the test kit using our NIS4 diagnostic technology for the NASH patients' clinical care including one manufacturer for the active ingredient in elafibranor and another manufacturer for the therapeutic units of elafibranor used in our clinical trials. Our business could be harmed if those third-party contractors fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices." is amended as follows (previously Section 2.2.3.2 and now Section 2.2.4.2):

The second paragraph of the risk factor is deleted and replaced by the following:

"While we believe that our current drugs 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 our trial evaluating elafibranor in PBC, in the process of being initiated, would be critical."

## 2.14 The risk factor in the Universal Registration Document entitled "We are exposed to a number of regulatory and commercial risks related to the United Kingdom leaving the European Union if the

# United Kingdom and the European Union are not able to come to an agreement regarding the modalities of the withdrawal of the United Kingdom." is amended as follows (previously Section 2.2.4.8 and now Section 2.2.5.8):

The second paragraph of the risk factor is deleted and replaced by the following:

"Our clinical trials in the United Kingdom are subject to the requirements of the Medicines and Healthcare products Regulatory Agency or MHRA and the regulations of the EMA. If, following Brexit, the United Kingdom and the European Union are not able to come to an organized withdrawal agreement, there may be a significant uncertainty regarding the continued application of such regulations in the United Kingdom. We plan to open new investigation sites in the United Kingdom for our trial evaluating elafibranor in PBC and other indications. In that context, we may not be certain that these trials will not be affected it the UK and the EU are not able to come to an organized withdrawal agreement. Furthermore, if we or our potential future partners obtain market approval within the European Union, this market approval may not allow us to commercially market our product candidates in the United Kingdom and we or our potential future partners may not be in a position to obtain the required approval from the British regulatory authority. If we or our potential future partners which could be considerable."

2.15 The risk factor in the Universal Registration Document entitled "Currently, we have no products approved for commercial sale, and to date we have not generated any recurring revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability." is amended as follows (Section number unchanged):

The fifth paragraph of the risk factor is deleted and replaced by the following:

"Furthermore, despite the decision taken in July 2020 to terminate the RESOLVE-IT trial, costs continue to be incurred in connection with such trial in the context of its termination."

2.16 The risk factor in the Universal Registration Document entitled "We will require substantial additional funding to commercialize our products, if approved, which may not be available to us or our current or future collaborators on acceptable terms, or at all, and, if not so available, may require us or them to delay, limit, reduce or cease our operations." is deleted and replaced by the following (Section number unchanged):

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

We are currently advancing elafibranor through clinical development for PBC and other drug candidates through clinical or preclinical development. Additionally, we are also planning formal validation studies of NIS4 in preparation for submitting the IVD test for marketing authorisation for clinical care of NASH patients.

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 for IVD tests using our NIS4 technology, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

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 NIS4 is uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products under development."

2.17 The risk factor in the Universal Registration Document entitled "Our stock price may never reach a price at which the bondholders will deem conversion economically viable, in which case we would need to repay the nominal amount at maturity in October 2022. The terms of our convertible bonds require us to meet certain operating covenants, and if we fail to comply with those covenants the bondholders would be able to accelerate our repayment obligations. Additionally, the conversion of some or all of our bonds into ordinary shares would dilute the ownership interests of existing shareholders." is deleted and replaced by the following (Section number unchanged):

"If the Transaction is not completed, we will not be in position to reimburse our debt and will have to contemplate alternative solutions in order to protect its interests. Our stock price may never reach a price at which the conversion of our OCEANEs (respectively, 29.60 Euros prior to the Transaction and 5.38 Euros after the Transaction) becomes economically viable and the redemption in cash of our OCEANEs could therefore be compromised.

In October 2017, we issued OCEANEs. The OCEANEs bear interest at a nominal rate of 3.5% payable semiannually in arrears on 16 April and 16 October of each year.

The OCEANEs will in practice only be converted if the Genfit stock price is higher than the implicit conversion price (plus coupon). Our stock price decreased significantly following the announcement of the disappointing RESOLVE-IT interim results and closed at 4.05 Euros on 21 December 2020. Historically our stock price has been highly volatile. If our stock price between now and the maturity of the OCEANEs (16 October 2025 (should the Transaction take place) or 16 October 2022 (the original maturity date, should the Transaction not take place)) does not reach a point making conversion of the OCEANEs economically viable, the OCEANEs will not be converted before their maturity. This will still be the case even if the Transaction (including a Modification of the Conversion Ratio) is completed, which would have the effect of lowering the implicit OCEANE conversion price from 29.60 Euros to 5.58 Euros per OCEANE.

Our stock price is largely dependent on the results of our ongoing clinical trials and in particular the results of our ELATIVE Phase 3 trial evaluating elafibranor in PBC for which the preliminary results are expected, as at the date of this Amendment, at the first quarter of 2023, the success of the development of our NIS4 technology, the ability of the Company to enter into new licensing agreements and/or partnerships and/or its ability to raise funds.

In this connection it should be borne in mind that if the Transaction does not take place and the original maturity date of 16 October 2022 remains in place, the results of the ELATIVE trial will not be available until after the maturity of the OCEANEs. In such a case, our bond debt will also continue to be 180 million Euros, as the Partial Buyback will not have taken place.

The stock price of the Company also depends on economic, financial and competitive factors that are beyond our control.

If the evolution of our stock price until the maturity date of the OCEANEs does not make it possible to reach the implicit stock price referred to above (whatever such price is), we will therefore be required to redeem at par on maturity.

We have conducted a specific review of our liquidity risk. On 31 October 2020, the Group had  $\in 189,509$  thousand in cash and cash equivalents (as opposed to  $\in 225,721$  thousand on 30 June 2020). On 31 October 2020, net debt (comprised of the book value of the OCEANEs and the current and non-current financial liabilities of the Group, less cash and cash equivalents) amounted to  $\in 5,275$  thousand (as opposed to net cash of  $\notin 41,084$  thousand on 30 June 2020). In view of such amounts as of 31 October 2020, the Company does not

believe it is exposed to short-term liquidity risk. In particular as of the date of this Amendment the Company believes that its cash and cash equivalents are sufficient to ensure its financing, in light of its current plans and obligations, for at least the next twelve months.

However on 16 November 2020 the Company announced that, despite the significant cost-savings initiatives it had implemented, the expected cash position on the maturity date of the 2022 OCEANEs would not allow the Company to repay the convertible bonds at par (corresponding to approximately 180 million Euros on the basis of the current maturity date of 16 October 2022). Consequently, the Company announced to all the Bondholders and the Shareholders its intention to proceed with the Transaction.

If the Transaction is not completed and the OCEANEs are not converted into shares before their maturity, the Company would therefore be unable to redeem the OCEANEs on their initial maturity date of 16 October 2022. It would then have to consider alternative solutions in order to protect its interests.

If the Transaction is completed, it remains a possibility that the amount of cash available on the new maturity date (16 October 2025) would require us to procure additional financial resources in order to proceed with redemption, including potentially by way of a fresh issue of convertible bonds or a new request to amend the terms and conditions of the OCEANES.

We may contract additional debt in the future, some of which may be secured. Even though the terms and conditions of our OCEANEs permit us to contract additional debt or to take other action in connection with the assumption of new debt up to a certain limit, the terms and conditions of the OCEANEs may have the effect of restricting our ability to repay such new debts as they fall due, and the repayment of such additional debts could compete with the redemption of the OCEANEs.

The issue agreement governing the OCEANEs contains negative covenants (maintenance of the issue's ranking) and events of default (non-payment of the principal or coupon, breach of an obligation under the issue agreement, cross-default and insolvency proceedings) which are customary for an instrument of this type. 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 OCEANEs, 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 fall.

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

2.18 The risk factor in the Universal Registration Document entitled "We are currently the subject of securities class action litigation in the United States and may become subject to additional litigation of this type, which could harm our business and financial condition." is deleted and replaced by the following (previously Section 2.2.7.9 and now Section 2.2.7.8):

"We are currently the subject of securities class action litigation with respect to the information furnished on elabibranor in the NASH treatment at the time of our initial public offering on Nasdaq and may become subject to additional litigation, which could harm our business, financial condition and reputation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. We may have actions brought against us by shareholders relating to past transactions, changes in our stock price or other matters. For example, in May 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint was filed

in state court in the Commonwealth of Massachusetts, naming us, our board of directors and certain members of our senior management as defendants, alleging that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. In October 2020, the plaintiff voluntarily dismissed the Commonwealth of Massachusetts action, but in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering. We intend to vigorously defend this action. However, the current litigation, as well as any potential future actions against us, could give rise to substantial damages, and thereby have a material adverse effect on our financial position, liquidity, or results of operations. Even if the current class action lawsuit is not resolved against us, the uncertainty and expense associated with shareholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The defence of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business."

2.19 The risk factor in the Universal Registration Document entitled "*The continuation and, as the case may be, the worsening of the COVID-19 pandemic, could adversely impact our business, including our pre-clinical studies and clinical trials, the supply of the active ingredient and therapeutic units of elafibranor, the preparation for commercialisation of our product candidates and the potential granting of regulatory approval required for their market launch.*" is deleted and replaced by the following (Section number unchanged):

"The continuation and, as the case may be, the worsening of the COVID-19 pandemic, could adversely impact our business, including our pre-clinical studies and clinical trials, the supply of the active ingredient and therapeutic units of elafibranor, the preparation for commercialisation of our product candidates and the potential granting of regulatory approval required for their market launch.

A new coronavirus strain, COVID-19, was identified in Wuhan, China in December 2019. Since then, the COVID-19 coronavirus has spread to several countries, including countries where the Company is headquartered, countries in which the Company has clinical trials in progress, countries where it plans to conduct clinical trials and countries in which major subcontractors for carrying out its clinical trials and the production units of the active ingredient suppliers and therapeutic units of elafibranor, are located.

Strict lockdown measures have been taken by the governments in the majority of countries where there has been a COVID-19 outbreak. Although some lockdown measures have been lifted since then, there is no guarantee that governments will not take additional measures in light of new outbreaks of the disease in certain regions, including France and the United States.

As such it is not possible as of the date of this Amendment to predict with certainty the economic impact and the severity of the resurgence of the current COVID-19 pandemic. However, a long-term pandemic with restrictive measures to contain or limit its spread, might lead to an economic slowdown in a market in which the Group is present, or create disruptions with a very significant impact on our activities, our clinical trials, the preparation for market launch of our product candidates and the potential granting of regulatory approval required for their market launch, notably:

- delays or difficulties in manufacturing active pharmaceutical ingredients or therapeutic units used in our clinical trials sites; particularly in the context of the current production unit of our therapeutic units of elafibranor having already experienced a temporary closure of 15 days due to a strong suspicion of COVID-19;
- delays or difficulties in enrolling patients in our clinical trials;

- delays or difficulties in clinical site initiation, including initiation of their activities, in particular for newly launched trials or trials in preparation, difficulties in recruiting clinical site investigators and clinical site staff; in particular, the delays incurred in the launch and the enrolment of patients for the ELATIVE Phase 3 trial evaluating elafibranor in PBC lead us to believe that its preliminary results may not be available until the beginning of 2023;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including due to illness among employees or their families or the desire of employees to avoid contact with large groups of people;
- additional costs due to the implementation of specific protocols for our current or upcoming clinical trial in order to comply with regulatory measures to protect the health of patients;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruptions of world trade that may affect the transportation of clinical trial materials such as our therapeutic units participating in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, in particular the FDA and the EMA, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delay in the timing of interactions with the FDA and the EMA due to the absence of federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19; and
- the refusal of the FDA or the EMA to accept data from clinical trials in affected geographies.

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

As of the date of this Amendment, some of our clinical trials linked to the RESOLVE-IT trial, which had been suspended due to the COVID-19 public health crisis, are being terminated as a result of the disappointing interim results of our RESOLVE-IT Phase 3 clinical trial (paediatric NASH trial and phase 2 trial on liver fat notably). Our ELATIVE Phase 3 clinical trial evaluating elafibranor in PBC, the operational launch of which was delayed due to the pandemic, and the phase 2 trial (independently conducted by Dr. Harrison) evaluating NTZ in liver fibrosis remain ongoing. Our NIS4 diagnostic technology continues to be deployed in the clinical

research field through the subsidiary of our commercial partner LabCorp - Covance. There have however been some limits and may be further limits to test utilization due to delays potentially experienced by some NIS4 clients as the result of the current COVID-19 situation. For similar reasons, the commercial deployment of the LDT integrating NIS4 technology, which is to be conducted by our partner LabCorp for use as a routine clinical care diagnostic test in the US and Canada thanks to our new partnership agreement signed in September, may experience delays.

The global outbreak of COVID-19 continues to evolve rapidly. The extent to which COVID-19 may impact our business, clinical trials and the preparation for commercialisation of our product candidates will depend on the future developments of that COVID-19 pandemic, which are highly uncertain and cannot be predicted with confidence, such as the geographic reach of the disease, the duration of the outbreak, restrictions on the movement of people, goods and capital in Europe and worldwide, social distancing measures, business closures or business disruptions, the effectiveness of actions taken around the world to contain and treat the disease and the effectiveness, take-up and rapidity of vaccination campaigns. In addition, we cannot predict the extent of the impact of this pandemic on the financial markets or on our stock price and as a result, on our ability to obtain additional funding if we should seek to raise additional funding. As of the date of this Amendment, the world economy is severely affected by this pandemic.

Depending on these factors, the pandemic has prevented and could prevent the Company in the future from using all or part of its current infrastructure; it could then become difficult for the Company and all of its subsidiaries to continue their activities for a significant period. Disaster recovery, continuity or reorganization plans may prove inadequate or insufficient. Moreover, if the pandemic and related measures were to be extended, these might cause in particular a delay in the regulatory review of the current and planned clinical trials as well as a delay in potential new drug applications. These events might have a particular impact on the US market launch schedule and therefore on the financial situation and perspectives of the Company."

#### **3 CORPORATE GOVERNANCE**

# 3.1 The paragraph entitled "*Board of Directors*" in Section 3.1.3 (*Composition of the Board of Directors*) of the Universal Registration Document is deleted and replaced by the following:

#### **Board of Directors**

Since 16 June 2017, the Company has been administered by a Board of Directors comprising (on the date of this Amendment) nine members, seven of whom are deemed to be independent directors within the meaning of the Middlenext Governance Code. Directors are appointed for a term of five years.

In September 2019 Jean-François Mouney resigned as Chief Executive Officer of the Company to devote himself entirely to his role as Chairman of the Board of Directors.

Within the meaning of such Code, which was updated in September 2016 and may be consulted on the website of Middlenext (www.middlenext.com), it is recommended for a large board that at least one third of the directors be independent in the case of a controlled company and that up to 50% of the directors be independent in the case of a controlling shareholder. There are five criteria justifying the independence of directors, characterised by the absence of any significant financial, contractual or family relationship likely to affect their independence of judgement:

- they must not be a salaried employee or corporate officer of the company or of a company in its group, and must not have held such a position within the last five years;
- they must not be a significant client, supplier or banker of the Company or its group, or a client, supplier or banker for whom the company or its group represents a significant share of its business within the last two years;
- they must not be a reference shareholder of the Company or hold a significant percentage of voting rights;
- they must not have a close family relationship with a corporate officer or reference shareholder;
- they must not have been an auditor of the Company within the last six years.

On condition that it justifies its position, the Board of Directors may consider one of its members to be independent if they do not fulfil all these criteria.

On 31 December 2019 and on the date of this Amendment, only Biotech Avenir SAS as the reference shareholder of the Company and its Chairman as a former corporate officer and salaried director of the Company are not deemed independent in accordance with the Middlenext Governance Code. In addition, even though Mr. Frédéric Desdouits in March 2019 became the Chief Executive Officer of a company which is a historical supplier of the Company (the relationship with the supplier significantly predates his appointment as a member of the Board of Directors) and he has therefore a significant business relationship with such company, the Board of Directors has concluded in light of the circumstances that such relationship did not negate his independence, in a context in which such supplier is furthermore deemed by the Board of Directors to contract with the Company on an arm's length basis, with Mr. Desdouits having since resigned from such position.

Following its annual ordinary general meeting held on 30 June 2020, Ms. Katherine Kalin and Mr. Eric Baclet joined the Board of Directors of the Company. Together, they bring more than 50 years of combined pharmaceutical experience and deep subject-matter expertise which will aid in the next phase of the Company's growth.

With Katherine Kalin, Catherine Larue, Anne-Hélène Monsellato and Florence Séjourné, the Board of Directors counts four women amongst its nine members, with the result that on the date of this Amendment the Board of

Directors is in compliance with French Law No. 2011-103 of 27 January 2011 on the balanced representation of women and men on executive boards.

There is no director elected by the employees who sits on the Board of Directors. Two employees acting as representatives of the Works Council attend meetings of the Board of Directors.

# 3.2 The following two tables are inserted after the tables summarising the appointments and functions of the members of the Board of Directors in Section 3.1.3 (*Composition of the Board of Directors*)

Katherine KALIN	
58 years old, British and American	Professional experience/Expertise
Member of the Board of Directors of GENFIT SA, on which she sits as an independent member Member of the Strategy and Alliances Committee No GENFIT shares held	Ms. Katherine Kalin has more than 25 years' experience in the health sector, including 15 years in senior management positions in two companies in the health sector, namely Johnson & Johnson (2002-2011) and Celgene (2012-2017). Ms. Katherine KALIN's experience as a director includes in particular her role as non-executive director of Clinical Genomics, a biotechnology company involved in the development of diagnostic solutions in the field of cancer, and Brown Advisory, a strategic consulting and investment firm where she currently works as a director and member of the audit and finance committees. Having lived in Asia, Europe and the United States of America, Ms. Katherine Kalin has significant international experience within the following companies: Nomura International Limited (Tokyo), McKinsey & Company Inc. (London, New York and New Jersey), Johnson & Johnson (New Jersey) and Celgene (New Jersey).
Term of office First appointment: 30 June 2020 by the Shareholders General Meeting Most recent renewal of appointment: N/A	<ul> <li>Directorships and other positions held in French and foreign companies</li> <li>Director and member of the Audit and Financial Risk Committee of Clinical Genomics</li> </ul>
<b>Expiry of current term of office:</b> At the ordinary general meeting held to approve the financial statements for the year ending on 31 December 2024	<ul> <li>Director and member of the audit and finance committees of Brown Advisory</li> <li>Director of Primari Analytics</li> <li>In the past five years, Ms. Katherine KALIN also held the following positions and functions (which she no longer holds):</li> <li>Chair and administrator of Summit Public Schools Board of Education until 2016</li> </ul>

Eric BACLET	
61 years old, French	Professional experience/Expertise
	Mr. Eric BACLET is a seasoned executive with
on which he sits as an independent member	extensive experience in the pharmaceutical industry

Eric BACLET	
Member of the Nomination and Compensation Committee No GENFIT shares held	gleaned in senior executive positions, having built and managed diverse and multicultural teams involved in the biopharmaceutical value chain throughout the world. From this background Mr. Eric BACLET has acquired extensive experience of international management from initial clinical development to final commercialisation. Mr. Eric BACLET has been responsible for portfolio strategies, international brand development, global marketing projects, global sales operations and the management of various geographic areas and countries. Mr. Eric BACLET has established professional points of reference in the delivery and management of significant commercial results and transformation plans with employee teams based on a customer-focussed approach and a high level of integrity. Since the latter half of the 1990s, he has held executive or corporate officer positions in various countries where Eli Lilly and Company has a presence (North Africa, Belgium, the United States and most recently in China (2009-2013) and Italy (2014-2017)).
<b>First appointment:</b> 30 June 2020 by the Shareholders General Meeting <b>Most recent renewal of appointment:</b> N/A	Directorships and other positions held in French and foreign companies • N/A
<b>Expiry of current term of office:</b> At the ordinary general meeting held to approve the financial statements for the year ending on 31 December	In the past five years, Mr. Eric BACLET also held the following positions and functions (which he no longer holds):
2024	<ul> <li>President of Lilly Italy</li> <li>Managing Director of Lilly Italian Hub Eli Lilly and Company until July 2017</li> </ul>

# 3.3 The table in Section 3.1.3 (*Composition of the Board of Directors*) on page 130 of the Universal Registration Document is deleted and replaced by the following:

	Independent director	Year of first appointment	Expiry of term of office	Audit Committee	Nomination and Compensation Committee	Strategy and Alliances Committee
Jean-François MOUNEY Chairman and Chief Executive Officer	No	1999 <sup>(1)</sup>	2021		Member	Chair
Xavier GUILLE DES BUTTES Vice-Chairman	Yes	2006 <sup>(2)</sup>	2021	Member	Chair	Member

	Independent director	Year of first appointment	Expiry of term of office	Audit Committee	Nomination and Compensation Committee	Strategy and Alliances Committee
Florence SÉJOURNÉ (representative of BIOTECH AVENIR SAS) Director	No	2010 (1999) <sup>(3)</sup>	2021			
Frédéric DESDOUITS Director	Yes	2014 <sup>(4)</sup>	2021			Member
Catherine LARUE Director	Yes	2017 <sup>(5)</sup>	2021		Member	
Anne-Hélène MONSELLATO Director	Yes	2017 <sup>(5)</sup>	2021	Chair		
Philippe MOONS Director	Yes	2015 <sup>(6)</sup>	2021	Member		
Katherine KALIN Director	Yes	2020	2024			Member
Eric BACLET Director	Yes	2020	2021		Member	

(1) As a member of the Executive Board.

(2) As a member of the Supervisory Board.

(3) Biotech Avenir SAS was appointed a member of the Supervisory Board of the Company for the first time on the incorporation of the Company on 15 September 1999. Florence SÉJOURNÉ has been its permanent representative since 2010, first of all on the Supervisory Board and then on the Board of Directors of the Company.

(4) As a member of the Supervisory Board.

(5) As members of the Board of Directors.

(6) As members of the Supervisory Board.

## 3.4 Section 3.1.5. (*Representations relating to members of the Board of Directors or Senior Management*) of the Universal Registration Document is deleted and replaced by the following:

#### Service contracts between the Company and members of the Board of Directors

There exist no service contracts between the members of the Board of Directors and the Company or its subsidiaries providing for the grant of any benefits.

#### Representations relating to administrative bodies and Senior Management

To the knowledge of the Company as of the date of this Amendment:

- there exist no family links between the members of the Board of Directors and the Senior Management of the Company;
- no member of the Board of Directors has over the last five years been convicted of fraud;
- no member of the Board of Directors has been associated over the last five years with any insolvency, sequestration or liquidation as either a member of any management, executive or supervisory body or as a chief executive officer;
- no member of the Board of Directors has over the last five years been prohibited by a court from sitting on a management, executive or supervisory body of any company or participating in the management or conduct of the business of a company; and
- no criminal charges have been brought against and/or no official public sanction has been imposed on any member of the Board of Directors of the Company by any statutory or regulatory authority (including designated professional bodies).

#### Conflicts of interests at the level of the executive bodies and Senior Management

- Certain members of the Board of Directors are direct or indirect shareholders of the Company (see breakdown in Section 3.2 (*Remuneration and benefits*) of the Universal Registration Document).
- On the date of this Amendment and to the knowledge of the Group, there exists no conflict of interests between the private interests of the members of the Board of Directors of the Company and the interests of the Company.
- Mr. Jean-François Mouney, the Chairman of the Board of Directors of the Company, is also the chair of the Management Board of Biotech Avenir SAS, in which he holds 17.1% of shares. As of 31 December 2019 Biotech Avenir held 4.86% of the shares and 8.87% of the voting rights in the Company.
- There does not exist to the knowledge of the Company any agreement or understanding whatsoever which has been entered into by the shareholders, customers, suppliers or other persons pursuant to which any one of the members of the Board of Directors of the Company has been appointed a corporate officer. It is nonetheless specified that the Company has a customer-supplier type relationship with PCAS, which was managed by Mr. Frédéric Desdouits between March 2019 and March 2020, but such relationship pre-existed the appointment of Mr. Frédéric Desdouits as a Director of the Company.
- To the knowledge of the Group and as of the date of this Amendment, no restriction has been accepted by the persons referred to in Section 3.1.3 (*Composition of the Board of Directors*) of the Universal Registration Document, as amended by this Amendment, on the transfer of their stakes in the Company.

#### Information about the contracts entered into by the directors and the Company

- The Chairman of the Board of Directors and the Chief Executive Officer of the Company each has a corporate officer contract.
- No contracts have been entered into by the Company and the members of the Board of Directors other than the indemnification agreements entered into in the context of the listing of the Company on Nasdaq Global Select Market intended to protect each one of them, the Chief Executive Officer and the members of the Executive Committee against any liability and to pay them an advance on costs in connection with any action resulting from performance of their duties in the service of the Company.

#### 4 NON-FINANCIAL PERFORMANCE

#### Section 4.3.1 (*Personnel-related matters*) is supplemented by the following:

On 30 September 2020, in support of this new strategy, the Company announced the implementation of an extensive cost-savings programme, including an employment protection plan (*plan de sauvegarde de l'emploi*) in France, which is being implemented on the date of this Amendment. The employment protection plan was submitted for information and consultation purposes to the Company's Employment and Economic Council, agreed with the relevant union representative and approved by the DIRECCTE. The Company aims to reduce the total headcount of its staff from approximately 200 on 30 June 2020 to 125.

#### 5 FINANCIAL AND ACCOUNTING INFORMATION OF THE COMPANY

# 5.1 The following information supplements Chapter 5 (*Financial and accounting information*) of the Universal Registration Document.

#### Key figures from the 2020 half-year results:

The key figures from the 2020 half-year results of the Group are:

- cash and cash equivalents of 225.7 million Euros as of 30 June 2020, compared to 276.7 million Euros as of 31 December 2019;
- Operating revenue and other income of 5.9 million Euros (compared to 5.4 million Euros as of 30 June 2019) corresponding principally to a research tax credit of 5.2 million Euros in the first half of 2020 (compared to 5.3 million Euros for the preceding half-year);
- total operating expenses of 55.0 million Euros (compared to 51.3 million Euros as of 30 June 2019), 67% of which is attributable to R&D.

The increase in operating expenses between the two periods is mainly attributable to increased marketing and pre-marketing expenses, which were 9.5 million Euros in the first half of 2020, compared to 2.9 million Euros in the first half of 2019. Such marketing and pre-marketing expenses will have decreased greatly in the second half of 2020, given the suspension of work in respect of the pre-marketing of elafibranor in NASH following the termination of that programme in July 2020.

General and administrative expenses (8.2 million Euros in the first half of 2020 compared to 9.5 million Euros in the first half of 2019), as well as research and development expenses (36.9 million Euros in the first half of 2020 compared to 38.9 million Euros in the first half of 2019) decreased slightly from one half-year to the next. These expenses will gradually decrease, starting in the second half of the year as a result of the Company having decided to terminate clinical trials in connection with the development of elafibranor in NASH, to stop all non-strategic work and programmes and to implement a cost-savings plan over three years. Significant expenses related to the termination of the RESOLVE IT trial shall continue to accrue in the second half of 2020 and in 2021.

As a result of such variations in revenues and expenses, a net loss of 53.0 million Euros was booked on 30 June 2020 (compared to 51.1 million Euros as of 30 June 2019). By way of a reminder, the net loss for the 2019 fiscal year amounted to 65.1 million Euros.

The table below is the Condensed Statement of Net Income for the Group drawn up in accordance with IFRS for the first half of 2020 and includes a comparison with the first half of 2019.

-	For the six-month period ended			
(in € thousands, except earnings per share data)	June 30, 2019	June 30, 2020		
Revenues and other income				
Revenue	1	122		
Other income	5 3 5 6	5 745		
Revenues and other income	5 3 5 7	5 867		
Operating expenses and other operating income (expenses)				
Research and development expenses	(38 908)	(36 867)		
General and administrative expenses	(9 517)	(8 251)		
Marketing and market access expenses	(2 876)	(9 491)		
Other operating income (expenses)	7	(423)		
Operating income (loss)	(45 936)	(49 163)		
Financial income	1 755	2 095		
Financial expenses	(7 240)	(6 102)		
Financial profit (loss)	(5 485)	(4 007)		
Net profit (loss) before tax	(51 422)	(53 170)		
Income tax benefit (expense)	289	159		
Net profit (loss)	(51 132)	(53 011)		
Attributable to owners of the Company	(51 132)	(53 011)		
Attributable to non-controlling interests				
Basic and diluted earnings (loss) per share				
Basic and diluted earnings (loss) per share (€/share)	(1,64)	(1,36)		

The consolidated financial statements as of 30 June 2020 are annexed as Schedule 1 to this Amendment.

# 5.2 The following information supplements Chapter 5 (*Financial and accounting information*) of the Universal Registration Document.

#### Cash position

As of 30 September 2020 the Company held cash and cash equivalents of 199.3 million Euros, compared to 303.0 million Euros a year earlier.

As of 30 June 2020, cash and cash equivalents totalled 225.7 million Euros.

#### Revenues

Revenues for the first nine months of 2020 was 350 thousand Euros, compared to 31 million Euros for the same period in 2019.

Revenues for the third quarter resulted mainly from services provided and revenues under the licensing and collaboration agreements signed with LabCorp and Terns Pharmaceuticals.

#### **6** ADDITIONAL INFORMATION

# A new Section 7.6 (*Legal and arbitration proceedings*) is inserted into Chapter 7 (*Additional information*) of the Universal Registration Document:

"Readers are referred to Notes 24 and 28 to the consolidated financial statements as of 31 December 2020 included in the Universal Registration Document, to Note 6.23 to the consolidated financial statements as of 30 June 2020 annexed as Schedule 1 to this Amendment and to Section 7.2 of this Amendment for a description of the principal disputes to which the Company is a party.

Save for the proceedings and litigation described in the Universal Registration Document and this Amendment, there exist no other governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware) which have had or may have significant effects on the Company's financial position or profitability."

#### 7 SIGNIFICANT EVENTS POST-DATING THE PUBLICATION OF THE HALF-YEAR BUSINESS AND FINANCIAL REPORT OF THE COMPANY

#### 7.1 The Transaction

In October 2017 the Company issued OCEANEs.

The OCEANEs were issued at a price of 29.60 Euros per OCEANE and bear interest at an annual rate of 3.5% payable semi-annually in arrears on 16 April and 16 October of each year.

As at the date of this Amendment, the OCEANEs grant the right to be allocated new and/or existing shares in the Company on the basis of a conversion/exchange ratio of one (1) share to one (1) OCEANE.

The OCEANEs were admitted to trading on Euronext Access<sup>™</sup> (ISIN: FR0013286903).

On 16 November 2020 the Company announced that despite the robust cost-cutting measures implemented by the Company, forecast available cash on the maturity date of the OCEANEs would not as matters stands make it possible to contemplate repaying the nominal amount of the OCEANEs in cash. The Company accordingly announced to all Bondholders and Shareholders its intention to proceed with the Transaction.

On 23 November 2020 and 7 December 2020, the Company announced to the Bondholders and Shareholders the final terms of the Transaction:

#### Amendment of the terms and conditions of the OCEANES

The Company has proposed the Adjustments to the OCEANEs to the Bondholders and the Modification of the Conversion Ratio to the Shareholders.

On the basis of the Modification of the Conversion Ratio, the implied conversion price (nominal amount of 29.60 Euros per bond divided by the conversion ratio of one (1) OCEANE to five and a half (5.5) new or existing shares) would be 5.38 Euros per OCEANE, representing a conversion premium of 18.8% on the closing share price of 4.53 Euros on 4 December 2020 (the last closing share price recorded prior to the announcement of the definitive outcome of the Partial Buyback) and a conversion premium of 32.2% compared to the average volume-weighted average price between Monday 16 November and Friday 20 November 2020 (*i.e.* the five (5) trading days prior to the announcement by the Company of the final terms of the Transaction on 23 November 2020).

The number of New Shares which may potentially be subscribed for in the event of the conversion of all remaining OCEANEs outstanding after the Partial Buyback on the basis of the new conversion ratio of one (1) OCEANE to five and a half (5.5) new or existing shares is 17,522,016 New Shares, or 45.1% of the current share capital of the Company (compared to 15.6% of the current share capital of the Company on the basis of the current conversion ratio of one (1) OCEANE to one (1) new or existing share). In the event of a full conversion of the OCEANEs which remain outstanding after the Partial Buyback into New Shares, the Bondholders would hold 31.08% of the share capital of the Company (30.8% in the event of the exercise of all outstanding share warrants (BSA) and stock options and the vesting of the outstanding free shares).

The Modification of the Conversion Ratio will be put to a vote of the Shareholders at the Shareholders' Meeting.

The Adjustments to the OCEANEs will be put to a vote of the Bondholders at the Bondholders' Meeting.

#### <u>Partial Buyback of the OCEANEs</u>

The Company and certain Bondholders have entered into 40 Repurchase Agreements at the Total Repurchase Price of 47.48 million Euros and covering 2,895,260 OCEANEs in total, namely 47.6% of outstanding OCEANEs.

The Repurchase Price includes the coupon having accrued between the last coupon payment date (16 October 2020) and the Partial Buyback Settlement Date, which amounts to 0.30 Euros or 1.83% of the Repurchase Price.

The Repurchase Price represents a discount of 44.6% on the nominal value of one OCEANE.

The Partial Buyback is subject to:

- the approval of the Modification of the Conversion Ratio by the Shareholders' Meeting; and
- the approval of the Adjustments to the OCEANEs by the Bondholders' Meeting.

The Adjustments to the OCEANEs shall apply only to those OCEANEs which remain outstanding after the Partial Buyback, namely 3,185,821 OCEANEs representing 52.4% of their nominal amount, namely 94,300,301.60 Euros.

As of 30 November 2020 and prior to the Transaction, to the knowledge of the Company its share capital and voting rights are allocated as follows:

				Pre-Tra	insaction			
		Undilut	ed basis		Diluted basis <sup>(1)</sup>			
Shareholders	Number of shares	% of the share capital	Total voting rights	% of the voting rights	Number of shares	% of the share capital	Total voting rights	% of the voting rights
Pascal Prigent <sup>(2)</sup>	10,700	0.03%	10,700	0.03%	30,712	0.07%	30,712	0.06%
Biotech Avenir <sup>(3)(5)</sup>	1,888,618	4.86%	3,657,370	8.88%	1,888,618	4.15%	3,657,370	7.65%
Florence Séjourné <sup>(3)(4)</sup>	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Jean-François Mouney <sup>(2)(3)(5)</sup>	21,897	0.06%	21,968	0.05%	82,711	0.18%	82,782	0.17%
Xavier Guille des Buttes <sup>(5)</sup>	1,842	0.00%	1,842	0.00%	6,842	0.02%	6,842	0.01%
Frédéric Desdouits	111	0.00%	111	0.00%	5,111	0.01%	5,111	0.01%
Philippe Moons	310	0.00%	310	0.00%	5,310	0.01%	5,310	0.01%
Anne-Hélène Monsellato	0	0.00%	0	0.00%	5,000	0.01%	5,000	0.01%
Catherine Larue	0	0.00%	0	0.00%	5,000	0.01%	5,000	0.01%
Total held by Members of the Board of Directors	1,912,778	4.92%	3,681,601	8.94%	1,998,592	4.40%	3,767,415	7.88%
Université de Lille <sup>(5)</sup>	451,250	1.16%	902,500	2.19%	451,250	0.99%	902,500	1.89%
Fondation Partenariale de l'Université de Lille <sup>(5)</sup>	200,000	0.51%	200,000	0.49%	200,000	0.44%	200,000	0.42%
Liquidity Agreement <sup>(6)</sup>	58,619	0.15%	0	0.00%	58,619	0.13%	0	0.00%
Other shareholders <sup>(2)</sup>	36,225,270	93.22%	36,393,332	88.36%	42,721,153	93.97%	42,889,215	89.75%
TOTAL	38,858,617	100%	41,188,133	100% <sup>(7)</sup>	45,460,326	100%	47,789,842	100% <sup>(7)</sup>

(1) Assuming (i) the exercise of all the 71,760 subscription warrants (BSA) and 374,920 options to subscribe for or purchase issued shares and the definitive allocation of all 73,948 issued free shares as at 30 November 2020 and (ii) the conversion into 6,081,081 New Shares issued by the Company of all the 6,081,081 OCEANEs on the basis of the current conversion ratio of one (1) OCEANE for one (1) New Share.

(2) Holding updated to reflect the purchase of 6,700 ordinary shares in the Company by Pascal Prigent and 7,000 ordinary shares in the Company by Jean François Mouney on 13 May 2020.

(3) Jean-François Mouney is the chairman of Biotech Avenir. Biotech Avenir is owned 17.1% by Jean-François Mouney, 9.9% by Florence Séjourné, 15.8% by 13 employees of the Company and 57.2% by third parties (16 natural persons).

(4) Florence Séjourné is the permanent representative of Biotech Avenir on the Board of Directors of the Company.

(5) These persons are bound by a shareholders' agreement. As at the date of this Amendment, the parties to the shareholders' agreement holding shares of the Company are: Université de Lille, Fondation partenariale de l'Université de Lille, Finorpa SCR, Biotech Avenir and MM. Jean-François Mouney, Xavier Guille de Buttes and Charles Wohler. The shareholders' agreement *inter alia* grants a pre-emption right to Biotech Avenir or any shareholder having signed the shareholders' agreement designated by Biotech Avenir, in the event of a private sale being contemplated by a shareholder who is a party to such shareholders' agreement of all or any of their shares in the Company, insofar as the planned sale (when aggregated with all sales completed in a given year) involves at least 2% of the share capital.

(6) Number of shares held by the Company itself under the liquidity agreement as at 30 November 2020.

(7) Rounded percentage to reflect the shares held by the Company under the liquidity agreement which are without voting rights.

On the date of this Amendment, on the basis of the number of shares and voting rights held as of 30 November 2020 and post-Transaction, to the knowledge of the Company its share capital and voting rights are allocated as follows:

	Post-Transaction and post-issue of all New Shares								
	Undiluted basis				Diluted basis <sup>(1)</sup>				
Shareholders	Number of shares	% of the share capital	Total voting rights	% of the voting rights	Number of shares	% of the share capital	Total voting rights	% of the voting rights	
Pascal Prigent <sup>(2)</sup>	10,700	0.02%	10,700	0,02%	30,712	0.05%	30,712	0.05%	
Biotech Avenir <sup>(2)(4)</sup>	1,888,618	3.35%	3,657,370	6,23%	1,888,618	3.32%	3,657,370	6.17%	
Florence Séjourné <sup>(2)(3)</sup>	0	0.00%	0	0.00%	0	0.00%	0	0.00%	
Jean-François Mouney <sup>(2)(3)(5)</sup>	21,897	0.04%	21,968	0.04%	82,711	0.15%	82,782	0.14%	
Xavier Guille des Buttes <sup>(5)</sup>	1,842	0.01%	1,842	0.00%	6,842	0.01%	6,842	0.01%	
Frédéric Desdouits	111	0.00%	111	0.00%	5,111	0.01%	5,111	0.01%	
Philippe Moons	310	0.00%	310	0.00%	5,310	0.01%	5,310	0.01%	
Anne-Hélène Monsellato	0	0.00%	0	0.00%	5,000	0.01%	5,000	0.01%	
Catherine Larue	0	0.00%	0	0.00%	5,000	0.01%	5,000	0.01%	
Total held by Members of the Board of Directors	1,912,778	3.39%	3,681,601	6.27%	1,998,592	3.51%	3,767,415	6.36%	
Université de Lille <sup>(5)</sup>	451,250	0.80%	902,500	1.54%	451,250	0.79%	902,500	1.52%	
Fondation Partenariale de l'Université de Lille <sup>(5)</sup>	200,000	0.35%	200,000	0.34%	200,000	0.35%	200,000	0.34%	
Liquidity Agreement <sup>(6)</sup>	58,619	0.10%	0	0.00%	58,619	0.10%	0	0.00%	
Other shareholders <sup>(2)</sup>	53,747,286	95.33%	53,915,348	91.83%	54,162,088	95.19%	54,330,150	91.73%	
including Bondholders	17,522,016	31.08%	17,522,016	29.84%	17,522,016	30.79%	17,522,016	29.58%	
TOTAL	56,380,633	100%	58,710,149	100% <sup>(7)</sup>	56,901,261	100%	59,230,777	100%	

(1) Assuming the exercise of all 71,760 subscription warrants (BSA) and 374,920 options to subscribe for or purchase issued shares and the definitive allocation of all 73,948 issued free shares as at 30 November 2020.

(2) Holding updated to reflect the purchase of 6,700 ordinary shares in the Company by Pascal Prigent and 7,000 ordinary shares in the Company by Jean François Mouney on 13 May 2020.

(3) Jean-François Mouney is the chairman of Biotech Avenir. Biotech Avenir is owned 17.1% by Jean-François Mouney, 9.9% by Florence Séjourné, 15.8% by 13 employees of the Company and 57.2% by third parties (16 natural persons).

(4) Florence Séjourné is the permanent representative of Biotech Avenir on the Board of Directors of the Company.

(5) These persons are bound by a shareholders' agreement. As at the date of this Amendment, the parties to the shareholders' agreement holding shares of the Company are: Université de Lille, Fondation partenariale de l'Université de Lille, Finorpa SCR, Biotech Avenir and MM. Jean-François Mouney, Xavier Guille de Buttes and Charles Wohler. The shareholders' agreement *inter alia* grants a pre-emption right to Biotech Avenir or any shareholder having signed the shareholders' agreement designated by Biotech Avenir, in the event of a private sale being contemplated by a shareholder who is a party to such shareholders' agreement of all or any of their shares in the Company, insofar as the planned sale (when aggregated with all sales completed in a given year) involves at least 2% of the share capital.

(6) Number of shares held by the Company itself under the liquidity agreement as of 30 November 2020.

(7) Rounded percentage to reflect the shares held by the Company under the liquidity agreement which are without voting rights.

#### 7.2 Litigation

In May 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint, captioned Schwartz v. Genfit S.A. et al., was filed in state court in the Commonwealth of Massachusetts, naming the Company, our board of directors and certain members of our senior management as defendants. The complaint alleged that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. The complaint sought unspecified compensatory damages. In October 2020, the plaintiff voluntarily withdrew its action filed in state court in the Commonwealth of Massachusetts.

However, in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering. The Company and the defendants intend to vigorously defend this action. The financial impact of the claim cannot be quantified at this stage.

#### 8 STATEMENT OF THE PERSON RESPONSIBLE FOR THIS AMENDMENT TO THE UNIVERSAL REGISTRATION DOCUMENT

"I hereby certify that, having taken all reasonable care for such purpose, the information contained in this Amendment to the Universal Registration Document is to the best of my knowledge true and accurate and contains no omission that could make it misleading."

Loos, 22 December 2020

Mr. Pascal Prigent

Chief Executive Officer of the Company

#### 9 **RECONCILIATION TABLE**

The reconciliation table below reproduces the headings and sub-headings used in Annex 1 to Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 and refers to the pages or Sections of the Universal Registration Document and this Amendment on which the information required under each such heading and sub-heading may be found.

		Universal Registration Document		Amer	ndment
		Sections	Pages	Sections	Pages
1	Persons responsible, third party information, experts' reports and competent authority approval				
1.1	Identity of persons responsible	7.5.1.1	323	8	57
1.2	Declaration of persons responsible	7.5.1.2	323	8	57
1.3	Name, business address, qualifications of persons acting as an expert	7.5.2	323		
1.4	Confirmation in relation to information sourced from a third party	7.5.2	323		
1.5	Statement in relation to the competent authority	-	1	-	1
2	Statutory auditors				
2.1	Identity of statutory auditors	7.3.1	321 <i>et seq</i> .		
2.2	Any change of statutory auditors	7.3.1	321 <i>et seq</i> .		
3	Risk factors	2; Note 5 to the consolidated financial statements		2	18 et seq.
4	Information about the Company				
4.1	Legal and commercial name	7.1.1.1	314		
4.2	Place of registration, registration number and LEI	7.1.1.2	314		
4.3	Date of incorporation and length of life	7.1.1.3	314		
4.4	Domicile and legal form, legislation under which the Company operates, country of incorporation, address and telephone number of its registered office and website with disclaimer.	7.1.1.4	314		

		Universal Registration Document		Amendment	
		Sections	Pages	Sections	Pages
5	Business overview				
5.1	Principal activities				
5.1.1	Nature of Company's operations	1.1; 1.2; 1.4; 4.2	6 et seq.; 8 et seq.; 15 et seq.; 161	1.1 ; 1.2 and 1.4	6 et seq. ; 9 et seq. and 12 et seq.
5.1.2	New products and/or services	N/A	N/A		
5.2	Principal markets	Note; 1.2; 1.4.3	2; 8; 33; 199	1.2; 1.4.3	9 et seq. and 12 et seq.
5.3	Important events	<ul><li>1.1; 1.2;</li><li>1.3;</li><li>1.4.2; Note</li><li>28 to the</li><li>consolidated</li><li>financial</li><li>statements</li></ul>	6 et seq.; 8 et seq.; 11 et seq.; 18 et seq.; 239 et seq.	1.1 ; 1.2 ; 1.3 and 1.4	6 et seq. ; 9 ; 10 et seq. and 16 et seq.
5.4	Strategy and objectives	1.3; 4.2	11 <i>et seq.</i> ; 161	1.3	10 et seq.
5.5	Dependence on patents, licences, contracts or new manufacturing processes	1.5; 2.2.3; 2.2.5	39 et seq.; 90 et seq.; 98 et seq.		
5.6	Statement regarding its competitive position	1.6	47 et seq.	1.5	15 <i>et seq</i> .
5.7	Investments				
5.7.1	Material investments made	5.1.3.1	186 et seq.		
5.7.2	Material investments in progress or for which commitments made	5.1.3.2; 5.1.3.3	187		
5.7.3	Information relating to joint ventures and associated undertakings	1.8.3; Note 25 to the consolidated financial statements; Note 27 to the consolidated financial statements 5.6.5.4	64; 235 et seq.; 238 et seq.; 276 et seq.	1.6.2	16 et seq.

		Universal Registration Document		Amendment	
		Sections	Pages	Sections	Pages
5.7.4	Environmental issues that may affect utilisation of the tangible fixed assets	4.3.4	172 et seq.		
6	Organisational structure				
	Brief description of the Group	1.8.1; 4.2	63; 161		
	List of significant subsidiaries	1.8; 5.6.6	63 et seq.; 279		
7	Operating and financial review				
7.1	Financial position				
7.1.1	Development of performance and financial position including financial and where appropriate non-financial key performance indicators	4.2; 4.3; 4.4; 5	161; 162 et seq.; 175; 178 et seq.	4; 5; Schedule 1	48; 49 <i>et</i> <i>seq.</i> and 68 <i>et seq.</i>
7.1.2	Likely future development and activities in the field of research and development	1.3	11 <i>et seq</i> .	1.3	10 et seq.
7.2	Operating results				
7.2.1	Significant factors, unusual or infrequent events or new developments	5.1.1	178		
7.2.2	Reasons for material changes in net sales or revenues	5.1.1	178 et seq.		
8	Capital resources				
8.1	Information concerning capital resources	5.1.2; 5.5.1; 5.5.5; Note 4 to the consolidated financial statements; Note 17 to the consolidated financial statements 5.6; Note 9 to the company accounts	182; 192; 196 et seq.; 206; 223; 246; 257	5.1; 5.2 and Schedule 1	49 <i>et seq.</i> and 68 <i>et</i> <i>seq.</i>
8.2	Cash flows	5.1.2; 5.5.4	185 et seq.; 195		
8.3	Borrowing requirements and funding structure	5.1.2; Note 10 to the	185 et seq.; 195; 182 et		

		Universal F Docu	Registration ment	Amer	dment
		Sections	Pages	Sections	Pages
		consolidated financial statements; Note 12 to the consolidated financial statements; Note 12 of the company accounts	seq.; 215 et seq.; 261		
8.4	Restrictions on the use of capital resources	5.1.2	185		
8.5	Anticipated sources of funds	2.2.7; 5.1.2	108 et seq.; 185		
9	Regulatory environment				
	Description of the regulatory environment that may affect the Company's business	1.7; 2.2.6	49 et seq.; 104 et seq.	1.5	16 et seq.
10	Trend information				
10.1	Description of the most significant trends and any significant change in the financial performance of the group since the end of the last financial period	1.2; 1.3; 1.4.1; 1.6; 2.2.8; 5.2; Note 28 to the consolidated financial statements 5.6.7; 5.8	8 et seq.; 11 et seq.; 15 et seq.; 47 et seq.; 112; 189; 239; 279 et seq.; 284		
10.2	Events reasonably likely to have a material effect on prospects	1.2; 1.3; 1.4.1; 1.6; 2.2.8; 5.2; Note 28 to the consolidated financial statements 5.6.7; 5.8	8 et seq.; 47 et seq.; 112; 189; 239; 279 et seq.	1.2 ; 1.3 ; 1.5 and 5	9; 10 et Seq; 16; and 49 et seq.
11	Profit forecasts or estimates				
	Published profit forecasts or estimates	5.3	190	1	1

		Universal Registration Document		Amendment	
		Sections	Pages	Sections	Pages
11.2	Statement setting out principal assumptions for forecasts	5.3	190		
11.3	Statement of comparability with historical financial information and consistency with accounting policies	5.3	190		
12	Administrative, management and supervisory bodies and senior management				
12.1	Information about members	3.1.2; 3.1.3	120 et seq.; 121 et seq.	3.1; 3.2 and 3.3	43 et seq. ; 44 et seq. and 45 et seq.
12.2	Conflicts of interests	3.1.5	137	3.4	46 et seq.
13	Remuneration and benefits				
13.1	Remuneration paid and benefits in kind	3.2; Note 26 to the consolidated financial statements 5.6.5.3	138 et seq.; 236 et seq.; 275 et seq.;		
13.2	Amounts set aside or accrued to provide for pension, retirement or similar benefits	3.2.2	151		
14	Board practices				
14.1	Date of expiry of current terms of office	3.1.3	123 et seq.		
14.2	Members of the administrative, management or supervisory bodies' service contracts with the Company	3.1.5	137	3.4	46 et seq.
14.3	Information about the audit and remuneration committees	3.1.4.2	133 et seq.		
14.4	Statement of compliance with the applicable corporate governance regime	3.1.1; 3.1.3	120; 131		
14.5	Potential material impacts on corporate governance	3.1.3	122		
15	Employees				
15.1	Number of employees	4.2; 4.3.1; 5.6.5.1; 5.7	1; 4; 161; 162; 271; 284	4	55

		Universal Registration Document		Amendment	
		Sections	Pages	Sections	Pages
15.2	Shareholdings and stock-options	3.2.1; 3.2.4; Note 20 to the consolidated financial statements; 5.6.5.2; 6.1.2	138 et seq.; 155 et seq.; 225 et seq.; 272 et seq.; 288 et seq.		
15.3	Arrangements for involving the employees in the capital	3.2.4; 6.1.2	156 et seq.; 288 et seq.		
16	Major shareholders				
16.1	Shareholders holding more than 5% of the share capital	6.1.1	286 et seq.	7.1	54 and 55
16.2	Existence of different voting rights	6.1.1; 7.1.2.3.2	287; 317		
16.3	Direct or indirect control	6.1.1	287		
16.4	Arrangements of which the operation may result in a change in control	6.5.7; 7.1.2.5.3	311 <i>et seq.</i> ; 317		
17	Related party transactions	Note 25 to the consolidated financial statements; Note 27 to the consolidated financial statements 7.2	235 et seq.; 238; 318		
18	Financial information concerning the Company's assets and liabilities, financial position and profits				
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18.1.2	Change of accounting reference date	N/A	N/A	N/A	N/A

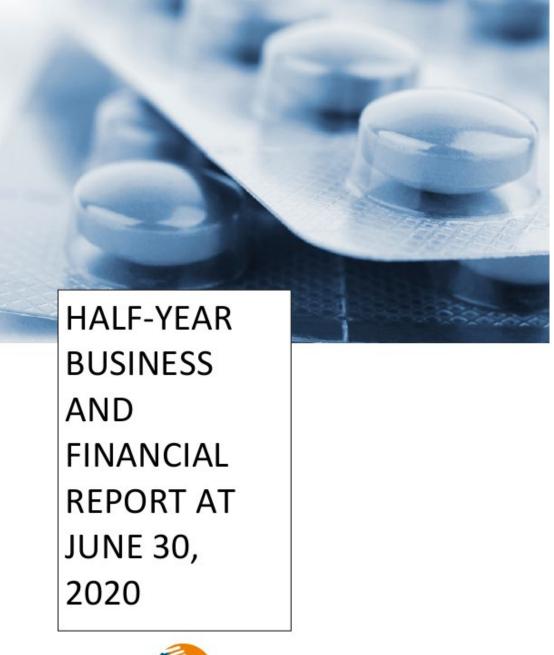
		Universal Registration Document		Amer	ndment
		Sections	Pages	Sections	Pages
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		Universal Registration Document		Amendment	
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#### 10 SCHEDULE

Schedule 1: Consolidated financial statements of the Company to 30 June 2020





HALF-YEAR FINANCIAL REPORT AS OF JUNE 30, 2019

### HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS UNDER IFRS

FOR THE HALF-YEAR ENDED JUNE 30, 2020

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#### CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

ASSETS		As of		
(in C thousands)	Notes	December 31, 2019	June 30, 2020	
Current assets				
Cash and cash equivalents	6.	276,748	225,721	
Current trade and others receivables	9.	12,033	8,938	
Other current assets	11.	1,968	3,540	
Inventories	-	5	5	
Total - Current assets		290,753	238,204	
Non-current assets				
Intangible assets	7.	920	894	
Property, plant and equipment	8.	16,453	15,507	
Other non-current financial assets	10.	1,727	1,595	
Deferred tax assets	21.	-	_	
Total - Non-current assets		19,100	17,997	
Total - Assets		309,853	256,200	
SHAREHOLDERS' EQUITY AND LIABILITIES		As o	of	
(in C thousands)	Notes	December 31, 2019	June 30, 2020	
Current liabilities				
Current convertible loans	12.	1,313	1,313	
Other current loans and borrowings	12.	3,226	3,222	
Current trade and other payables	13.	36,917	34,961	
Current deferred income and revenue	-	140	141	
Current provisions	14.	2,061	2,070	
Total - Current liabilities		43,657	41,706	
Non-current liabilities				
Non-current convertible loans	12.	164,142	166,760	
Other non-current loans and borrowings	12.	14,939	13,342	
Non-current trade and other payables	13.	451	451	
Non-current employee benefits	16.	1,408	1,503	
Deferred tax liabilities	21.	1,193	1,057	
Total - Non-current liabilities		182,132	183,112	
Shareholders' equity				
Share capital	16.	9,715	9,715	
Share premium		377,821	378,334	
Retained earnings (accumulated deficit)		(238,340)	(303,662	
Currency translation adjustment		14	7	
Net profit (loss)		(65,145)	(53,011	
Total shareholders' equity - Group share		84,065	31,382	
Non-controlling interests				
Total - Shareholders' equity		84,065	31,382	
Total - Shareholders' equity & liabilities		309,853		
*		309,653	256,200	

		For the six-month	period ended
(in C thousands, except earnings per share data)	Notes	June 30, 2019	June 30, 2020
Revenues and other income			
Revenue		1	122
Other income	17.	5,356	5,745
Revenues and other income		5,357	5,867
Operating expenses and other operating income (expenses)			
Research and development expenses	18.	(38,908)	(36,867)
General and administrative expenses	18.	(9,517)	(8,251)
Marketing and market access expenses	18.	(2,876)	(9,491)
Other operating income (expenses)	18.	7	(423)
Operating income (loss)		(45,936)	(49,163)
Financial income	20.	1,755	2,095
Financial expenses	20.	(7,240)	(6,102)
Financial profit (loss)		(5,485)	(4,007)
Net profit (loss) before tax		(51,422)	(53,170)
Income tax benefit (expense)	21.	289	159
Net profit (loss)		(51,132)	(53,011)
Attributable to owners of the Company		(51,132)	(53,011)
Attributable to non-controlling interests		_	_
Basic and diluted earnings (loss) per share			
Basic and diluted earnings (loss) per share (€/share)	22.	(1.64)	(1.36)

#### CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE LOSS

		For the six-month	h period ended
(in C thousands)	Notes	June 30, 2019	June 30, 2020
Net profit (loss)		(51,132)	(53,011)
Actuarial gains and losses net of tax	15.	(128)	_
Other comprehensive income (loss) that will never be reclassified to			
profit or loss		(128)	-
Exchange differences on translation of foreign operations		1	(7)
Other comprehensive income (loss) that are or may be reclassified to			
profit or loss		1	(7)
Total other comprehensive income (loss)		(51,260)	(53,018)
Attributable to owners of the Company		(51,260)	(53,018)
Attributable to non-controlling interests		-	-

(in C thousands)	For the six-month period ended June 30, 2019	For the year ended December 31, 2019	For the six-month period ended June 30, 2020
Cash flows from operating activities			
+ Net profit (loss)	(51,132)	(65,145)	(53,011)
+ Non-controlling interests	-	-	-
Reconciliation of net loss to net cash used in operating activities			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets	1,542	3,263	1,737
+ Impairment and provision for litigation	1,804	357	124
+ Expenses related to share-based compensation	356	1,657	513
- Gain on disposal of property, plant and equipment	(1)	(19)	(2)
+ Net finance expenses (revenue)	5,669	11,437	5,848
+ Income tax expense (benefit)	(289)	(576)	(159)
+ Other non-cash items including Research Tax Credit litigation	(11)	1,702	92
Operating cash flows before change in working capital	(42,063)	(47,324)	(44,859)
Change in:	•		
Decrease (increase) in trade receivables and other assets	(10,103)	(1,640)	1,523
(Decrease) increase in trade payables and other liabilities	5,307	1,284	(2,026)
Change in working capital	(4,797)	(356)	(504)
Income tax paid	_	_	_
Net cash flows used in operating activities	(46,859)	(47,680)	(45,362)
Cash flows from investment activities			
- Acquisition of property, plant and equipment	(65)	(2,030)	(785)
+ Proceeds from disposal of / reimbursement of property, plant and			
equipment	(0)	2,517	-
- Acquisition of financial instruments	(128)	(160)	(49)
Net cash flows provided by (used in ) investment activities	(193)	327	(834)
Cash flows from financing activities			
+ Proceeds from issue of share capital (net)	126,479	126,486	-
+ Proceeds from subscription / exercise of share warrants	-	43	-
+ Proceeds from new loans and borrowings net of issue costs	-	_	-
- Repayments of loans and borrowings	(1,513)	(1,884)	(1,601)
- Financial interests paid (including finance lease)	(3,234)	(7,785)	(3,230)
Net cash flows provided by (used in ) financing activities	121,732	116,860	(4,831)
Increase (decrease) in cash and cash equivalents	74,680	69,508	(51,027)
Cash and cash equivalents at the beginning of the period	207,240	207,240	276,748
Cash and cash equivalents at the end of the period	281,920	276,748	225,721

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Share ca	pital			Retained			Total		
	Number	Share	Share	Treasury	earnings (accumulated	Currency translation	Net profit	shareholders' equity	Non- controlling	Total shareholders'
(in € thousands)	of shares	capital	premium	shares	deficit)	adjustment	(loss)	Group share	interests	equity
As of January 1, 2019	31,183,921	7,796	251,554	(730)	(158,167)	6	(79,521)	20,939	_	20,939
Net profit (loss)	_	_	_	_	_	_	(51,132)	(51,132)	_	(51,132)
Other comprehensive income (loss)	-	-	-	-	(128)	1	_	(128)	_	(128)
Total comprehensive income (loss)	-	-	-	-	(128)	1	(51,132)	(51,260)	-	(51,260)
Allocation of prior period profit (loss)	-	-	-	-	(79,521)	-	79,521	_	-	-
Capital increase	7,647,500	1,912	124,567	-	_	_	_	126,479	_	126,479
Equity component of OCEANE net of deferred taxes	-	-	-	-	-	-	-	-	-	-
Share-based compensation	-	-	356	_	-	-	-	356	-	356
Treasury shares	-	-	-	(469)	-	-	-	(469)	-	(469)
Other movements		_					_	_	_	
As of June 30, 2019	38,831,421	9,708	376,477	(1,199)	(237,815)	7	(51,132)	96,045	_	96,045
Net profit (loss)	-	-	-	_	-	-	(14,012)	(14,012)	-	(14,012)
Other comprehensive income (loss)	-	-	-	-	(40)	8	-	(32)	-	(32)
Total comprehensive income (loss)	-	-	-	-	(40)	8	(14,012)	(14,044)	-	(14,044)
Allocation of prior period profit (loss)	-	-	-	-	-	-	-	-	-	-
Capital increase	27,196	7	-	-	(7)	-	-	(0)	-	(0)
Equity component of OCEANE net of deferred taxes	-	-	-	-	-	-	-	-	-	-
Share-based compensation	-	-	1,301	-	-	-	-	1,301	-	1,301
Treasury shares	-	-	-	721	-	-	-	721	-	721
Other movements			43					43		43
As of December 31, 2019	38,858,617	9,715	377,821	(478)	(237,862)	14	(65,145)	84,065	-	84,065
Net profit (loss)	-	-	-	-	-	-	(53,011)	(53,011)	-	(53,011)
Other comprehensive income (loss)	-	-	-	-	-	(7)	-	(7)	-	(7)
Total comprehensive income (loss)	-	-	-	-	-	(7)	(53,011)	(53,018)	-	(53,018)
Allocation of prior period profit (loss)	-	-	-	-	(65,145)	-	65,145	-	-	-
Capital increase	-	_	-	_	_	-	_	_	_	-
Share-based compensation	-	-	513	-	-	-	-	513	-	513
Treasury shares	-	-	-	(178)	-	-	-	(178)	-	(178)
Other movements										
As of June 30, 2020	38,858,617	9,715	378,334	(656)	(303,006)	7	(53,011)	31,382	_	31,382

The expenses incurred in 2019 in relation to the Initial Public Offering are deducted from the share issue premium.

## 1. THE COMPANY

Founded in 1999 under the laws of France, GENFIT S.A. (the "Company") is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments.

The Company focuses its research and development (R&D) efforts with the aim to potentially market therapeutic and diagnostic solutions to combat certain metabolic, inflammatory, autoimmune and fibrotic diseases affecting in particular the liver (such as non- alcoholic steatohepatitis - NASH) and more generally gastroenterological diseases.

The consolidated financial statements of the Company include the financial statements of GENFIT S.A. and those of its wholly-owned subsidiaries: GENFIT CORP (U.S. subsidiary) and GENFIT PHARMACEUTICALS SAS (French subsidiary),together referred to in these notes to the consolidated financial statements as "GENFIT" or the "Group".

# 2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE REPORTING PERIOD

#### 2.1. RESOLVE-IT - Major Events in the Period and Events after the Reporting Period

#### Major Events in the Period

In May 2020, the Company announced the results from the interim analysis of the RESOLVE-IT Phase 3 trial. Elafibranor did not meet the predefined primary surrogate efficacy endpoint of NASH resolution without worsening of fibrosis, nor the secondary endpoints in the ITT population of 1,070 patients.

The response rate in the 717 patients enrolled on study drug was 19.2% for patients who received elafibranor 120mg compared to 14.7% for patients in the placebo arm. On the fibrosis key secondary endpoint, 24.5% of patients who received elafibranor 120mg achieved fibrosis improvement of at least one stage compared to 22.4% in the placebo arm. The other key secondary endpoint related to metabolic parameters did not achieve statistical significance.

While the topline results do not support an application for accelerated approval of elafibranor by the FDA under Subpart H or conditional approval by the European Medicines Agency ("EMA"), the Company announced, also in May, its intention to review in detail the full dataset and conduct additional analyses in order to understand why the placebo response rate was higher than what was expected before making a decision regarding continuation of the RESOLVE-IT trial.

#### **Events after the Reporting Period**

After this review process, of which the main steps took place in July, a decision has been made to terminate early the Phase 3 RESOLVE-IT trial evaluating the efficacy and safety of elafibranor in NASH with fibrosis. The costs pertaining to the termination of this study (regulatory activities, final visits for each patient, site closures, data recording, study report production, finalization of the Trial Master File, supply contract termination clause, etc...) are estimated to reach an amount between 19 and 22 million euros, of which some costs in US dollars have been included on the basis of the September 1, 2020 exchange rate.

Following this decision, the Group is currently conducting an analysis of its impact on the scientific equipment assets that were dedicated to the RESOLVE-IT study, in order to identify those that would be usable for the study of elafibranor in PBC (ELATIVE), and those that should be divested or discarded. The net accounting value of this

## 2. MAJOR EVENTS IN THE PERIOD AND EVENTS AFTER THE REPORTING PERIOD (Continued)

equipment as of June 30, 2020 is €2,149 (including leased assets). The potential depreciation and sale proceeds will be assessed during the second half of 2020 upon completion of the analysis.

This estimated does not include costs related to the Group's reorganization projects (see note 2.3 "Other Events after the Reporting Period").

# 2.2. COVID-19 - Major Events in the Period and Events after the Reporting Period

#### **Major Events in the Period**

A new coronavirus strain, COVID-19, was identified in Wuhan, China in December 2019. Since then and particularly since the closing date, the COVID-19 coronavirus has spread to several countries, including the United States. and several European countries, including countries in which the Company has clinical trials in progress, in countries where it plans to conduct clinical trials and in countries in which major subcontractors for carrying out its clinical trials and the production units of the active ingredient suppliers and therapeutic units of elafibranor, its most advanced drug candidate, are located. As of June 30, 2020, closing date of the half-year financial statements, the main impacts of this unprecedented spread of COVID-19 on its activities are the following:

- All phase 1 trials which include pharmacokinetic, food effect and bioequivalence studies have been
  put on hold.
- Enrollment of patients in the PK/PD trial in pediatric patients with NASH as well as the Phase 2 study
  addressing liver fat have also been paused.
- The initiation of the Phase 2 combination study, as well as that of the Phase 3 study in patients with PBC, have been put on hold.
- NIS4 continues to be deployed in the clinical research field through our commercial partner Labcorp/Covance. There may be some limits in test utilization due to delays potentially experienced by some NIS4 clients of Labcorp/Covance as the result of the current COVID-19 situation, but internal teams have kept progressing the in-vitro diagnostic (IVD) aspect of the program.
- Although the COVID-19 pandemic is rapidly evolving, and our plans may change accordingly, at this
  stage we do not anticipate any supply disruption for any of our current or planned studies.
- All supporting activities pertaining to continuation of ongoing studies or the initiation of new studies will continue in order to minimize potential delays when the COVID-19 pandemic crisis subsides.

# Events after the Reporting Period / Impact of the discontinuation of the RESOLVE-IT trial and the COVID-19 pandemic

Some studies that had been put on hold since the beginning of the COVID-19 outbreak have been early terminated or a decision was taken not to initiate them, following the RESOLVE-IT trial termination. These decisions were taken independently of any impact from the COVID-19 situation or any safety concerns regarding the Company's drug candidates.

Phase 1 studies have been early terminated due to having sufficient data to address research objectives. The only exception to this is the bioequivalence part of the bioequivalence/food effect study, which has resumed.

Some Phase 2 studies have been early terminated, including the pediatric PK/PD study and the hepatic fat study.

The Phase 2 combination study will not be conducted.

R&D programs which do not support our two core programs of PBC and NIS4 have been terminated.

The recruitment of the first patient in the Phase 3 study of elafibranor in PBC is planned during the month of September 2020, after a delay from its original schedule in Q1 2020 due to the COVID-19 pandemic. We expect the recruitment period to last 18 months instead of 12 months as originally planned before the COVID-19 pandemic.

## 2.3. OTHER EVENTS AFTER THE REPORTING PERIOD

#### Reorganization

Due to the impact on the workforce of the termination of the study on elafibranor in NASH, GENFIT has initiated as of September 29, 2020, a significant reorganization project, which should result in a headcount reduction.

#### Labcorp

In September, the Company has announced the signature of a new licensing agreement with Labcorp for the development and commercial deployment of an LDT integrating NIS4 technology on the routine clinical care diagnostic tests market in the United States and Canada.

#### OCEANEs

GENFIT is considering a proposal to the holders of its OCEANEs of a nominal amount of €180 million and due on October 16, 2022 and to its shareholders, of a modification of the terms thereof. The Company aims to initiate this process by the end of the year in order to adapt the structure of its balance sheet to its new strategy.

# 3. BASIS OF PRESENTATION

The six-month 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"), at June 30, 2020. The term IFRS includes International Financial Reporting Standards ("IFRS"), International Accounting Standards (the "IAS"), as well as the Interpretations issued by the Standards Interpretation Committee (the "SIC"), and the International Financial Reporting Interpretations Committee ("IFRIC"). Comparative figures are presented for the year ended December 31, 2019 and the half year ended June 30, 2020.

In accordance with European Commission Regulation No 1606/2002, these consolidated financial statements for the six-month period ended June 30, 2020 have been prepared in accordance with IAS 34 relating to interim financial information, the IFRS standard as adopted by the European Union, and must be read in conjunction with the most recent consolidated annual financial statements for the year ended December 31, 2019. They do not include all the information required for a complete set of financial statements in accordance with IFRS but a selection of notes explaining significant events and transactions with a view to understanding the changes in the Group's financial position and performance since the last annual consolidated financial statements.

The consolidated financial statements have been prepared using the historical cost measurement basis except for certain assets and liabilities that are measured at fair value in accordance with IFRS.

These condensed consolidated financial statements for the six month period ended June 30, 2020 were prepared under the responsibility of the Board of Directors that approved such statements on September 29, 2020.

The principal accounting methods used to prepare the condensed Consolidated Financial Statements are described below.

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

#### 3.1. Changes in accounting policies and new standards or amendments

With the exception of the changes mentioned thereafter, the accounting policies applied in these interim sixmonth consolidated financial statements are the same as those applied in the Group's consolidated year-end financial statements.

The new standards listed below are effective from 1 January 2020 but they do not have a material effect on the Group's financial statements as of June 30, 2020 financial statements.

- Amendments to References to Conceptual Framework in IFRS Standards
- Definition of a Business (Amendments to IFRS 3)
- Definition of Material (Amendments to IAS 1 and IAS 8)
- Interest Rate Benchmark Reform (Amendments to IFRS 9, IAS 39 and IFRS 7)

It is also to be noted that amendments to IFRS 16 in relation with rent concessions were not applicable for the Group since no concession was obtained by Genfit regarding its rental agreements.

The application decision of the IFRIC decision regarding the rental duration has not been applied to the half-year financial statement; as the Group needs sufficient time, the impact analysis of this final decision by the IFRS IC is still ongoing. Its implementation may result in an extension of the rental period initially considered and cause a review of the rent liabilities and the use rights pertaining to the affected rental agreements.

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

The main recent changes to the Standards that are required to be applied for an annual period beginning after 1 January 2020 are listed below.

- IFRS 17 Insurance Contracts (effective date: 1 January 2021)
- Classification of Liabilities as Current or Non-current Amendment to IAS 1 (effective date: 1 January 2023)

#### 4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies used for these interim financial statements are the same as those used for the most recent consolidated annual financial statements.

## 5. FINANCIAL RISKS MANAGEMENT

The condensed, consolidated half year accounts do not include all of the information regarding the management of financial risks which are described in the Registration Statement Form 20 F for the reporting period ended on December 31, 2019.

#### 5.1. Foreign exchange risk

The nature and exposure of the Group to currency risk has evolved. It had been anticipated that a growing portion of its operations would be denominated in US dollars, and the Group decided not to convert into euros the US dollar denominated cash it raised in March 2019 IPO. The Company expected to use cash held in US dollars to meet expenses denominated in this currency over the next few years.

Because of the decision to initiate the termination of the RESOLVE-IT trial (see note 2 "Events after the Reporting Period"), the Group has started to implement a cost savings plan in the second half of 2020 and will manage a smaller number of transactions denominated in foreign currencies or indirectly exposed to currency risk.

## 5. FINANCIAL RISKS MANAGEMENT (Continued)

The increase in the overall exposure of the Company to this risk will depend, in particular, on:

- · the currencies in which the Group receives its revenues;
- the currencies chosen when agreements are entered into, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on drug or biomarker candidates;
- · the ability, for its co-contracting parties to indirectly transfer foreign exchange risk to the Company; and
- the Group's foreign exchange risk policy.
- · the fluctuation of foreign currencies against the euro.

During the first half of 2020, the Company did not use any specific hedging arrangements in light of the Company's decision to leave a significant part of its cash and cash equivalents in US dollars.

The following table presents the sensitivity of the cash and cash equivalents and expenses of the Group to a fluctuation of 10% of the US dollar against the Euro in the 2019 and 2020 semesters:

## Sensitivity of the Group's cash and cash equivalents

to a variation of +/- 10% of the US dollar against the euro	Aso	ſ
(in C thousands or in US dollar thousands, as applicable)	December 31, 2019	June 30, 2020
Cash and cash equivalents denominated in US dollars	153,438	126,725
Equivalent in euros, on the basis of the exchange rate described below	136,583	113,168
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	151,758	125,742
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	124,166	102,880

Sensitivity of the Group's expenses to a variation of +/- 10% of the US dollar against the euro	For the six-month	period ended
(in C thousands or in US dollar thousands, as applicable)	June 30, 2019	June 30, 2020
Expenses denominated in US dollars	18,079	35,531
Equivalent in euros, on the basis of the exchange rate described below	15,886	31,730
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	17,651	35,255
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	14,442	28,845

June 30, 2020 : Equivalent in euros, on the basis of a 1 euro = 1.1198 US dollar ratio December 31, 2019 : Equivalent in euros, on the basis of a 1 euro = 1.1234 US dollar ratio

Cash, cash equivalents and financial assets	As of		
(in C thousands or in US dollar thousands, as applicable)	December 31, 2019	June 30, 2020	
At origin, denominated in EUR			
Cash and cash equivalents	139,863	112,593	
Current and non current financial assets	1,614	1,522	
Total	141,477	114,115	
At origin, denominated in USD			
Cash and cash equivalents	136,884	113,128	
Current and non current financial assets	113	73	
Total	136,997	113,201	
Total, in EUR			
Cash and cash equivalents	276,748	225,721	
Current and non current financial assets	1,727	1,595	
Total	278,474	227,316	

#### 5. FINANCIAL RISKS MANAGEMENT (Continued)

# 5.2. Interest rate risk

As of June 30, 2020, the Group was only liable for governmental advances or conditional advances with no interest or interest at a fixed rate, generally below market rate, and for fixed-rate bank loans.

As of June 30, 2020 the Group's financial liabilities totaled, €184,637 (€183,619 as of December 31, 2019, net of the equity component of the convertible loan and debt issue costs). Current borrowings are at a fixed rate. The Group's exposure to interest rate risk through its financial assets is also insignificant due to low market rates and since these assets are mainly euro-denominated Undertakings for the Collective Investment of Transferable Securities (UCITs), medium-term negotiable notes or term deposits with progressive rates denominated in euros or US dollars.

## 5.3. Liquidity risk

The Group's loans and borrowings mainly consist of bonds convertible or exchangeable into new or existing shares (OCEANE), repayable for a nominal amount of €180 million and maturing on October 16, 2022, government advances related to research projects, of which the repayment in function of the commercial success of the related research project, and bank loans. (see note 12.2.1 "Refundable and conditional advances")

The Company has conducted a specific review of its liquidity risk and considers that it is able to meet its future maturities. As of June 30, 2020, the Group had  $\notin$  227,316 in cash and cash equivalents and other financial assets ( $\notin$  278,474 as of December 31, 2019). The Company does not believe it is exposed to liquidity risk within the next twelve months. 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.

# 5.4. Credit risk

Credit risk is the risk of financial loss if a customer or counterparty to a financial asset defaults on their contractual commitments. The Group is exposed to credit risk due to trade receivables and other financial assets.

The Group's policy is to manage this risk by transacting with third parties with good credit standards.

# 6. CASH AND CASH EQUIVALENTS

The main components of cash equivalents were:

- UCITS and interest-bearing current accounts, available immediately;
- · Term accounts, available within the contractual maturities or by the way of early exit; and
- · negotiable medium term notes, available with a quarterly maturity or by the way of early exit.

These investments, summarized in the tables below, are short-term, highly liquid and subject to insignificant risk of changes in value. a low risk of changes in value.

# 6. CASH AND CASH EQUIVALENTS (Continued)

Cash and cash equivalents	As e	r
(in C thousands)	December 31, 2019	June 30, 2020
Short-term deposits	263,147	208,669
Cash on hand and bank accounts	13,601	17,052
TOTAL	276,748	225,721
Short-term deposits	As o	r
(in C thousands)	December 31, 2019	June 30, 2020
UCITS	3,096	3,093
TERM ACCOUNTS	215,018	167,036
INTEREST-BEARING CURRENT ACCOUNT	45,033	38,540
TOTAL	263,147	208,669

# 7. INTANGIBLE ASSETS

Intangible assets consist mainly of office and administrative software as well as scientific software and license agreements purchased by the Group.

# 7. INTANGIBLE ASSETS (Continued)

Accumulated depreciation and impairment

TOTAL - Accumulated depreciation and impairment

Software

Other intangibles

TOTAL - Net

Patents

The following tables show the variations in intangible assets for the half-year ended June 30, 2020:

Intangible assets-Variations	As of December 31,			Translation		As of December 31.
(in C thousands)	2018	Increase	Decrease	adjustments	Reclassification	2019
Gross						
Software	2,049	340	(29)	_	378	2,739
Patents	21	70	_	-	_	91
Other intangibles	313	65	0	_	(378)	_
TOTAL-Gross	2,384	475	(29)	_	_	2,830
Accumulated depreciation and impairment						
Software	(1,567)	(350)	29	-	-	(1,888)
Patents	(21)	_	_	-	_	(21)
Other intangibles	-	-	-	-	-	-
TOTAL - Accumulated depreciation and	1					
impairment	(1,588)	(350)	29			(1,910)
TOTAL - Net	796	125	_	_		920
Intangible assets - Variations (in C thousands)	As of December 31, 2019	Increase	Decrease	Translation	s Reclassificatio	As of June 30, n 2020
Gross						
Software	2,739	94	(6	) –	- 3	8 2,864
Patents	91	-	_	-		- 91
Other intangibles	-	38	_	-	- (3	8) —
TOTAL - Gross	2,830	132	(6	)		- 2,956

(1,888)

(1,910)

920

(21)

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(158)

\_ \_

(158)

(26)

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(2,041)

(2,062)

894

(21)

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# 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment - Variations	As of December 31,			Translation		As of December 31.
(in C thousands)	2018	Increase	Decrease	adjustments	Reclassification	2019
Gross						
Buildings on non-freehold land	1,458	12,219	-	-	(1,447)	12,229
Scientific equipment	10,879	556	(120)	-	(54)	11,260
Fittings	1,531	66	-	-	(5)	1,592
Vehicles	99	_	_	_	_	99
Computer equipment	1,446	227	(15)	_	11	1,669
Furniture	361	31	(3)	-	_	389
In progress	0	242	(1,737)	_	1,496	_
TOTAL - Gross	15,774	13,339	(1,875)	-	-	27,238
Accumulated depreciation and impairment						
Buildings on non-freehold land	(1)	(1,215)	-	-	-	(1,216)
Scientific equipment	(5,988)	(1,303)	119	_	_	(7,172)
Fittings	(769)	(105)	-	_	_	(875)
Vehicles	(45)	(21)	-	-	_	(66)
Computer equipment	(915)	(252)	12	_	_	(1,155)
Furniture	(292)	(13)	3	_	_	(303)
In progress	-	-	-	-	-	-
TOTAL - Depreciation and impairment	(8,010)	(2,909)	133	_		(10,785)
TOTAL - Net	7,765	10,430	(1,741)	-	-	16,453

Property, plant and equipment - Variations	As of December 31.			Translation		As of June 30,
(in C thousands)	2019	Increase	Decrease	adjustments	Reclassification	2020
Gross						
Buildings on non-freehold land	12,229	_	_	-	-	12,232
Scientific equipment	11,260	383	(135)	-	_	11,509
Fittings	1,592	80	_	-	114	1,786
Vehicles	99	-	_	-	_	99
Computer equipment	1,669	66	(0)	_	3	1,737
Furniture	389	8	-	-	-	397
In progress	_	116	-	_	(116)	_
TOTAL - Gross	27,238	653	(135)	-	-	27,759
Accumulated depreciation and impairment						
Buildings on non-freehold land	(1,216)	(712)	_	-	-	(1,926)
Scientific equipment	(7,172)	(678)	134	-	-	(7,716)
Fittings	(875)	(58)	_	-	_	(932)
Vehicles	(66)	(10)	_	_	-	(76)
Computer equipment	(1,155)	(137)	-	-	-	(1,292)
Furniture	(303)	(8)	_	-	_	(310)
In progress	_	_	-	-	_	-
TOTAL - Depreciation and impairment	(10,785)	(1,602)	134	· _		(12,252)
TOTAL - Net	16,453	(949)	(1)	-	-	15,507

Assets related to contracts that were classified as finance leases under IAS 17 are scientific equipment. As mentioned above, these contracts were treated in the same manner under IFRS 16. Their net carrying value as of June 30, 2020 amounted to  $\notin$ 1,143 (as of December 31, 2019:  $\notin$ 1,413).

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

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

The right of use asset and depreciation as of June 30, 2020 in the table above are related to :

- The line item "Building on non freehold land", of €11,976 and €1,894 respectively;
- The line item "Scientific equipment", at €4,346 and €3,203, respectively.

Regarding equipment dedicated to the RESOLVE-IT study, please see section 6.2 "Major Events in the Period and Events after the Reporting Period".

# 9. TRADE AND OTHER RECEIVABLES

Trade and other receivables - Total	As o	d Contraction of Cont
(in C thousands)	December 31, 2019	June 30, 2020
Trade receivables, net	207	305
Research tax credit	9,585	6,684
Social security costs receivables	5	12
VAT receivables	1,814	1,583
Grants receivables	3	3
Other receivables	420	352
TOTAL	12,033	8,938

Trade and other receivables - Current	As of	As of		
(in C thousands)	December 31, 2019	June 30, 2020		
Trade receivables, net	207	305		
Research tax credit	9,585	6,684		
Social security costs receivables	5	12		
VAT receivables	1,814	1,583		
Grants receivables	3	3		
Other receivables	420	352		
TOTAL	12.033	8,938		

Trade and other receivables - Non-current	A	sof
(in C thousands)	December 31, 2019	June 30, 2020
Trade receivables, net	-	-
Research tax credit	-	-
Social security costs receivables	-	-
VAT receivables	-	-
Grants receivables	-	-
Other receivables	-	_
TOTAL		_

# Research tax credit

The research tax credit of €8.125 million due for 2019 was received in May 2020.

The research tax credit of €6,684 receivable as of June 30, 2020 includes:

- a partial payment of the assessment (€333) due to an ongoing tax audit
- the balance of the amount due for the 2014 fiscal year (€1,140)
- the balance of the amount due for the 2016 fiscal year (€447), the two amounts are used as partial
  compensation with the assessment notices and the tax notice related to the 2014 CIR, as discussed in
  section 6.23 "Litigation and contingent liabilities"

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# 9. TRADE AND OTHER RECEIVABLES (Continued)

- the amounts received following the favorable decision of the Montreuil court (€432 and €29) having been deducted
- To this amount related to the dispute with the French Tax Authorities described in section 6.23
   "Litigation and Contingent Liabilities" should be added to the amount estimated at June 30, 2020 of the
   research tax credit receivable of €5,224.

# 9. TRADE AND OTHER RECEIVABLES (Continued)

As of June 30, 2020, The research tax credit litigation wascovered by a provision of €1,892, which reflects no change in comparison to December 31, 2019 and appears as a liability in the consolidated statement of financial position.

## Other receivables

As of June 30, 2020:

The line item "other receivables" primarily consists of credit notes from suppliers for €352.

# 10. OTHER FINANCIAL ASSETS

Other financial assets consisted of the following:

Financial assets - Total	- As o	r
(in C thousands)	December 31, 2019	June 30, 2020
Loans	307	328
Deposits and guarantees	396	424
Liquidity contract	1,023	843
TOTAL	1,727	1,595
Financial assets - Current	As o	r
(in C thousands)	December 31, 2019	June 30, 2020
Loans	-	-
Deposits and guarantees	-	-
Liquidity contract	-	-
TOTAL		_
Financial assets - Non current	Aso	r
(in C thousands)	December 31, 2019	June 30, 2020
Loans	307	328
Deposits and guarantees	396	424
Liquidity contract	1,023	843
TOTAL	1,727	1,595

The liquidity contract consists of a share buyback program contracted to an investment service provider in order to facilitate the trading listing of the Group's shares.

As of June 30, 2020, the liquidity account had a cash balance of €843.

As of June 30, 2020, CMC-CIC Market Solutions holds on behalf of Genfit 47,698 shares, recorded as a deduction from equity for €240.

## 11. OTHER ASSETS

Other assets of  $\in 1,968$  and  $\in 3,540$  as of December 31, 2019 and as of June 30, 2020, respectively, consisted of prepaid expenses related to current operating expenses.

# 12. LOANS AND BORROWINGS

# 12.1. Breakdown of convertible loan

On October 16, 2017, the Company issued OCEANEs (due October 16, 2022) for an aggregate nominal amount of €180 million.

Convertible loans - general overview	
Number of bonds	6 081 081
Nominal amount of the loan	179 999 997,60 EUR
Nominal unit value of the bonds	29,60 €
Conversion / exchange premium	30 %
	To GENFIT's reference share price (22,77 €).
Annual nominal interest rate	3,5 %
	Payable semi-annually in arrears
Annual nominal interest rate	7,2 %
Offering	2017/16/10
	At par
Redemption	2022/16/10
	Redemption prior to maturity at the option of the Compan
	from 11/06/2020 if the arithmetic volume-weighted avera
	price
	of GENFIT's listed share price and the then prevailing
	conversion ratio
	(over a 20-trading period) exceeds 150% of the nominal
	value of the OCEANEs.
Convertible loans - Total	As of
(in C thousands)	December 31, 2019 June 30, 2020
Convertible loans	165,454 168,07
TOTAL	165,454 168,0
Convertible loans - Current	As of
(in C thousands)	December 31, 2019 June 30, 2020
Convertible loans	1,312 1,31
TOTAL	1,312 1,31
Convertible loans - Non current	As of
(in C thousands)	December 31, 2019 June 30, 2020
· · · · · · · · · · · · · · · · · · ·	
Convertible loans	164,142 166,70 164,142 166,70

The conversion of all of the convertible bonds would result in a dilution of 15.6% (expressed as a percentage of share capital at June 30, 2020).

# 12. LOANS AND BORROWINGS (Continued)

# 12.2. Breakdown of loans and borrowings

Other loans and borrowings consisted of the following:

Other loans and borrowings - Total	As o	ſ	
(in C thousands)	December 31, 2019	June 30, 2020	
Refundable and conditional advances	3,229	3,229	
Bank loans	2,645	2,093	
Obligations under leases	12,281	11,233	
Accrued interests	2	1	
Other financial loans and borrowings	7	7	
TOTAL	18,165	16,564	
Other loans and borrowings - Current	Aso	r	
(in C thousands)	December 31, 2019	June 30, 2020	
Refundable and conditional advances	-	_	
Bank loans	1,105	1,091	
Obligations under leases	2,112	2,122	
Accrued interests	2	1	
Other financial loans and borrowings	7	7	
TOTAL	3,226	3,222	
Other loans and borrowings - Non current	As o	r	
(in C thousands)	December 31, 2019	June 30, 2020	
Refundable and conditional advances	3,229	3,229	
Bank loans	1,540	1,002	
Obligations under leases	10,169	9,111	
Accrued interests	-	-	
Other financial loans and borrowings	-	-	

# 12.2.1. Refundable and conditional advances

TOTAL

Refundable and conditional advances - general overview (in C thousands)	Total amount allocated	Receipts	Repayments	Effets of discounting	Net book value As of June 30, 2020
BPI FRANCE - IT-DIAB	3,229	3,229		_	3,229
Development of a global strategy for the prevention and	management of	of type 2 diab	etes		
TOTAL					3,229

14,939

13,342

The following table summarizes the advance outstanding as of June 30, 2020

# BPI FRANCE IT-DIAB

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

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

defined in the framework agreement. With respect to the Group, the aid consisted of a  $\notin$ 3,229 conditional advance and a  $\notin$ 3,947 non-repayable government grant. The conditional advance is not refundable except in the event of success.

The program ended on December 31, 2014. In the event of success, defined as the commercial spin-offs of the IT-Diab program which involves products for the treatment or diagnosis of type 2 diabetes, the financial returns generated will be used initially to repay the  $\in$ 3,229 conditional advance. 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  $\notin$ 14,800.

As provided in the project assistance contract, the Company sent a letter to BPI in December 2019 in order to notify it of the Labcorp and Terns contracts while indicating that elafibranor was now aimed at treating hepatic diseases and no longer Type 2 diabetes as provided for in the aid agreement. Genfit proposed to BPI to establish a statement of abandonment of the IT DIAB project on which the above advance is based. Following this letter, the parties met in March 2020 for the presentation of the Company's arguments and in June 2020 following the results of the RESOLVE IT study. In this context, Genfit is awaiting BPI's position on new financial terms related to this situation and a draft amendment to the repayable advance agreement.

# 12.2.2. Bank loans

The Group did not take any new loan in 2020.

Bank loans	Facility	Interest	Available As of December 31,		Outstanding As of December 31,
(in C thousands)	size	rate	2019	Installments	2019
CDN 5	500	0.46%	-	48 monthly	366
CIC 5	1000	0.69%	0	60 monthly	554
CDN 4	600	0.36%	0	48 monthly	226
BNP 4	800	0.87%	0	60 monthly	537
CIC 4	265	0.69%	_	60 monthly	111
BNP 3	1050	0.80%	0	20 quarterly	525
NEUFLIZE 2	500	1.10%	0	12 quarterly	0
BNP 2	500	0.80%	0	20 quarterly	177
CDN 3	500	0.72%	_	60 monthly	135
CIC 3	500	0.85%	0	16 quarterly	0
BNP	500	2.00%	0	20 quarterly	0
Other	0	-	0		14
TOTAL	6,715				2,646

# 12. LOANS AND BORROWINGS (Continued)

Bank loans (in C thousands)	Facility	Interest	Available As of June 30, 2020	Installments	Outstanding As of June 30, 2020
CDN 5	500	0.46%	_	48 monthly	303
CIC 5	1000	0.69%	0	60 monthly	454
CDN 4	600	0.36%	0	48 monthly	151
BNP 4	800	0.87%	0	60 monthly	457
CIC 4	265	0.69%	-	60 monthly	85
BNP 3	1050	0.80%	0	20 quarterly	420
NEUFLIZE 2	500	1.10%	0	12 quarterly	0
BNP 2	500	0.80%	0	20 quarterly	127
CDN 3	500	0.72%	-	60 monthly	85
CIC 3	500	0.85%	0	16 quarterly	0
BNP	500	2.00%	0	20 quarterly	0
Other	0		0		12
TOTAL	6,715				2,094

# 12.3. Maturities of financial liabilities

Maturity of financial liabilities	As of June 30,	Less than	More than				
(in C thousands)	2020	1 year	2 years	3 years	4 years	5 years	5 years
BPI FRANCE - IT-DIAB	3,229	-	-	-	-	-	3,229
TOTAL - Refundable and conditional							
advances	3,229	-	-	-	-	-	3,229
Convertible loans	168,072	1,312	-	166,760	-	-	-
Bank loans	2,093	1,091	761	241	_	-	-
Leases	11,233	2,122	1,987	1,239	1,110	1,109	3,666
Accrued interests	1	1	_	-	_	-	-
Other financial loans and borrowings	7	7	-	-	_	-	_
TOTAL - Other loans and borrowings	181,407	4,534	2,748	168,239	1,110	1,109	3,666
TOTAL	184,636	4,534	2,748	168,239	1,110	1,109	6,896

# 12. LOANS AND BORROWINGS (Continued)

The convertible bond of a nominal amount of  $\notin$ 180 million results in the payment of yearly interest of  $\notin$ 6,300 (payable semi-annually) and a reimbursement at par due in less than 3 years (in October 2022).

Regarding the IT-DIAB advance, see section 12.2.1 - "Refundable and conditional advances".

# 13 TRADE AND OTHER PAYABLES

Trade and other payables consist of the following :

Trade and other payables - Total	As	of
(in € thousands)	December 31, 2019	June 30, 2020
Trade payables	32,753	30,082
Social security costs payables	3,598	4,376
VAT payables	2	8
Taxes payables	487	380
Other payables	527	564
TOTAL	37,368	35,411

Trade and other payables - Current	As a	of
(in C thousands)	December 31, 2019	June 30, 2020
Trade payables	32,753	30,082
Social security costs payables	3,598	4,376
VAT payables	2	8
Taxes payables	487	380
Other payables	76	114
TOTAL	36,917	34,961

Trade and other payables - Non current	As of	
(in C thousands)	December 31, 2019	June 30, 2020
Trade payables	-	-
Social security costs payables	-	-
VAT payables	-	-
Taxes payables	_	-
Other payables	451	451
TOTAL	451	451

## 14. PROVISIONS

As of June 30, 2020, this line item amounted to €2,071 (€2,061 as of December 31, 2019).

The accruals recorded are mainly related to the research tax credit. See section 6.23 "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 plans with the employer contributions recognized as expense as incurred. The Group has no actuarial liabilities in connection with these plans. Expenses recorded in the half years ended June 30, 2020 and June 30, 2019 amounted to  $\notin$ 414 and  $\notin$ 451 respectively.

# 14. EMPLOYEE BENEFITS (Continued)

French law also requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement, which are accounted for as a defined benefit plan. Benefits do not vest prior to retirement. The liability is calculated as the present value of estimated future benefits to be paid, applying the projected unit credit method whereby each period of service is seen as giving rise to an additional unit of benefit entitlement, each unit being measured separately to build up the final. At June 30, 2020, pension provisions recorded were €1,503 as compared to €1,408 at December 31, 2019.

For the half years ended June 30, 2020 and June 30, 2019, the provision for retirement indemnities is calculated on the basis of one-half of the expected expenses for the corresponding period, taking into account the updated assumption for the discount rate.

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

Population	Per	manent staff
Retirement age	65	
Terms of retirement		tiated by the ployee
Life expectancy		the basis of the SEE table
Probability of continued presence in the company at retirement age	On the basis of the DARES table	
Rate	As of	t
(in C thousands)	December 31, 2019	June 30, 2020
Salary growth rate - in 2021	5.80%	5.80%
Salary growth rate - beyond	3.00%	3.00%
Discount rate	0.75%	0.75%

The discount rates are based on the market yield at December 31, 2019 and at June 30, 2020 on high quality corporate bonds.

#### 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 C thousands)	As of June 30, 2020
Defined benefit obligation as of January 1, 2019	1,085
Current service cost	138
Interest cost on benefit obligation	17
Actuarial losses on obligation	168
Past service costs	-
Defined benefit obligation as of December 31, 2019	1,408
Current service cost	90
Interest cost on benefit obligation	5
Actuarial losses / (gains) on obligation	-
Past service costs	-
Defined benefit obligation as of January 1, June 30, 2020	1,503

The actuarial difference mainly results from the change in discount rate.

	Retirement and post-er	mployment benefits
Sensitivity of the Group's retirement and post-employment benefits	Changes in	Impact /
to a variation of the discount rate	assumptions	present value of
(in C thousands)	/ discount rate	the undertaking
	0.25%	(51)
	-0.25%	53

# 16. EQUITY

Ordinary shares are classified under shareholders' equity. Any shareholder, regardless of nationality, whose shares are fully paid-in and registered for at least two years, is entitled to double voting rights under the conditions prescribed by law (Article 32 of the Company's bylaws).

At June 30, 2020, 2,326,600 shares have been held for more than two years and entitle their holders to double voting rights (5.99% of the issued share capital).

#### Changes in share capital in 2020

None.

#### Changes in share capital in 2019

The Chairman and CEO, acting on a decision and delegation from the Board of Directors on March 13, 2019, decided on March 26, 2019, in accordance with the 17th and 18th resolutions of the Shareholders Meeting of June 15, 2018, to proceed with a capital increase by offering ordinary shares in the form of American Depositary Shares in the United States and a private placement of ordinary shares in Europe and other countries outside the United States. This transaction led to the issuance of 7,647,500 new shares representing a subscription of a gross amount of €137.6 million. Settlement delivery took place on March 29, 2019 and the share capital has been increased accordingly.

In addition, the Chief Executive Officer, acting on a decision and delegation from the Board of Directors on November 27, 2019, determined on December 16, 2019, with retroactive effect to December 15, 2019, that some of the performance and attendance conditions of the AGA D 2016-1 and AGA D 2016-2 and all of the AGA S 2016-2 free shares had been satisfied. 7,796 free shares were thus definitively vested and the same number of new shares were created. The share capital was increased accordingly.

# 16. EQUITY (Continued)

Finally, the Chief Executive Officer, acting on a decision and delegation from the Board of Directors on November 21, 2017, determined on January 2, 2020, with retroactive effect to December 31, 2019, that some of the performance and attendance conditions of the AGA D 2017-1 and all of the AGA S 2017-1 free shares has been satisfied. As a result, 19,400 free shares definitively vested and the same number of new shares were created and the share capital was increased accordingly.

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

# 17. OTHER INCOME

Other income consisted of the following:

A of June 30, 2020, the Group recognized in "Other operating income"  $\in$  509 for exchange gains on trade receivables linked to services denominated in US dollars ( $\in$  623 were recognized as financial income in the first half of 2019).

Other income	For the six-mon	For the six-month period ended		
(in € thousands)	June 30, 2019	June 30, 2020		
CIR tax credit	5,350	5,224		
Other operating income (including CICE tax credit)	4	519		
Government grants and subsidies	2	3		
TOTAL	5,356	5,745		

# 18. OPERATING EXPENSE

	Of which:						
			Contracted				Gain /
		Raw	research and		Other	Depreciation,	(loss) on
	For the	materials	development		expenses	amortization	disposal of
	six- month						
On the second all the second as been	period	and	activities		(maintenance,	and	property,
Operating expenses and other operating income (expenses)	ended	concurrables	conducted by	Employee	fees, travel,	impairment	plant and
(expenses)	June 30.	consumations		Employee	rees, travel,	impairment	plant and
(in C thousands)	2019	used	third parties	expenses	taxes)	charges	equipment
Research and development expenses	(38,908)	(1,068)	(25,909)	(6,206)	(2,564)	(3,161)	) —
General and administrative expenses	(9,517)	(109)	(1)	(4,082)	(5,244)	(82)	) —
Marketing and market access expenses	(2,876)	(5)	-	(883)	(1,963)	(26)	) —
Other operating income and (expenses)	7	_	_	_	6	-	1
TOTAL	(51,293)	(1,182)	(25,910)	(11,170)	(9,764)	(3,269)	1

# 18. OPERATING EXPENSE (Continued)

				Of which:			
			Contracted				Gain /
		Raw	research and		Other	Depreciation,	(loss) on
	For the	materials	development		expenses	amortization	disposal of
	six- month period	and	activities		(maintenance,	and	property,
Operating expenses and other operating income							
(expenses)	ended	consumables	conducted by	Employee	fees, travel,	impairment	plant and
(in C thousands)	June 30, 2020	used	third parties	expenses	taxes)	charges	equipment
Research and development expenses	(36,867)	(1,197)	(24,337)	(6,591)	(3,287)	(1,455)	_
General and administrative expenses	(8,251)	(133)	(42)	(3,845)	(3,963)	(269)	-
Marketing and market access expenses	(9,491)	(4)	(1)	(744)	(8,697)	(44)	-
Other operating income (expenses)	(423)		_	_	(425)	-	2
TOTAL	(55,031)	(1,333)	(24,379)	(11,180)	(16,372)	(1,769)	2

Research and development expenses at each reporting date take into account estimates for ongoing activities subcontracted as part of the clinical trials and not yes invoiced, on the basis of detailed information provided by subcontractors and reviewed by the Group's internal departments. The accuracy of these estimates for some types of expenses improves with the progression of the trials and the review of their determination methods.

The decrease in subcontracting cost in 2020 is due to the suspension or termination of some studies in the context of the COVID-19 pandemic. See note 2 "Major Events in the Period and Events after the Reporting Period".

The personnel expenses are similar since the growth in workforce (203 as of June 30, 2020 vs. 174 as of June 30, 2019) is compensated by the absence of incentive bonuses in 2020.

The change in "other operating expenses" is related in particular to the costs related to the facilities and their maintenance, intellectual property expenses, and more particularly the increase in expenses related to the preparation of the marketing of elafibranor in NASH.

## 18. OPERATING EXPENSE (Continued)

The change in "net depreciation expense and provision" is mainly related to the provision for the Research Tax Credit dispute recognized in 2019.18.1. Employee expenses

Employee expenses	For the six-month period ended		
(in C thousands)	June 30, 2019	June 30, 2020	
Wages and salaries	(7,998)	(7,811)	
Social security costs	(2,748)	(2,770)	
Changes in pension provision	(69)	(87)	
Share-based compensation	(356)	(513)	
TOTAL	(11,170)	(11,180)	

# Headcount at June 30

	For the six-month period ended		
Number of employees at year-end - detail	June 30, 2019	June 30, 2020	
Average number of employees	162	201	
Average age of employees	38 years 11 months	38 years 05 months	
Number of employees			
Research and development	100	107	
Services related to research and development	17	21	
Administration and management	57	68	
Marketing and commercial	-	7	
TOTAL	174	203	

# 19. SHARE-BASED COMPENSATION

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

Share-based compensation granted to employees and executive officers in 2014 through 2019 corresponds to redeemable share warrants ("Bons de Souscriptions et/ou d'Acquisition d'Actions" or "BSAAR"), stock options ("SO") and free shares ("actions gratuites" or "AGA")

Share-based compensation granted to board members and consultants in 2014, 2015, 2017 and 2019 corresponds to share warrants ("Bons de Souscriptions d'Actions" or "BSA").

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 terms and conditions of these plans are detailed in the 2019 Universal Registration Document.

No instruments were exercised during the year, 2019 and the first half of 2020.

No new plans were put in place in the first half of 2020.

The expense recognized pursuant to IFRS 2 was €513 as of June 2020 and €1,645 in 2019

#### 20. FINANCIAL INCOME AND EXPENSES

Financial income and expenses	For the six-month period ended	
(in C thousands)	June 30, 2019	June 30, 2020
Financial income		
Interest income	103	1,154
Foreign exchange gain	673	938
Other financial income	979	3
TOTAL - Financial income	1,755	2,095
Financial expenses		
Interest expenses	(5,599)	(5,777)
Interest expenses for leases	(70)	(71)
Foreign exchange losses	(1,563)	(246)
Other financial expenses	(8)	(8)
TOTAL - Financial expenses	(7,240)	(6,102)
FINANCIAL GAIN (LOSS)	(5,485)	(4,007)

Financial expenses for loans and borrowings are due to the interest on the OCEANEs, mainly due to interest payments at a rate of 3.5% and the discounting of the bond debt at an effective interest rate of 7.2%. The discounting of bond debt consists of bringing the amount of the debt component of the bond issue to the amount that will be repaid (or converted) at maturity, by the recognition of a theoretical annual interest expense resulting from the accretion over the period of an amount equivalent to the equity component at an effective interest rate.

The increase in financial income is due to the increase in interest on term accounts. GENFIT has decided to keep some of its cash in US dollars. See note 6 "Cash and cash equivalents".

## 21. INCOME TAX

#### 21.1. Losses available for offsetting against future taxable income

At June 30, 2020, the tax loss carry forwards for the Company amounted to €440,561, (€384,471 as of December 31, 2019).

Such carry forwards can be offset against future taxable profit within a limit of €1 million per year, plus 50% of the profit exceeding this limit. Remaining unused losses will continue to be carried forwards indefinitely.

#### 21.2. Deferred tax assets and liabilities

The Group's main sources of deferred tax assets and liabilities as of June 30, 2020 related to:

Tax losses carry forwards: €440,561 (compared to €384,471 as of December 31, 2019);

Temporary differences related to:

- the OCEANE: a deferred tax liability of €2,629 and an asset of €1,572, i.e., a net deferred tax liability of €1,057; and
- post-employment benefits: a deferred tax liability of €376 offset by an asset of the same amount;

The Company offsets its deferred tax assets and liabilities ( $\notin$ 1,572 and  $\notin$ 2,629, respectively), as permitted by IAS 12, resulting in a net deferred tax liability of  $\notin$ 1,057.

The income tax benefit for the period is mainly due to the decrease in the net deferred tax liability over the period.

Oher than as it relates to deferred tax assets recognized based on the available deferred tax liabilities, no other deferred tax asset has been recognized as it is not probable that taxable profit will be available to offset deductible temporary differences and tax loss carry forwards.

## 22. EARNINGS PER SHARE

The components of the earnings (loss) per share computation are as follows:

	For the six-month period ended		
Earnings per share	June 30, 2019	June 30, 2020	
Profit (loss) for the period (in € thousands)	(51,132)	(53,011)	
Weighted average number of ordinary shares for the period	31,183,921	38,858,617	
Profit (loss) per share (in €)	(1.64)	(1.36)	

Basic loss per share is equal to diluted loss per share.

# 23. LITIGATION AND CONTINGENT LIABILITIES

#### Class Action

On May 14, 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint, captioned Schwartz v. Genfit S.A. et al., was filed in state court in the Commonwealth of Massachusetts, naming us, our board of directors and certain members of our senior management as defendants. The complaint alleges that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. The complaint seeks unspecified compensatory damages. We and the defendants intend to defend the matter vigorously. The financial impact of this action cannot be evaluated at this time.

#### Dispute over research tax credit calculation

1. Context

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

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

## 2. Subject matter of the dispute

The dispute with the French tax authorities pertained mainly to collaborative research alliances with companies partners in the pharmaceutical industry. The tax authorities contended that, in these alliances, the Company is 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 these 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 demonstrate that they were not sub-contracting agreements.

On April 5, 2018, the Administrative Court of Montreuil partially accepted the Company's claims on the CIR for 2010, 2011 and 2012, in particular, on the qualification of collaborative research. On June 28, 2018, the

# 23. LITIGATION AND CONTINGENT LIABILITIES (Continued)

Administrative Court of Montreuil accepted the Company's claim on the CIR for 2014. On September 11, 2018, following the judgment, the Company was repaid €432.

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

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

#### 3. Provision

The Company has decided not to appeal the Court of Appeals decision, and therefore has recognized a provision totaling €1,892, which includes the 2014 CIR and for which it did not seek to continue before the court of appeals during a hearing in March 2020, which has ended this dispute. The Company still awaits the final calculation by the tax authorities.

# 24. RELATED PARTIES

Biotech Avenir SAS and The NASH Epidemiology InstituteTM, an endowment fund set up by the Company, are related parties within the meaning of IAS 24.9.

The registered office of Biotech Avenir SAS and that of The NASH Epidemiology InstituteTM are located at the same address as the Company. These domiciliations are provided without charge.

# 24. RELATED PARTIES (Continued)

#### **Biotech Avenir**

Biotech Avenir SAS is a holding company incorporated in 2001 by the Company's founders. Most of its share capital is currently held by individuals, i.e., the four co-founders of the Company and approximately thirteen Company employees.

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

At June 30, 2020, Biotech Avenir SAS held 4.86% of the share capital of the Company.

The Company did not carry out any transactions with Biotech Avenir in 2020, with the exception of the domiciliation without charge.

#### The NASH Epidemiology Institute TM

The NASH Education Program TM (which became The NASH Epidemiology Institute TM ) 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 between the Group and The NASH Epidemiology Institute TM totaled €2 in the first half 2020 and €32 in the first half 2019. The Group has no obligations with respect to The NASH Epidemiology Institute TM as of June 30, 2020.

#### PCAS Group

Mr. Frédéric Desdouits, administrator of the Company since June 2014 and currently a member of the Board of Directors of the Company, has been appointed CEO of the PCAS Group in March 2019. The active ingredient of elafibranor being produced by a production unit of the PCAS Group since 2014 and Mr. Desdouits having become its CEO, he has therefore become a related party per IAS 24.9 since March 2019.

In January 2020, the Company signed a Memorandum of Understanding with PCAS with the intent to manage the conditions under which the PCAS Group will implement internally and at the request of the Company a second production source of the active principle in an intent to secure its supply, and realize the necessary investment for this operation and the increase in production capacity for the active ingredient in order to prepare for a potential NDA. PCAS will bear the cost of the transfer of technology between the current production unit and this second supply source, of €255, except in case of discontinuation of the RESOLVE-IT program. Because of the decision made on July 22, 2020 to terminate it, this cost will be included in the costs of study termination, which will be recognized in the second half of 2020. See note 2 "Major Events in the Period and Events after the Reporting Period".

## 25. COMPENSATION OF CORPORATE OFFICERS

On September 2, 2019, the Board of Directors accepted the resignation of the Chairman and Chief Executive Officer of the Company and decided to separate the roles of Chairman of the Board of Directors and Chief Executive Officer of Genfit SA with effect from September 16, 2019.

At the same meeting, the Board of Directors appointed the Chief Executive Officer of the Company and confirmed the former Chairman and Chief Executive Officer in his functions as Chairman of the Board of Directors and member of certain committees of the Company's Board of Directors.

## 25. COMPENSATION OF CORPORATE OFFICERS (Continued)

Under these conditions, the following table details the compensation paid to the Chairman and Chief Executive Officer in during the during the half year 2019. A second table presents the compensation paid to the Chief Executive Officer during the half year 2020 (after the change in governance).

Compensation paid to the Chairman during the period from January 1, 2019 to June, 2019	For the six-month June 30, 2019	period ended June 30, 2020
Short-term employee benefits (gross + employer's social contributions, paid)	1,171	_
Post-employment pension & medical benefits	-	-
Share-based payment transactions	-	-
Director fees Genfit Corp (net)	15	-
TOTAL	1,186	
Compensation paid to the Chief Executive Officer	For the six-month	period ended
Compensation paid to the Chief Executive Officer during the period from January 1, 2020 to June 30, 2020	For the six-month June 30, 2019	period ended June 30, 2020
during the period from January 1, 2020 to June 30, 2020		June 30, 2020
during the period from January 1, 2020 to June 30, 2020 Short-term employee benefits (gross + employer's social contributions, paid)		June 30, 2020
during the period from January 1, 2020 to June 30, 2020 Short-term employee benefits (gross + employer's social contributions, paid) Post-employment pension & medical benefits		June 30, 2020

Within this total, only the portion of the amounts paid in 2019 to the Chairman and Chief Executive Officer pursuant to the 13th resolution of the Annual General Meeting of June 13, 2019, for the part of the Incentive Plan corresponding to that portion of work on the initial public offering of the Company on the Nasdaq Global Select Market carried out in 2018, i.e., ¾ of the amount due, i.e. a gross amount of €562,893. However, in May 2020, the Chairman of the Board of Directors decided to the balance of €187,631 gross, which had been accounted for in the 2019 fiscal year..

The Chairman of the Board of Directors, Jean-François Mouney, receives a fixed compensation. He also has use of a company vehicle and the Group's insurance and disability plan. These benefits are totaled in the table above in the "Other compensation" line. The Chairman of the Board of Directors also receives attendance fees granted for his participation in the work of some of the committees of the Board of Directors.

The Chief Executive Officer's corporate contract contains a clause whereby, in the event of termination, he would receive a non-compete indemnity equal to: twelve (12) months of fixed compensation, calculated on the basis of the gross amounts due for the past twelve months ended and increased, where applicable, by the amount of the annual variable compensation due for the previous year. This compensation is intended to compensate the prohibition made to the Chief Executive Officer, for a period of 12 months following the termination of his functions, for whatever reason, to work in any way whatsoever with certain companies carrying out a directly competitive activity of the Company.

In addition, the Chief Executive Officer, except in the event of gross negligence within the meaning of labor law, shall receive severance pay equal to: twelve (12) months of fixed compensation, calculated on the basis of the gross amounts due for the twelve past completed months and increased, where applicable, by the amount of annual variable compensation due for the previous year. This compensation will be paid one month after his effective termination of activity within the Group. The compensation will not be paid if, on his initiative, the Chief Executive Officer leaves the Company to exercise new functions or changes functions within the Group, or even if he has the possibility of asserting in the short term his retirement rights. It is also specified that any sum paid under the non-competition clause will be deducted from the sums due under the severance pay and vice

## 25. COMPENSATION OF CORPORATE OFFICERS (Continued)

versa. The total and maximum commitment represented by this indemnity (gross, employer charges and payroll tax) as of June 30, 2020 would amount to €399.

The directors' fees and other compensation due and paid to the non executive directors are as follow:

Attendance fees and other forms of remuneration	Amounts due*	Amounts paid*	Amounts due*	Amounts paid*
payable to each of the non executive officer (in euros)	June 3	For the six-month June 30, 2019		. 2020
Jean-François MOUNEY(1)		.,		
Attendance fees	-	-	15.000	15,000
Other remuneration	_	_	100.098	100,098
Total	· -	-	115,098	115,098
Xavier GUILLE DES BUTTES				
Attendance fees	19,293	17,549	44,690	33,790
Other remuneration	_	_	_	_
Total	19,293	17,549	44,690	33,790
Frédéric DESDOUITS				
Attendance fees	9,919	6,431	25,070	17,390
Other remuneration	-	-	_	_
Total	9,919	6,431	25,070	17,390
BIOTECH AVENIR	•			
Represented by Florence Séjourné				
Attendance fees	-	-	-	_
Other remuneration	-	_	_	-
Total	_	_	_	_
Philippe MOONS				
Attendance fees	13,407	12,099	27,250	16,350
Other remuneration	-	_	_	_
Total	13,407	12,099	27,250	16,350
Anne-Hélène MONSELLATO(3)	•			
Attendance fees	17,549	17,113	29,430	18,530
Other remuneration	-	_	_	_
Total	17,549	17,113	29,430	18,530
Catherine LARUE(3)				
Attendance fees	7,303	6,431	25,070	20,710
Other remuneration	-	-	-	-
Total	7,303	6,431	25,070	20,710
TOTAL	67,471	59,623	266,608	221,868

The attendance fees of Mr. Jean-François Mouney, which are presented above, refer to the period from January 1 to June 30, 2020.

In addition, the Company has provided corporate officers, directors and members of the Executive Committee a "directors and officers" insurance against claims relating to certain actions they may take in the performance of their duties. For the12-month period starting in March 2020, the insurance premium including the IPO insurance policy premium for the implementation of this insurance coverage amounted to €1,316.

#### 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 Contract Manufacturing Organizations (CMOs) for clinical and commercial supply manufacturing, commercial and pre-commercial activities, research and development activities and other services and products for operating purposes. The Group's agreements generally provide for termination with specified periods of advance notice. Such agreements are generally cancelable contracts and not included in the description of the Group's contractual obligations and commitments.

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

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

#### **Deposits and guarantees**

GENFIT has guaranteed its rental payment obligation under the lease agreement for the headquarters in Loos, France in the amount of  $\notin$ 542 at June 30, 2020 ( $\notin$ 542 as of December 31, 2019). The amount of first demand guarantee has been elevated to  $\notin$ 590 as of August 22, 2020, as after the extension of its headquarters in April 2019.

#### Obligations in respect of the co-ownership of intellectual property rights

To date, the Company has not been required to license any third-party intellectual property to develop drug candidates and biomarker candidates that comprise its portfolio of proprietary programs and products.

The Company ensures, with regard to these programs, that the collaboration or subcontracting agreements that it is required to enter into, systematically stipulate that the results of the research are the Company's property. This is particularly the case for research consortia, in which the Group is associated with university laboratories and other biotechnology companies. It therefore holds all the intellectual property rights over its portfolio of proprietary programs and products.

On the other hand, the agreements signed in the framework of the Company's historical co-research alliances with partners in the pharmaceutical industry provided that the intellectual property rights of the drug candidates developed under these alliances belonged to the partners. These agreements also provided that the Company had intellectual property rights over the innovative technologies discovered on this occasion, even if it had to grant a royalty free and non-exclusive license to the industrial partner for the purpose of developing drug candidates discovered under the co-research programs.

To date, Sanofi remains the only industrial partner likely to still have exploitation rights on a drug candidate developed as part of its historical co-research alliance with the Company and therefore able to use on a royalty-free basis, but not exclusively, technologies developed by the Company under this program. The other historic partners have informed the Company of their decision not to exploit or stop exploiting the results of joint research. Nevertheless, to date, Sanofi has not communicated to the Company its desire to continue the development of this program despite the last research phase shared with the Company's teams having ended in May 2015.

GRANT THORNTON

Membre français de Grant Thornton International

ERNST & YOUNG et Autres

This is a free translation into English of the statutory auditors' review report on the half-yearly fluancial information issued in French and is provided solely for the convenience of English-speaking users. This report includes information relating to the specific verification of information given in the Group's halfyearly management report. This report should be read in conjunction with, and construed in accordance with, French law and professional standards applicable in France.



Period from 1 January to 30 June 2020

Statutory auditors' review report on the half-yearly financial information



HALF-YEAR BUSINESS AND FINANCIAL REPORT AS OF JUNE 30, 2020

#### GRANT THORNTON

Membre français de Grant Thornton International 29, rue du pont 92200 Neuilly-sur-Seine S.A.S. au capital de € 2.297.184 623 013 843 R.C.S. Nanterre

> Commissaire aux Comptes Membre de la compagnie régionale de Versailles

#### ERNST & YOUNG et Autres

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Commissaire aux Comptes Membre de la compagnie régionale de Versailles

# GENFIT

Period from 1 January to 30 June 2020

#### Statutory auditors' review report on the half-yearly financial information

# To the Shareholders,

In compliance with the assignment entrusted to us by your Annual General Meeting and in accordance with the requirements of article L. 451-1-2 III of the French Monetary and Financial Code (*Code monétaire et financier*), we hereby report to you on:

- the review of the accompanying condensed half-yearly consolidated financial statements of Genfit, for the period from 1 January to 30 June 2020;
- · the verification of the information presented in the half-yearly management report.

These condensed half-yearly consolidated financial statements were prepared under the responsibility of the Board of Directors on 29 September 2020 on the basis of the information available at that date in the evolving context of the crisis related to COVID-19 and of the difficulties in assessing its impact and the prospects for the future. Our role is to express a conclusion on these financial statements based on our review.

## 1. Conclusion on the financial statements

We conducted our review in accordance with professional standards applicable in France. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with professional standards applicable in France and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed half-yearly consolidated financial statements are not prepared, in all material respects, in accordance with IAS 34 – standard of the IFRS as adopted by the European Union applicable to interim financial information.

Without modifying our conclusion, we draw your attention to the matter set out in note 6.2 "Major events of the period and post-balance sheet events" to the condensed half-yearly consolidated financial statements, regarding the expected impacts of the decision to stop the Resolve-It trial in July 2020 and of the COVID-19 pandemic.

#### 2. Specific verification

We have also verified the information presented in the half-yearly management report, prepared on 29 September 2020, on the condensed half-yearly consolidated financial statements subject to our review.

We have no matters to report as to its fair presentation and consistency with the condensed half-yearly consolidated financial statements.

Neuilly-sur-Seine and Lille, 30 September 2020

The Statutory Auditors

French original signed by:

GRANT THORNTON Membre francais de Grant Thornthon international ERNST & YOUNG et Autres

Jean-François Baloteaud

Sandrine Ledez

Genfit