UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 20-F
(Mark One)

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

OR

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

For the fiscal year ended December 31, 2022

OR

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

OR

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

Date of event requiring this shell company report

Commission File Number 001-38844
GENFIT S.A.
(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)
France
(Jurisdiction of incorporation or organization)
Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France
(Address of principal executive offices)
Pascal Prigent
Chief Executive Officer
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(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

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

*****_Not for trading, but only in connection with the registration of the American Depositary Shares._

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary shares: 49,834,983 shares outstanding as of December 31, 2022**

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

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

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

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INTRODUCTION

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

“GENFIT,” the GENFIT logo, “RESOLVE-IT”, “NIS4”, "NIS2+", “ELATIVE”, "NASHnext", and other trademarks or service marks of GENFIT S.A. appearing in this Annual Report on Form 20-F, or annual report, are the property of GENFIT S.A. or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this annual report are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this annual report are the property of their respective owners. We do not intend to use or display other companies’ trademarks and trade names to imply any relationship with, or endorsement or sponsorship of us by, any other companies.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our plans to develop and commercialize elafibranor, tests powered by our NIS4 technology or its improvements and our other drug candidates;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, including the timing of availability of data from our clinical trials;
- our ability to successfully expand and advance our pipeline of drug candidates, including through in-licensing agreements;
- our and our collaborators' ability to expand the research, clinical and commercial use of diagnostics incorporating our NIS4 technology or its improvements;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals;
- the clinical utility and market acceptance of our drug candidates and tests powered by our NIS4 technology or its improvements;
- the potential clinical utility of our product candidates and their potential advantages over existing therapies as well as those in development;
- our ability to establish and maintain manufacturing and supply arrangements for our product candidates;
- our ability to build our commercial organization in the event we elect to directly commercialize any approved products;
- the ability of third parties with whom we contract to successfully conduct, supervise and monitor clinical trials for our product candidates;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our ability to maintain, protect and enhance our intellectual property rights and proprietary technologies and to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- our estimates regarding future revenues, expenses and needs for additional financing, including our ability to fund our existing programs and execute our strategy based on our current financial position; and
- other risks and uncertainties, including those listed in this annual report under the caption "Risk Factors."

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

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

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

SUMMARY RISK FACTORS

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

- Our drug candidate development activities are focused primarily on the development of our drug candidate elafibranor in PBC as well as on other drug candidates for which development is less advanced. Drug development is subject to a number of risks.
- Clinical failure can occur at any stage of clinical development, as was the case with our Phase 3 RESOLVE-IT trial of elafibranor in NASH. The results of earlier clinical trials are not necessarily predictive of future results and elafibranor in PBC or any other product candidate that we or our collaborators advance through clinical trials may not have favorable results in later clinical trials, which may delay, limit or prevent our ability to receive regulatory approval or marketing authorization.
- Delays in the commencement, enrollment and completion of clinical trials, including our Phase 3 ELATIVE trial of elafibranor in PBC, could result in increased costs to us and delay or limit our ability and that of Terns Pharmaceuticals, Inc., or Terns Pharmaceuticals, or Ipsen Pharma SAS, or Ipsen, our partners for elafibranor, and that of any future collaborators, to obtain regulatory approval for elafibranor and our other drug candidates.
- We cannot be certain that elafibranor or any of our other product candidates, even if they meet clinical and regulatory requirements, will receive regulatory approval or certification, as applicable, and without regulatory approval or certification, we will not be able to market our product candidates.
- We have obtained breakthrough therapy designation from the FDA for elafibranor in the treatment of PBC and we, or our collaborators, may seek to avail ourselves of various designation mechanisms (such as orphan drug designation, Fast Track and breakthrough therapy designation) to accelerate the development or approval of our other drug candidates, including GNS561 in CCA 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, or other product candidates, will receive marketing approval for this indication.
- Our future capital resources depend in large part on the success of development of elafibranor in PBC. Because our access to alternative financing is limited, failure in PBC could impact our strategic decisions with respect to the development of our other product candidates and may affect the development or timing of our business prospects.
- We will require substantial additional funding to develop and commercialize our products, if approved, as well as to reinforce our pipeline, which may not be available to us, or to 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.
- Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.
- If we, or our current and future collaborators are unable to establish sales, marketing and distribution capabilities for elafibranor or our other product candidates, we may not be successful in commercializing those product candidates if and when they are approved.
- We have entered, and may in the future enter into, collaboration, licensing or co-marketing agreements with third parties for the development and eventual commercialization of our product candidates and NIS4 diagnostic technology or its improvements and may not generate revenues from these agreements.
- We depend on third-party contractors for a substantial portion of our operations, namely contract research organizations or CROs for our clinical trials and contract manufacturing organizations or CMOs for manufacturing of our active ingredients and therapeutic units and may not be able to control their work as effectively as if we performed these functions ourselves.
- We rely entirely on third parties for the manufacturing of our drug candidates and the future manufacturing of an in-vitro diagnostic, or IVD, powered by NIS4 or its improvements for use as a clinical diagnostic. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product or tests, or fail to do so at acceptable quality levels or prices.
- Starting in mid-2020 and into 2021, we embarked on a significant strategic reorientation which resulted in a significant changes to our organization and workforce. As a result, we may encounter difficulties in managing development of our product candidate pipeline, which could disrupt our operations.
- If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability or that of a potential future partner to commercialize our product candidates successfully may be adversely affected.
- Currently, besides NASHnext commercialized by our partner, Labcorp, we have no products approved for commercial sale, and to date we have not generated any significant recurring revenue from product sales. As a result, our ability to sustainably reduce our losses, reach lasting profitability, as a result of such types of revenue, and maintain our shareholders equity on our own is unproven, and we may never achieve or sustain profitability.
- Our ability to be profitable in the future will depend on our ability and that of our current or future collaborators to obtain marketing approval for and commercialize our product candidates, particularly our lead product candidate, elafibranor, and the NASHnext, a Laboratory Developed Test, or LDT, or an IVD powered by NIS4 or its improvements for clinical care.

- Our stock price may never reach a price at which certain bondholders will deem conversion economically viable, in which case we would need to repay the nominal amount at maturity in October 2025. The terms of our convertible bonds require us to meet certain operating covenants, and if we fail to comply with those covenants the bondholders would be able to accelerate our repayment obligations. Additionally, the conversion of some or all of our bonds into ordinary shares would dilute the ownership interests of existing shareholders
- The market price of our equity securities is particularly volatile and may decline regardless of our operating performance.
- The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of our ordinary shares and ADSs.
- The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

PART I

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

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

Item 3. Key Information.

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

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

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

In 2019, we entered into a licensing and collaboration agreement with Terns Pharmaceuticals for elafibranor in China, Hong Kong, Macau and Taiwan (Greater China), and in December 2021, the remaining worldwide rights to elafibranor in all indications were licensed to Ipsen. As part of the collaboration with Ipsen, elafibranor, our most advanced drug candidate, is currently being evaluated in a Phase 3 ELATIVE clinical trial in primary biliary cholangitis, or PBC. Pursuant to this agreement, we remain responsible for the conduct of the Phase 3 ELATIVE study until mid-2023 when it will be fully transferred to Ipsen.

Only two treatments are currently approved and marketed in this indication, UDCA, approved by the FDA to treat PBC in 1997, and Ocaliva, approved by the FDA and European Commission for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, and these treatments do not meet the medical needs of all patients. A limited number of treatments are therefore approved for the management of this disease and we have little experience with drug development in this disease area. The development and approval of drug candidates to treat PBC may therefore present an even higher level of risk than in other indications.

We expect the topline results of the Phase 3 ELATIVE clinical trial will be available towards the end of the second quarter of 2023, and it is possible that this clinical trial, and our other ongoing or future clinical trials in general, could fail to meet their primary endpoints, as was the case with our Phase 3 RESOLVE-IT trial evaluating elafibranor in non-alcoholic steatohepatitis, or NASH, in 2020, or are delayed, additional development is necessary. Despite a favorable outcome in clinical trials, the regulatory authorities may also consider that the clinical results of these trials are insufficient to grant or maintain a marketing authorization. These different risks are further described below.

Our development programs, other than elafibranor, are at a much earlier stage of development. Clinical development of these product candidates faces similar risks and challenges as our development of elafibranor in PBC.

A failure of our Phase 3 clinical trial for elafibranor in PBC, or a delay or the failure to receive related marketing authorization for the product would therefore have a negative impact, even more so since it would impact our most advanced product candidate in our portfolio of drug candidates. As a result, our ability to fund our other programs could be severely impacted which could significantly affect the future of our Group.

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

Clinical failure can occur at any stage of our clinical development or those of our current partner or a future partner. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we or our collaborators do, which may delay, limit or prevent regulatory approval or marketing authorization.

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

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

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

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

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

We are currently conducting our Phase 3 ELATIVE trial of elafibranor in PBC for which the last patient in the double-blind part of the study was enrolled in June 2022. In addition, we have launched two clinical studies in the first half of 2023, including a Phase 1/2a study for GNS561 in cholangiocarcinoma, or CCA, and a Phase 2 study in VS-01 in acute on chronic liver failure, or ACLF. Delays in the commencement, enrollment and completion of our clinical trials or those of our partners, Terns Pharmaceuticals or Ipsen or any future collaborator, could increase our product development costs or limit our ability to obtain regulatory approval of our drug candidates. In the past, we have experienced some delays in enrollment in our clinical trials, including in our RESOLVE-IT clinical trial in NASH. We have also experienced, and may continue to experience delays and challenges in enrollment in clinical trials due to the COVID-19 pandemic, for example with patients postponing site visits due to developing COVID, or having to be re-screened because they fell out of the screening window. COVID also led to administrative backlogs at sites and with regulatory authorities due to continued high volumes of trials and staffing shortages.

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

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

- inability to demonstrate sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- inability to validate test methods to support quality testing of the drug substance and drug product;
- inability to determine dosing and clinical trial design;
- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- inability to reach agreements on acceptable terms with prospective contract research organizations, or CROs, trial sites and contract manufacturing organizations or CMOs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and CMOs;
- 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, European Medicines Agency or EMA, the competent authorities of European Economic Area, or EEA, countries or other non-U.S. regulators regarding the scope or design of our clinical trials, which may occur at various times, including subsequent to the initiation of the clinical trial;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- varying interpretations of our data, and regulatory commitments and requirements by the FDA, EMA, European Commission and similar foreign regulatory authorities;
- 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, or positive opinions from Ethics Committees, to conduct a clinical trial at their respective sites;
- lack of effectiveness of product candidates during clinical trials;
- suspension or termination by a data and safety monitoring board, or DSMB, that is overseeing the clinical trial;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- severe or unexpected drug-related adverse effects experienced by patients, death of a patient during a trial or any determination that a clinical trial presents unacceptable health risks;
- a breach of the terms of any agreement with, or termination for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, or investigators leading clinical trials on our product candidates;
- inability to timely manufacture or deliver sufficient quantities of the product candidate, or other consumables required for preclinical studies or clinical trials;
- difficulty identifying, recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the rarity of the disease or condition, the rarity of the characteristics of the population being studied (for example PBC, ACLF and CCA), 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 or with products with the same mechanism of action as our product candidates;
- global health pandemics such as COVID-19, armed conflicts, war or natural disasters; and
- inability to retain enrolled patients after a clinical trial is underway.

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

As we engage in other large and complicated trials and trials in advanced disease populations, including our ongoing Phase 3 ELATIVE trial evaluating elafibranor in PBC, we may experience a number of complications that may negatively affect our plans or our development programs. The ELATIVE trial in particular is made complex by the fact that it is an orphan disease with a small number of patients and the fact that one of our competitor's product is the only one to have recently received market approval in this indication, and another Phase 3 trial in PBC is enrolling patients at the same time as ours which may compromise our ability to retain or recruit patients or complete the trial on time. Potential discussions with the FDA, the EMA, competent authorities of EEA countries or other regulatory authorities outside the United States or EEA 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 collaborators. Any difficulty retaining patients may delay or produce negative or inconclusive results from our clinical trials, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. Any delay or compromises with respect to our clinical trials may have a material adverse effect on our business or diminish our competitive position relative to other biotechnology or pharmaceutical companies.

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

We currently have no products approved for sale and we cannot guarantee that we or any of our current or future collaborators will ever have marketable products. Our business and financial situation currently depends substantially on the successful development and commercialization of elafibranor in PBC. Our ability to generate near-term revenue derived from product sales will depend on the successful development and regulatory approval of elafibranor in PBC by our collaborators, and in particular, Ipsen, in the United States, the EEA and other countries.

The development of drug candidates and NIS4 technology and issues relating to their approval, CE marking, and marketing are subject to extensive regulation by the FDA in the United States, and EMA, European Commission (EC) and competent authorities of EEA countries in the EEA and comparable foreign regulatory authorities in other countries, with regulations differing from country to country.

We or our current or future collaborators will not be permitted to market our drug candidates in the United States or the EEA until we receive approval of a New Drug Application, or NDA, from the FDA or a marketing authorization, or MA, from the European Commission (based on the positive opinion of the EMA), as applicable. The same is true for other countries, including the United Kingdom since Brexit. We have not submitted at this time any marketing applications for any of our product candidates and neither have Ipsen nor Terns Pharmaceuticals, our development partners for elafibranor, for its products. NDAs, marketing authorization applications or MAAs and MAs in other countries must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. These marketing applications must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a NDA, MA or other marketing authorization is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval.

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

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

If we, our collaborators Ipsen and Terns Pharmaceuticals or a future partner are unable to obtain approval from the FDA, the EC or other comparable foreign regulatory authorities for elafibranor and our other product candidates, or approval or certification of an IVD using NIS4 technology or its improvements, or if, subsequent to approval or certification, we, our collaborators Ipsen or Terns Pharmaceuticals or a future partner are unable to successfully commercialize elafibranor, an IVD using NIS4 technology or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

We are currently developing GNS561 in cholangiocarcinoma in a Phase 1b/2 trial with trametinib, a MEK-targeting protein kinase inhibitor and may pursue other combination programs in the future, which present additional risks in comparison with single drug programs.

We are currently developing GNS561 in cholangiocarcinoma in a Phase 1b/2 trial with trametinib, an MEK-targeting protein kinase inhibitor. We may also assess in the future, as part of some of our other current programs or future programs, the potential combinations of some of our drug candidates in combination with other treatments or other of our drug candidates. medications.

Patients enrolled in this and future trials may not be able to tolerate these drug candidates in combination with other treatments. Even if any drug candidate in development were to receive marketing approval or be marketed for use in combination with other existing treatments, we would still be exposed to the risks that the FDA, EMA or other regulatory authorities may withdraw approval of the treatment used in combination with our drug candidate or that safety, efficacy, manufacturing or supply issues arise with such existing treatments. Combination treatments are commonly used for the treatment of cancers and we would be exposed to similar risks if we developed another of our drug candidates for use in combination with other treatments for indications other than cancer. This could result in our own products, if approved, being taken off the market or being less commercially successful.

We may also evaluate our current drug candidates or any other future drug candidates in combination with other treatments that have not yet been approved for marketing by the FDA, EMA or other regulatory authorities. We or potential current or future partners would not be able to commercialize and sell these drug candidates if, in the end, these associated treatments do not obtain marketing approval.

We have obtained breakthrough therapy designation from the FDA for elafibranor in the treatment of PBC and we, or our collaborators, may seek to avail ourselves of various designation mechanisms (such as orphan drug designation, Fast Track and breakthrough therapy designation) to accelerate the development or approval of our other drug candidates, including GNS561 in CCA 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, or other product candidates, will receive marketing approval for this indication.

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

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

In addition, even if one or more drug candidate qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may also seek Fast Track designation from the FDA, apply for the EMA's similar program called PRIME, or seek orphan drug designation for our product candidates in the future, and even if granted, these designations may not lead to accelerated regulatory approval, or approval at all.

Even though we have obtained orphan drug designation for elafibranor for the treatment of PBC in both the US and EEA, we, or Ipsen, may not be able to obtain or maintain the benefits associated with orphan drug status, including market exclusivity. We have also received and may continue to seek orphan drug designation for other of our product candidates, but we may not be able to obtain it or maintain the benefits associated.

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

We received orphan drug designation in both the US and the EEA for elafibranor for the treatment of PBC in 2019, and Ipsen may request the orphan drug designation for elafibranor in another indication or for other drug candidates that we may develop in the EEA and/or the United States. GNS561 also received orphan drug designation in the United States for the treatment of CCA, and VS-01 received orphan drug designation in both the United States and EEA for treatment of ACLF and in the United States for treatment of hyperammonemic crisis. We may also seek orphan drug designation for future product candidates and indications.

However, we or our partners may not receive such designation for other drug candidates that we or our partners may develop in the EEA and/or the United States or for any other drug candidate in any other jurisdiction, or for elafibranor, VS-01 or GNS561 in any other indication. Even if we or our partners successfully receive the orphan drug designation, the orphan drug designation does not necessarily guarantee market exclusivity on a given market. Even if we or our partners successfully obtain the exclusivity pertaining to the orphan drug designation for any of our drug candidates, this exclusivity may not protect the product efficiently as exclusivity may be suspended under certain circumstances. In the United States, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EEA, the exclusivity pertaining to the orphan drug designation will not prevent the marketing approval of a similar drug for the same condition if the later drug is shown to be safer, more effective or otherwise clinically superior to the first drug, or if the owner of the market approval of the first product does not have the capacity to deliver sufficient quantities of the product. In addition, if another orphan designated product receives marketing approval and exclusivity for the same condition as the one for which we or a future partner seek to develop a drug candidate, we or our partner may not be able to receive approval of our drug candidate by the relevant regulatory authorities for a significant period of time.

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

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

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

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

The EEA and third countries have equivalent laws and obligations that could equally impact the approval of our product candidates.

Our future capital resources depend in large part on the success of development of elafibranor in PBC. Because our access to alternative financing is limited, failure in PBC could impact our strategic decisions with respect to the development of our other product candidates and may affect the development or timing of our business prospects.

Our future capital resources depend in large part on the success of development of elafibranor in PBC. Top-line results in the Phase 3 ELATIVE clinical trial are expected towards the end of the second quarter of 2023, and it is possible that the study may not meet its primary or secondary endpoints or demonstrate an acceptable safety profile. Because we have limited access to capital to fund our operations, failure of the PBC program, a delay or the refusal of marketing authorization in this indication could significantly negatively affect our resources available to allocate to research, collaboration, management and financial resources toward particular compounds, programs, product candidates or therapeutic areas. We may be restricted in the opportunities we can pursue, and we may be required to collaborate with third parties to advance a particular product candidate at terms that are less than optimal to us. Because of our limited resources, we may also have to decline to pursue opportunities that may otherwise prove to be profitable.

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

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

In addition, our product candidates are being developed as potential treatments for severe, life-threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. For example, PBC patients may suffer from other co-morbidities such as osteoporosis that may increase the likelihood of certain adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our product candidates or some other factor, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates. We cannot ensure that additional or more severe adverse side effects with respect to elafibranor, NTZ, GNS561, VS-01 or any other drug candidate will not develop in current or future clinical trials or commercial use, which could delay or preclude their regulatory approval, limit their commercial use or require them to be taken off the market.

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

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

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

The development of our NIS4 technology and its variations and improvements, including NIS2+, and tests powered by this technology requires access to clinical trials, data and clinical samples in NASH patients and therefore our development is also subject to the risks related to these trials.

In support of the development of our drug candidates, we conduct research and development programs to identify new, innovative diagnostic strategies, in particular to determine the population of patients to be treated. We initially developed NIS4 diagnostic technology and have sought to continually make improvements, with the primary objective of making it easier to identify patients with NASH who are eligible for therapeutic intervention. Our NIS2+ technology is one of the improvements on NIS4 and carries with it the same objective.

Today, NIS4 technology is out-licensed to Labcorp and Q Squared Solutions LLC or Q2 to allow them to develop and deploy a test powered by NIS4 technology in the clinical research space. Since 2020, we have also out-licensed to Labcorp, the rights to develop NIS4 technology as an LDT and in 2021, Labcorp launched NASHnext, an LDT powered by NIS4 technology to provide broad clinical availability of the test to specialty and primary care physicians across the U.S. and Canada and to identify patients with significant fibrosis or at-risk of NASH. Labcorp is leveraging its deep experience in commercializing innovative diagnostics to educate providers on NASH and the importance of non-invasive testing. We believe this agreement will enable broader test availability to support evidence generation, demonstration of clinical utility, and favorable market access of the test powered by NIS4 technology. We intend to benefit from these advantages to support the next step of the development, clearance, and commercialization of an in vitro diagnostic medical device or IVD powered by NIS4 or its variations to enable even broader availability of the clinical diagnostic outside of the central lab setting.

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

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

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

Despite the care applied to the development of NIS4 technology, we could discover, after the development phase, inherent defects in the product or technology that were undetectable or inconspicuous defects based on the existing technical and scientific knowledge during the development. A failure may occur at any time during one of these clinical developments. The results of earlier clinical trials or studies does not allow predicting future results and NIS4 technology may not obtain favorable results in ongoing or future clinical studies. Results for additional clinical trials may not validate earlier positive results from other trials, which could call into question NIS4 technology's utility and medico-economic benefit. It is possible, in particular, that an LDT or IVD powered by NIS4 or its variations, at the time of its launch on the market for clinical care, will not replace the current tests and medical examinations. In that case, the place of a test powered by NIS4 or its variations, initially or as a complement or substitute of certain examinations would have to be assessed through additional clinical studies that would allow evaluating its medico-economic benefit often required to obtain reimbursement. The results of these studies may not support the use of a test using NIS4 technology within the standard of care in a way that meets the needs of clinical practitioners or demonstrates a favorable economic outcome. With such results, a test powered by NIS4 or its variations may not obtain reimbursement, especially in European countries, which could materially affect product sales.

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

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

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

In order to reach the largest number of NASH patients possible, we intend to develop an IVD powered by NIS4 technology or its improvements to identify patients with NASH and fibrosis who may be eligible for therapeutic interventions in a field where no NASH-specific non-invasive test has been approved or CE marked nor commercialized for clinical care to date and for which clinical experience is currently limited. Our development approach relies therefore on new methodologies. It is thus possible that, in this context, our clinical trials do not meet a favorable outcome or that, despite a favorable outcome, regulatory authorities determine that the results of our clinical trials or those of our collaborators are insufficient to grant market approval or CE Certificates of Conformity for an IVD test using the NIS4 technology for clinical care.

In order to be allowed to directly market and sell an IVD powered by NIS4 or its improvements in the EEA, IVD manufacturers must demonstrate compliance of their products through a conformity assessment procedure, which, depending on the risk classification of the product, may involve a Notified Body. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure. The successful completion of the conformity assessment procedure is a prerequisite to being able to affix the CE mark to products, allowing manufacturers to market IVDs in the EEA. In the United States, the product must achieve FDA approval/clearance. Other relevant regulatory requirements must be met to market in other countries. In the United States, IVD tests are regulated as medical devices.

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

We currently do not have any IVD approved, cleared or CE marked test that has been approved for marketing through such a regulatory process and we cannot guarantee that we or potential collaborators will ever develop marketable IVD tests. We have not submitted any marketing applications for any IVD test with the FDA, nor submitted any application for certification with any Notified Body in the EEA, and, in particular, we have not submitted any marketing application for NIS4.

Concurrently with evaluating the FDA approval process for our IVD test, we are collecting data to submit an application to a Notified Body in the EEA to obtain a CE Certificate of Conformity and to affix the CE mark to the IVD in the EEA. Like the U.S. approval process, the conformity assessment process preceding the delivery of a CE Certificate of Conformity by a Notified Body permitting the affixing of the CE mark in the EEA may be lengthy and expensive, and the exact date of a CE Certificate of Conformity, if achieved at all, remains hard to predict.

Each regulatory authority may indeed refuse to issue approval or certification, impose conditions to such issuance, or require additional data prior to issuance, even when such approval or certification would have been already granted by regulatory authorities in other jurisdictions. Regulatory authorities may also modify their approval or certification policies, particularly by adding new or additional conditions to grant approval or certification. As an example, Regulation (EU) 2017/746 (IVDR) governing IVDs in the EEA entered into application on May 26, 2022. The changes to the regulatory system implemented in the EEA by the IVDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels of individual IVDs, requirements for conformity assessment by Notified Bodies of most IVDs, additional requirements concerning the scope and content of quality management systems, traceability of products and transparency as well as increased responsibility of economic operators, including those required of importers and distributors within the EEA of products manufactured in third countries. We are also required to provide clinical data in the form of a performance evaluation report as part of the conformity assessment process prior to CE marking and in post marketing clinical follow-up activities. Fulfillment of the obligations imposed by the IVDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the IVDR.

We or our potential collaborators may be subject to delays in obtaining the CE Certificate of Conformity required to affix the CE Mark to our IVD and market a test using NIS4 or its improvements for clinical care, or even not be successful in receiving certification, due to the entry into force the IVDR in the EEA. Such delay or failure may have an unfavorable impact on our ability to market a test using NIS4 technology or its improvements and our ability to generate direct or indirect revenue from this activity.

Even after regulatory approval or CE Certificates of Conformity have been granted or declarations of commercialization have been filed with regulatory authorities, IVD tests remains subject to materiovigilance and market-surveillance obligations concerning incidents and risks of incidents related to their use. Even though such incidents may occur and lead regulatory authorities to suspend, vary or even revoke the market authorization or CE Certificates of Conformity of such products. Regulatory authorities may also conclude that procedures put in place by us or our collaborators are insufficient in order to identify and handle incidents, and could suspend commercialization of the products until these procedures are considered sufficient.

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

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

The commercial success of elafibranor as a potential treatment for PBC or in other indications, an LDT or IVD powered by NIS4 or its improvements or our other drug candidates, if approved or cleared, will depend upon their acceptance among the medical community, including physicians, healthcare payors and patients. Given that there are a limited number of products approved for the treatment of PBC, we do not know the degree to which elafibranor would be accepted as a therapy, if approved. Additionally, we cannot be assured that NASHnext, or IVD powered by NIS4 or its improvements will be accepted by the medical community as a means of identifying patients with NASH or fibrosis who may be appropriate candidates for therapeutic intervention, and even if an LDT or IVD powered by NIS4 or its improvements is used, a physician may still require additional testing (e.g. liver biopsy) to confirm diagnosis. The degree of market acceptance of elafibranor, NASHnext or IVD powered by NIS4 or its improvements 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 other cholestatic diseases like ACLF or CCA, or an alternative to liver biopsy for the diagnosis of NASH and fibrosis;
- limitations in the approved clinical indications or patient populations for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- limitations or warnings, including boxed warnings, contained in our drug candidates' FDA- or EC-approved labeling, if and when approved;
- in the case of elafibranor, the ability of our partners, Ipsen and Terns Pharmaceuticals or of a potential future collaborator to access the PBC market or in other future indications;
- for an LDT powered by NIS4 or its improvements , the ability of our partner, Labcorp or of a potential future collaborator to access the clinical research or clinical diagnostic market;
- for an IVD powered by NIS4 or its improvements, our ability to develop, obtain regulatory approval and commercialize an IVD test for clinical care;
- lack of significant adverse side effects;
- sales, marketing and distribution support;

- availability of coverage and adequate reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies or diagnostic solutions at similar or lower cost, including generics and over-the-counter products;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug or diagnostic candidates are designated under physician diagnostic and treatment guidelines for the treatment of the indications for which we, our partners Ipsen and Terns Pharmaceuticals or a potential future partner have received regulatory approval;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

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

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

We have no sales, marketing or distribution experience and if we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved. To develop internal sales, distribution and marketing capabilities, we would need to invest significant amounts of financial and management resources, prior to any confirmation that our product candidates will be approved. Worldwide development and commercialization rights for elafibranor, our most advanced drug candidate, are licensed exclusively to Ipsen in PBC and in all other indications, with the exception of rights licensed to Terns Pharmaceuticals for the development and commercialization of elafibranor in NASH and PBC in mainland Greater China. Additionally, in connection with the development of NIS4 technology, we entered into license agreements with Labcorp and Q2 to allow them to develop and deploy a test powered by NIS4 technology in the clinical research space. Since 2020, Labcorp also holds rights to develop and commercialize an LDT powered by NIS4 technology to specialty and primary care physicians across the U.S. and Canada. We are therefore heavily dependent on the sales, marketing and distribution capabilities of our partners Ipsen, Terns Pharmaceuticals and Labcorp.

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

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

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

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

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

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

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals and in the EEA following an MA from the European Commission are subject to pervasive and continuing regulation by the EC, the EMA, or national regulatory authorities in EEA countries and the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug.

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

Depending on the outcome, the FDA, EC, or national regulatory authorities of the EEA countries could revoke, suspend or vary the previously granted approval.

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA, EC, or national regulatory authorities of the EEA countries to approve applications or supplements to approved applications, or suspension, variation or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other comparable foreign regulatory authorities strictly regulate marketing, labelling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other comparable national and foreign regulatory authorities enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil, criminal and administrative penalties. Industry associations may also actively supervise promotional activities and report any non-compliance to the competent authorities. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA and other comparable foreign regulatory authorities do not regulate the behavior of physicians in their choice of treatments but the FDA and other comparable foreign regulatory authorities do restrict manufacturer’s communications on the subject of off-label use of their products.

Similarly, in the EEA, IVDs are strictly regulated and our IVDs will be subject to vigilance, post-market surveillance, quality management systems and many other regulatory requirements imposed by the IVDR. The advertising and promotion of IVDs in the EEA is subject to EEA countries' national laws applying the IVDR, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of IVDs. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals, which could negatively impact our business, operating results and financial condition.

In addition, if we are able to affix the CE mark to an IVD powered by NIS4 for marketing in the EEA, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of such products in the EEA. We would also be required comply with IVD reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any IVD we would manufacture or distribute, fines, suspension, variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. All manufacturers placing IVDs on the market in the EEA are legally bound to report incidents within strict deadlines and trends involving devices they produce or sell to the regulator authority, in whose jurisdiction the incident occurred. Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or regulatory action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products.

In addition, any significant changes made to CE marked IVDs placed on the EEA market, or substantial changes to the related quality assurance system affecting the IVD, must be notified to the Notified Body having delivered the related CE Certificate of Conformity. Obtaining variation of existing CE Certificates of Conformity or a new CE Certificate or Conformity can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

If a regulatory authority of an EEA country finds a violation of the IVDR obligations for which we are considered to be responsible we may be subject to a wide variety of enforcement actions, ranging from warning letters, injunction letters, ordering recalls, fines, seizing affected products, civil penalties and criminal prosecution.

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

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

Our ability to successfully commercialize any of our product candidates or that of our current or future collaborators, if approved, also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government authorities, such as Medicare and Medicaid in the United States, private health insurers and health maintenance organizations. These third-party payors determine which medications they will cover and establish reimbursement levels. Assuming we or our current or future collaborators obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us or our collaborators to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our collaborators obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, is significantly impacting the provision of, and payment for, healthcare. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. There have been executive, judicial and Congressional challenges, as well as a number of recent health reform measures by the Biden administration, that have impacted certain aspects of the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to additional judicial or Congressional challenges in the future. It is unclear how such challenges and the health reform measures of the Biden administration will impact the ACA and our business.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, the IRA, among other things (i) directs the Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, at both the federal and state levels in the United States, as well as internationally, may result in more rigorous coverage criteria and lower reimbursement from both government funded programs as well as private payors, and in additional downward pressure on the price that we receive for any approved product candidate.

In some non-U.S. countries, the proposed pricing and reimbursement conditions for a drug must be approved by relevant authorities before it may be lawfully marketed. Reimbursement may in some cases be unavailable. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Non-U.S. countries may approve a specific price for the medicinal product, may refuse to reimburse a product at the price set by the manufacturer or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for elafibranor or any of our other product candidates that may be approved.

In addition, many EEA countries periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in EEA countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA countries, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA countries. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EEA countries.

Legislators, policymakers and healthcare insurance funds in the EEA may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of EEA countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EEA and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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

Our ability or that of a potential future collaborator to successfully commercialize an LDT or IVD powered by NIS4 or its variations will depend on the availability of an approved drug to treat NASH and also on the extent to which coverage and adequate reimbursement for this test will be available from third-party payors, such as government health administration authorities, private health insurers and other organizations. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of a newly commercialized diagnostic test. As of the date of this annual report, NASHnext has not obtained reimbursement status in the countries where it is commercialized by Labcorp. It is uncertain as to what extent third-party payors will provide coverage for NASHnext, another LDT or IVD powered by NIS4 or its variations, if commercialized for clinical care. We will also likely experience volatility in the coverage and reimbursement of NASHnext, another LDT or IVD test due to contract negotiation with third-party payors and implementation requirements.

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

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

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

- economic weakness, including inflation;
- political instability, armed conflict or war in particular economies and markets, such as in Ukraine;
- global pandemics like COVID-19;
- the burden of complying with complex and changing non-U.S. regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in non-U.S. countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or other governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some countries outside the United States, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing reimbursement landscapes globally;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by laws outside the United States in the event of a contract dispute.

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

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

Future sales of our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, armed conflict, such as in Ukraine, wars, the COVID-19 pandemic or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for elafibranor, NASHnext or another LDT or IVD powered by NIS4 or its improvements or any of our product candidates that are approved for commercialization in the future. In addition, the increase of inflation rates following the COVID-19 pandemic era and the current armed conflict in Ukraine may additionally affect the commercialization of our products and product candidates.

Risks Related to the Dependency on Third Parties

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

Under our supervision, we outsource substantial portions of our operations to third-party service providers, including preclinical studies and clinical trials, collection and analysis of data and manufacturing of our drug candidates and the realization of certain analyses performed under our agreements with Labcorp and Q2 pertaining to an LDT or IVD powered by NIS4 technology or its variations for use in the clinical research and clinical diagnostics markets. In particular, we subcontract certain elements of the design and/or conduct of our clinical trials to CROs, as well as the manufacturing of our active ingredients and therapeutic units to CMOs, especially with regard to our Phase 3 ELATIVE trial evaluating elafibranor in PBC.

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

This strategy means that we do not directly control certain key aspects of our product development, such as:

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

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

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

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

We rely entirely on third parties for the manufacturing of our drug candidates and the future manufacturing of an IVD powered by NIS4 or its variations for use as a clinical diagnostic . Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product or tests, or fail to do so at acceptable quality levels or prices.

We do not intend to manufacture the drug products, nor future test kits related to an IVD powered by NIS4 or its variations, that we or our collaborators plan to sell if approved, or successfully complete the conformity assessment procedure for use as a clinical diagnostic.

We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for the part of the ELATIVE trial under our responsibility, and have transferred responsibility to Ipsen for the remaining clinical and commercial manufacturing needs. If any of these suppliers should cease to provide services to us, or our collaborators, for any reason, we likely would experience delays in advancing our clinical trials and, if applicable, for the commercial launch while we or our collaborators identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

While we believe that our current inventory and drugs in production at various levels of the production chain are sufficient for our needs on a short-term basis, we and Ipsen rely on one supplier for the active ingredient in elafibranor and another manufacturer for the therapeutic units of elafibranor used in our clinical trials and, if applicable, for the provision of the first commercial lots. A failure at both of the storage sites of the therapeutic units used for the ongoing ELATIVE Phase 3 study evaluating elafibranor in PBC would be detrimental to our and Ipsen's clinical development plan.

For example, we have had to face the temporary closing of one of these units for a duration of 15 days due to a suspected case of COVID-19, even though this unit has indicated to us that this would not affect the provision of future clinical lots. However, in case of failure of these units, we may not be able to enter into additional long-term commercial supply agreements for elafibranor with other third-party manufacturers on terms sufficiently advantageous to us. We do not have agreements for long-term supplies of any of our other product candidates. Concerning NTZ, we use the already commercialized formulation in our clinical trials, which is available to purchase from pharmaceutical wholesalers and are therefore subject to market fluctuations in availability and price, in particular to cover the needs of the Phase 2a trial of NTZ in ACLF. Regarding the supply of GNS561, we depend on our partner Genoscience Pharma with whom we have signed a supply agreement to cover the needs of the Phase 1b/2a trial evaluating GNS561 in cholangiocarcinoma. We are also dependent on several CMOs to cover the supply needs of the trial evaluating VS-01 in the ACLF

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

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

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

In the event of a default, bankruptcy or liquidation of a subcontractor, a service provider (CRO or CMO) or a collaborator, such as Genoscience, with whom we have entered into a supply agreement or a dispute with one of these collaborators or service providers, we may not be able to enter into a new contract with a different subcontractor or service provider on commercially acceptable terms. In addition, failures of our subcontractors, collaborators or service providers in the course of their work could increase our development costs, delay obtaining regulatory approval or prevent the commercialization of our product candidates. Any of these factors could cause delays in launch or completion of our clinical trials, or of approval or disruption of commercialization of our products or product candidates, cause us to incur higher costs, prevent us or our potential future collaborators from commercializing our products and product candidates successfully or disrupt the supply of our products after commercial launch. Furthermore, if any of our partners, such as Genoscience Pharma, or contract manufacturers fail to deliver the required clinical or commercial quantities of finished product on acceptable commercial terms and we or our current or future collaborators are unable to find one or more replacement manufacturers capable of production at substantially equivalent cost, volume and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply and to have any such new source approved by the government agencies that regulate our products.

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

We have limited experience in product development and marketing and may seek to enter into collaborations with third parties for the development and potential commercialization of our product candidates including those at an early and preclinical stage, particularly those candidates outside of our main therapeutic areas of interest. We have entered into an exclusive licensing and collaboration agreement with Ipsen to develop and commercialize elafibranor for the treatment of PBC and other indications worldwide, with the exception of Greater China which is licensed to Terns Pharmaceuticals. Our NIS4 technology is licensed to two partners, both to Labcorp to allow them to deploy an LDT powered by NIS4 technology in the clinical research and clinical diagnostics spaces and also to Q2 in the clinical research space. Should we seek to collaborate with additional third parties with respect to our development programs, we may not be able to locate a suitable collaborator and may not be able to enter into an agreement on commercially reasonable terms or at all.

Any new collaboration may require additional expenditures, increase our short and long term investments, require us to issue new shares and dilute our existing shareholders or disrupt our management team or activities. With our current agreements, or even if we succeed in securing collaborators for the development and commercialization of elafibranor, our NIS4 technology, the NASHnext LDT or our other product candidates, we have limited control over the amount and timing that our collaborators may dedicate to the development or commercialization of our product candidates.

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

- the means and resources used within the framework of these agreements remain, for the most part, at the discretion of the partner;
- the partner might not fulfill its contractual obligations;
- the partner might interrupt the development or commercialization or decide to interrupt or not renew the development or commercialization programs due to a change in strategic orientation, a lack of financing or external factors such as an acquisition that would reallocate resources or induce different priorities;
- the partner might develop, independently or with the assistance of third parties, products, in the case of pharmaceuticals or in-vitro tests, in the case of diagnostic technologies that are in direct or indirect competition with our product candidates or future IVD powered by NIS4 or its variations if it believes that it is easier to successfully commercialize competing products under more attractive economic conditions than ours;
- the partner, as holder of the commercialization and distribution rights on a product candidate or technology for a set time period or a specific territory or territories, might not allocate sufficient resources to these activities;
- the partner might not protect or defend our intellectual property rights in an appropriate manner or might use exclusive information that belongs to us in a manner resulting in disputes that may compromise or discredit our exclusive information or expose us to potential disputes;
- the partner might not respect the property rights of third parties, which might expose us to litigation and potentially involve our liability;
- disputes might arise between us and the partner, which could result in delays or suspension of the commercialization of the product candidate, or legal action or costly procedures that would monopolize resources as well as divert management's attention;
- we might lose certain important rights obtained through these partnerships, notably in the case of change of control of our company;
- the collaboration might be terminated and, in such case, require additional financing to further develop or market the product candidate licensed to it;
- the partner has access to our discoveries and might use this information to develop future competing products;
- there may be conflicts between different partners that could negatively affect those partnerships and potentially others;
- the collaboration, due to its nature, might have a negative impact on our attractiveness for collaborators or potential acquirers;
- the collaboration might not result in the development and commercialization of the product candidate(s) in an optimal fashion or never fulfill its objectives;
- if the partner were to take part in a merger, the continuity of advancement and the central nature of our commercialization program might be delayed, reduced or suspended by it; and
- the partner may be unable to obtain the necessary marketing approvals.

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. For example, although we have entered into a license agreement with Labcorp to enable them to develop and commercialize an LDT powered by NIS4 or its variations for clinical research and clinical diagnostic purposes, there is no guarantee that our collaboration with Labcorp will result in widespread clinical or commercial use of NASHnext, an LDT powered by NIS4 technology for clinical care. Commercial launch of NASHnext in 2021 was slowed by COVID-19 and also impacted by the lack of approved treatment for NASH. Similarly, although we have entered into a collaboration and license agreement with Ipsen for the treatment of PBC and other indication worldwide, with the exception of Greater China which is licensed to Terns Pharmaceuticals, there is no guarantee that our partnership with Ipsen or Terns Pharmaceuticals will successfully result in a generalized clinical or commercial use of elafibranor for these indications and in those jurisdictions.

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

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

We do not currently and do not intend in the future to manufacture the drug candidates we or our collaborators intend to sell. We outsource the manufacturing of our products to third parties, who are, in turn, subject to ongoing regulation and periodic inspection by the national regulatory authorities of the EEA countries, FDA and other regulatory bodies to ensure compliance with current Good Manufacturing Practices, or cGMP. Any failure to follow and document their adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, may delay or prevent filing or approval of marketing applications for our product candidates, may lead to the shutdown of the third-party vendor or invalidation of drug product lots or processes and in some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our product candidates.

Failure to comply with applicable regulations could also result in the national regulatory authorities of the EEA countries, FDA or other applicable regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring us or our current or future collaborators to suspend or put on hold one or more of our clinical trials;
- suspending, varying or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us or our current or future collaborators or our third-party manufacturers to suspend manufacturing activities or product sales, imports or exports;
- requiring us or our current or future collaborators to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to our reputation, business, financial condition or operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure or that of our current or future collaborators to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the United States, EEA or elsewhere, our suppliers will have to pass an audit by the applicable regulatory authorities. We are dependent on our suppliers' cooperation and ability to pass such audits, and the audits and any audit remediation may be costly. Failure to pass such audits by us or any of our suppliers would affect our ability or that of our current or future collaborators to commercialize our product candidates in the United States, Europe or elsewhere.

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

Risks Related to Our Operations

Starting in mid-2020 and into 2021, we embarked on a significant strategic reorientation which resulted in significant changes to our organization and workforce. As a result, we may encounter difficulties in managing development of our product candidate pipeline, which could disrupt our operations.

In mid-2020 we terminated our development program of elafibranor in NASH and redefined our strategic priorities with respect to our product candidate pipeline. As a result, we implemented a multi-year cost reduction program and workforce reduction program that had a significant impact on our organization, infrastructure and operations. In 2021, given that our access to market financing was limited, we chose to enter into licensing and collaboration agreements to support the development and commercialization of certain of our product candidates, and elafibranor in particular, as well as the in-licensing of a product candidate developed by a third party, for which we need to develop our expertise.

In particular, this strategy of aquiring new product candidates developed by third-parties was realized in September 2022 with the acquisition of Versantis AG and its programs, and we may undertake a similar type of transaction or additional in-licensing projects in the future. In the context of these significant changes in our organization, the focus of our resources on managing the success of these partnerships and new programs could result in weaknesses in our infrastructure (including our internal control over financial reporting), give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among employees. These changes in our organization may lead to significant costs and may divert financial resources from other projects, such as the development of our other product candidates. If our management is unable to effectively manage these changes efficiently, our expenses may increase more than expected, our ability to generate or increase our revenue could be impacted and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the changes related to the significant strategic reorientation we have undertaken.

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

Our success depends to a significant degree upon the technical and management skills of our co-founders, scientific advisers, senior management team, including, in particular, Pascal Prigent, our chief executive officer, Jean-François Mouney, our chairman, Dean Hum, our chief scientific officer and Pascal Caisey, our chief operating officer. The loss of the services of Messrs. Prigent, Mouney, Hum or Caisey would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified scientific, management, marketing, technical, and sales executives and personnel, in particular in the new therapeutic areas where we need to build up our experience, despite the workforce reduction plan we implemented in 2020. We compete for key personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. In addition, there is risk of departures or difficulties in hiring qualified personnel following the announcement of disappointing clinical results, such as those we announced in May 2020 regarding our Phase 3 RESOLVE-IT trial and the aforementioned workforce reduction plan. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so could harm our operations and our growth prospects.

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

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

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

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

As part of our growth strategy, we have sought and intend to seek opportunities to in-license rights to drug candidates in clinical development. This could also include the acquisition of companies or technologies facilitating or enabling us to access to new medicines, new research projects, or new geographical areas, or enabling us to express synergies with our existing operations. If such acquisitions occur in the future, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions on favorable terms, which could require us to finance these acquisitions using our existing cash resources that could have been allocated to other purposes. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses or the expected synergies if we are unable to successfully integrate them with our existing operations and company culture.

In December 2021, we licensed the exclusive rights from Genoscience Pharma to develop and commercialize the investigational treatment GNS561 in CCA in the United States, Canada and Europe, including the United Kingdom and Switzerland. As CCA is a new therapeutic area for us, and despite our due diligence, or in the event we are unable to collaborate efficiently, we may not be successful in realizing the full potential of the GNS561 program.

We also acquired Versantis AG in September 2022 to strengthen our product candidate pipeline, including the drug candidates VS-01-ACLF, VS-01-HAC and VS-02 that we are developing respectively in ACLF, UCD and OA, and HE. As these three therapeutic areas are relatively or totally new to us, despite our due diligence and our evaluation of the potential of these programs, we may be unsuccessful in integrating the company or realizing the full potential of these programs and potential synergies. The anticipated benefits and synergies of this acquisition are based on projections and assumptions, not actual experience, and assume a successful integration.

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

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

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Any of these developments could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts or those of our current or collaborators and significantly increase our costs to recover or reproduce the lost data.

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, various other official fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application examination proceedings. We may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position or that of our current of future collaborators could suffer.

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

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

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

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

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technologies, the defendant could counterclaim that the patent covering one of our product candidates or technologies is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability of an asserted patent or patents are common. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, insufficient written description or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review or PGR and/or *inter partes* review and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. Similarly, we may initiate proceedings before the Patent Trial and Appeal Board, or PTAB, of the USPTO, such as PGR, derivation, or *inter partes* review, against patents granted to third parties. This may delay us from obtaining issued patents with similar claims in the United States and may prompt additional proceedings in the USPTO against such patent or against other third party applications or patents or may consider the need or benefit of entering into a license agreement with such third party or parties in order to exploit such patent alone or together with such other third party or parties. In the event that we do not prevail or the settlement terms with the adverse party are unfavorable, or we are unable to reach an agreement on terms sufficiently favorable to us, our ability to market our product candidates may be affected or delayed. The outcome following legal assertions of invalidity and unenforceability in the PTAB or the federal courts is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe could be less extensive than those in the United States and Europe, assuming that patent rights are obtained in the United States. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the federal and state laws in the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly in developing countries, do not favor the enforcement of patents and other intellectual property rights, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties for certain products. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

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

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

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

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

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. For example, in 2021 we filed a complaint in the U.S. District Court for the Northern District of California against CymaBay Therapeutics, Inc. ("CymaBay"). The suit alleged that CymaBay misappropriated our ELATIVE Phase 3 clinical trial Protocol synopsis for our drug candidate elafibranor in PBC (the "Protocol synopsis"). In February 2023, we reached a settlement agreement. The settlement agreement, which is confidential, reflects that CymaBay improperly received, reviewed and circulated our Protocol synopsis upon receipt, but also that CymaBay is not using any of our trade secrets in its clinical trials. CymaBay has not admitted legal liability and we and CymaBay have agreed to resolve the litigation completely.

From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations.

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

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

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

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

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

Risks Related to Legal and Other Compliance Matters

We are subject to transparency, ethics and healthcare laws and regulations that may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.

Healthcare providers and others in the healthcare and pharmaceutical sector will play a primary role in the clinical development and potential regulatory approval or certification of our product candidates and their recommendation and prescription, if approved or CE marked. Our arrangements with them and third party payors as well as our activities expose us to broadly applicable federal and state healthcare laws, which may restrict these arrangements and relations through which we research and develop our products, and if approved or CE marked, we or our current or future collaborators will market and distribute them. These laws may thus impact, among other things, our research, development, proposed sales, marketing and education programs of our product candidates that obtain marketing approval. Restrictions under applicable U.S. federal, state and non-U.S. healthcare laws and regulations include, but are not limited to, fraud and abuse laws, including the federal anti-kickback and false claims laws; healthcare data privacy and security laws, such as the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA; and transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals, including the federal Physician Payments Sunshine Act. Many states have similar laws that may differ from each other and federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payor. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law. Moreover, several states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These laws may include the French "Bertrand Law", French Ordinance n° 2017-49 of January 19, 2017 and Decree No. 2020-730 of June 15, 2020 relating to benefits offered by persons manufacturing or marketing health products or services, and the UK's Bribery Act 2010, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers or any company providing services related to their products that may be broader in scope than the federal requirements. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and their professional orders. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws, and foreign equivalents, may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

We, and our service providers, receive, process, store and use personal information and other data about our clinical trial participants, employees, partners and others. We, and our service providers, must comply with numerous foreign and domestic laws and regulations regarding privacy and the storing, sharing, use, processing, disclosure, security, and protection of personal information and other data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the EEA, the United States and elsewhere. Third parties (principally CROs during clinical trials) manage on our behalf a significant part of the personal data we may use.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information, known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to covered subcontractors and business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

In May 2018 the European Union General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect in the EEA. The GDPR imposes stringent data protection requirements for processing the information of individuals in the EEA. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expressly expanding the definition of personal data to include "pseudonymized" or key-coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators.

The GDPR also provides for more robust regulatory enforcement and greater penalties for noncompliance than previous data protection laws, including fines of up to €20 million or 4% of global annual revenue of any noncompliant company for the preceding financial year, whichever is higher. In addition to administrative fines, a wide variety of other potential enforcement powers are available to competent supervisory authorities in respect of potential and suspected violations of the GDPR, including extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by non-compliant actors. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

European Union data protection laws, including the GDPR, generally restrict the transfer of personal data from the EEA to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

The GDPR applies across the EEA in a broadly uniform manner. However, the GDPR provides that EEA countries may make their own further laws and regulations to introduce specific requirements related to the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes and genetic information. In addition, in France, the conduct of clinical trials is subject to compliance with specific provisions, which may include the filing of compliance undertakings with "reference methodologies" (such as the MR-001) adopted by the French data protection authority. This fact could expose us to multiple parallel regimes or may lead to, greater divergence on the law that applies to the processing of such data types across the EEA and/or United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use and share data and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

Additionally, other countries outside of the EEA, including Switzerland, the UK and China, have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. We strive to comply with all applicable requirements and obligations. However, new laws, policies, codes of conduct and legal obligations may arise, continue to evolve, be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and conflict with one another.

Any failure or perceived failure by us or third parties working on our behalf to adequately comply with applicable laws and regulations, any privacy and data security obligations pursuant to contract or pursuant to our stated privacy or security policies or obligations to third parties may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims, litigation, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, operations and financial performance. With substantial uncertainty over the interpretation and application of these laws, regulations and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in our efforts to do so.

We cannot assure that our CROs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive data in relation to which we are responsible will not experience data security incidents, which could have a corresponding adverse effect on our business, financial condition, results of operations and prospects, including putting us in breach of our obligations under privacy laws and regulations. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval or certification of and commercialize our product candidates and affect the prices we may obtain.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EEA. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EEA countries in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EEA level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EEA countries to use common HTA tools, methodologies, and procedures across the EEA, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EEA countries will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA countries for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EEA could be negatively affected.

In addition, the policies of the FDA, the competent authorities of the EEA countries, the EMA, the European Commission and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EEA recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EEA country, leading to a single decision for each EEA country. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EEA countries concerned, and a separate assessment by each EEA countries with respect to specific requirements related to its own territory, including ethics rules. Each EEA countries decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

Moreover, following the result of a referendum in 2016, the United Kingdom (UK) left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the European Union, the UK was subject to a transition period until December 31, 2020 (the Transition Period) during which European Union rules continued to apply. The UK and the European Union have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and European Union's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the European Union and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Northern Ireland will continue to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods. As part of the TCA, the European Union and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to

introduce significant changes to technical regulations or inspection procedures.

Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept European Union batch testing and batch release. However, the European Union continues to apply European Union laws that require batch testing and batch release to take place in the European Union territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the European Union market for commercial use. As it relates to marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EEA countries will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities will be required to place medicinal products on the market in Great Britain. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

Furthermore, in relation to IVDs, while the IVDR entered into application in the EU on 26 May 2022, the IVDR is not applicable in the UK. In the UK, IVDs are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which retains a regulatory framework similar to the framework set out by the IVDD. As a result, there will be some regulatory divergence in the UK from the EU. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE Mark for placing medical devices, including IVDs, on the market in Great Britain. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks (a CE Mark or a CE Mark and UKNI Mark will be required to place products on the Northern Ireland market). CE Marks will continue to be recognized in Great Britain for medical devices, including IVDs, until June 30, 2024, however all medical devices, including IVDs, must be registered with the MHRA, in order to be placed on the Great Britain market. The EU legal framework, including the IVDR, remains applicable in Northern Ireland (any products placed on the market in the NI must be compliant with EU law). From July 1, 2024, transitional arrangements will apply for CE and UKCA marked devices placed on the Great Britain market. The UK Medicines and Healthcare products Regulatory Agency also plans on introducing new legislation governing medical devices and IVDs with an aim to bring the new regulations into force by July 2024.

Since a significant proportion of the regulatory framework in the UK applicable to medicinal products and IVDs is derived from European Union Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval or certification and commercialization of our product candidates in the UK or the European Union, now that UK legislation has the potential to diverge from European Union legislation. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing medicinal products, IVDS or clinical trials, our development plans may be impacted or we will have to bear additional costs which could be considerable.

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

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

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

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical and diagnostic products that are intended to be tested and evaluated on humans in an initial phase, then commercialized. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient's condition, injury or even death. For example, our liability or that of our current or future collaborators could be sought after by patients participating in the clinical trials in the context of the development of the therapeutic or diagnostic products tested and unexpected side effects resulting from the administration of these products.

Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our collaborators, licensees, service providers and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products, which may harm our reputation. Patients may not follow warnings identifying potential known side effects, including some patients who should not be using our drug candidates.

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

Risks Related to our Financial Position and Capital Needs

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

We recorded a net loss of €23,719 thousand for the year ended December 31, 2022, and, other than the year ended December 31, 2021, have a history of recorded losses during prior years.

We have never generated any profits from the sale of approved products and we do not expect to become profitable from such sales in the foreseeable future. In 2020, in particular, the disappointing intermediate results of the RESOLVE-IT trial made profitability even less likely in the foreseeable future. More recently, although the collaboration and license agreement entered into with Ipsen in 2021 includes the prospect of receiving royalties in the event of, among other things, the success of the ELATIVE trial and the marketing of elafibranor in PBC, there is no assurance that this will occur on the timelines we expect or ever.

In recent years, our most significant revenue has resulted from one-time upfront payments received in 2019 under our license agreement with Terns Pharmaceuticals and in 2021 under our license agreement with Ipsen. To these are added, to a lesser extent, the reimbursements of our research tax credit or CIR, which alone have the character of significant recurring operating income, although our ability to continue to benefit from the CIR depends on our ability to continue to meet the criteria and decisions of French policy makers with respect to the scope or rate of the CIR benefit.

Revenues from our agreements with Labcorp/Covance and Q2 for the use of our NIS4 diagnostic technology and its improvements have so far been insignificant. Their eventual growth will depend on many external factors, including the market availability of a treatment for NASH, which remains uncertain.

Historically, we have also received funding from co-research alliances with other pharmaceutical companies, although we do not currently have any such alliances in place.

At the same time, we plan to continue to incur significant expenses for the development of some of our existing product candidates and new product candidates for which we acquire licensing rights, or preparation of the marketing of such products. We have devoted almost all of our resources to our research and development projects related to our drug candidates, to our NIS4 program, and at to a lesser extent to providing general and administrative support for our operations, protecting our intellectual property and engaging in activities to prepare for the potential commercialization of our drug candidates and an IVD powered by NIS4 or its variations. In addition, during the regulatory development process for some of our drug candidates and for IVD tests using our NIS4 technology or its variations, our operating costs may increase, particularly if the FDA, EMA or European Commission requires studies or clinical trials additional to those already planned, or, if a delay occurs in the realization of our clinical trials or in the development of one of our products.

As a result, we expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals with our current or future partners, as the case may be, for elafibranor in PBC and an IVD powered by NIS4 or its variations.

One of the potential consequences of such losses, and which we experienced at December 31, 2020, is the inability to maintain the amount of our equity at a level at least half of our share capital. As a result, and in accordance with Article L.225-248 of the French Commercial Code, we were required to submit to our June 30, 2021 general meeting a resolution to decide to continue our activities. This resolution was approved by our shareholders in June 2021, and we were able to reconstitute positive shareholders' equity at least equal to half of the share capital at June 30, 2021 and further reinforce our share capital at December 31, 2021 due to the agreement signed with Ipsen and their equity investment in December 2021, and therefore a third party is no longer able to sue to dissolve the company on these grounds. However, we could still face this situation again in the future depending on the development of our product candidates, in particular if the Phase 3 ELATIVE trial is unsuccessful, and we are unable to realize expected revenues from the potential success of elafibranor in PBC.

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

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

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

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

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

NASH is currently an under-diagnosed disease, and we believe that an LDT or IVD powered by NIS4 or its improvements will facilitate the identification of patients with NASH and fibrosis who may be eligible for therapeutic intervention. However, NASH is also a disease with no approved drug therapy. As such, there is significant uncertainty in the degree of market acceptance that future treatments or diagnostic tools will have among NASH patients and their healthcare providers as well as third-party payors. If an IVD powered by NIS4 or its improvements does not obtain marketing authorization or is unable to be commercialized, we, or our collaborators, may not be able to generate sufficient test volume to generate significant revenues. Even if an IVD powered by NIS4 or its improvements were approved, revenues from that IVD alone would not be sufficient alone for us to be profitable.

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

We will require substantial additional funding to develop and commercialize our products, if approved, as well as to reinforce our pipeline, which may not be available to us, or to 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 in PBC and our other drug candidates through clinical or preclinical development. Additionally, we are also considdering formal validation studies of an IVD powered by NIS4 technology in preparation for submitting the test for marketing authorization for clinical care. Developing pharmaceutical and diagnostic products, including conducting preclinical studies and clinical trials, along with obtaining necessary validation, is expensive.

Subject to obtaining regulatory approval of any of our drug candidates or an IVD powered by NIS4 or its improvements, we or our current or future collaborators expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate incurring significant expenses in connection with our planned commercialization of an IVD powered by NIS4 or its improvements, along with an increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States, France and other countries. We also expect to incur additional costs associated with operating as a public company in the United States and further plan on expanding our operations in the United States, Europe and in other territories. We could continue to require substantial additional capital in connection with our continuing operations, in particular to expand our pipeline, and to continue our clinical development and pre-commercialization activities.

In addition, access, in particular under acceptable conditions, to necessary financing is subject to contextual factors affecting the financial markets, investors and potential lenders. In addition, our convertible bond contract initially issued on October 16, 2017 contains customary restrictive covenants, some of which limit, but generally do not exclude, the creation of new guarantees on our assets and the incurring of additional indebtedness.

Because successful development of our drug candidates and diagnostic program is uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products under development.

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

On January 29, 2021, we amended the terms and conditions of our convertible bonds initially issued in October 2017, mainly to extend the maturity by an additional three years, from October 16, 2022 to October 16, 2025, and increase the conversion ratio from one (1) share per bond to 5.5 shares for one bond, i.e., an implicit conversion price of €5.38 per share instead of €29.60. In addition, we carried out a partial repurchase of 2,895,260 convertible bonds, representing 48% of the outstanding bonds, resulting in €94.3 million nominal amount of bonds remaining outstanding on January 29, 2021 (compared to €180 million nominal amount initially). Following the closing of the transaction, we received conversion requests covering 1,262,159 convertible bonds. As of the date of this annual report, 1,923,662 convertible bonds are outstanding, representing a nominal amount of €56,940 thousand (versus €180,000 thousand initially). We cannot guarantee that additional conversion will take place, or that only part of the remaining bonds will be converted, before the maturity of this loan. As of the date of this Annual Report, our stock price remains below €5.38, which is the theoretical conversion price of the OCEANEs. It is possible that if our stock price does not reach a price at which the bondholders will deem conversion economically viable, we will be required to repay the nominal amount at maturity in October 2025.

In addition, in 2021 we contracted three bank loans, for a total nominal amount of €15,250 thousand, including two loans guaranteed up to 90% by the French State (PGE) subscribed respectively in June and July 2021 (initial maturities of one year with options to stagger repayments up to six years), supplemented by a subsidized loan taken out in November 2021 (repayable in six years).

Our ability to repay these loans at maturity, and in particular our convertible bond due October 2025, depends in part on our future performance, which is subject to the success of our research and development programs, the ability of our partners and future partners to successfully commercialize our products, and future operations, as well as on economic, financial and competitive factors that are beyond our control. In addition, we may be required to incur additional debt in the future to meet our additional financing needs. Even if we are permitted by the terms and conditions of the convertible bonds, or our other bank loans, to incur additional debt or to take other measures with regard to incurring new debt, the terms of these loan could reduce our ability to repay new debts at maturity.

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

Finally, the conversion of some or all of our currently outstanding convertible bonds into ordinary shares would dilute the ownership interests of existing shareholders, including holders of our ADSs. Any sales in the public market of the ordinary shares issuable upon such conversion or any anticipated conversion of our convertible bonds into ordinary shares could adversely affect prevailing market prices of our ordinary shares or ADS and limit our ability to raise funds through capital raises. In addition, since 2016, we have set up several stock option plans, free allocation of free shares and stock warrants, many of which are still outstanding. We may in the future allocate or issue new equity-linked instruments, including convertible bonds or equity-linked compensation, the vesting and/or exercise of which could further dilute the ownership interests of shareholders, including holders of ADSs.

We have carried out a specific review of our liquidity risk and consider that we will be able to meet our maturities for the next 12 months. As of December 31, 2022, we had €136.0 million, in cash and cash equivalents. In addition, as of December 31, 2022, we had €4.6 million in other current financial assets which consisted of a single short-term instrument whose term was 180 days. In view of these amounts as of December 31, 2022, and in light of the renegotiation of the convertible bonds in January 2021, including the extension of their maturity, we do not consider that we are exposed to a short-term liquidity risk. In particular, we believe that the amount of cash, cash equivalents and other current financial assets is sufficient to ensure our financing, in view of its projects and current obligations, over the next twelve months.

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

As a French biopharmaceutical company, we have benefited from certain tax advantages, including, for example, the French Research Tax Credit, or CIR (Crédit d'Impôt Recherche), which is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess, if any, may be refunded. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and was €6.0 million for the year ended December 31, 2022. We believe, due to the nature of our business operations, that we will continue to be eligible to receive the CIR tax credit. However, if the French Parliament decides to eliminate, or to reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

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

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

The trading price for our ADSs and ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ADSs or ordinary shares at or above the price originally paid for the security. The market price for our ADSs and ordinary shares may be influenced by many factors, including:

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

- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our ordinary shares and ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares or ADSs and may otherwise negatively affect the liquidity of the trading market for our ordinary shares and ADSs.

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

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

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

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. We may have actions brought against us by shareholders relating to past transactions, changes in our stock price or other matters. For example, in May 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint was filed in state court in the Commonwealth of Massachusetts, naming us, our board of directors and certain members of our senior management as defendants, alleging that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. In October 2020, the plaintiff voluntarily dismissed the Commonwealth of Massachusetts action, but in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering. In August 2021, the Supreme Court of the State of New York, New York County, dismissed the complaint with prejudice. The plaintiff appealed, and in December 2022, the Supreme Court, Appellate Division, First Department affirmed the dismissal of the complaint, except that it deleted the phrase “with prejudice” from the Supreme Court’s judgment. The time to appeal the decision of the Appellate Division has expired. Future litigation could give rise to substantial damages, and thereby have a material adverse effect on our financial position, liquidity, or results of operations. Even if such actions are not resolved against us, the uncertainty and expense associated with shareholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

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

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of our ordinary shares and ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for our ordinary shares and ADSs could decrease, which could cause the price of our ordinary shares and ADSs or their trading volume to decline.

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our ordinary shares and ADSs. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ordinary shares or ADSs for the foreseeable future and the success of an investment in ordinary shares or ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ordinary shares or ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ordinary shares or ADSs will appreciate in value or even maintain the price at which our shareholders have purchased them. Investors seeking cash dividends should not purchase our ADSs or ordinary shares.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with accounting standards applicable in France. In addition, payment of dividends may subject us to additional taxes under French law. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

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

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

As of April 13, 2023, we had 49,834,983 ordinary shares issued and outstanding. Sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our ordinary shares and ADSs are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly.

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

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

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

The vast majority of the members of our board of directors and senior management and certain experts named in this annual report are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Courts outside the United States may refuse to hear a U.S. securities law claim because non-U.S. courts may not be the most appropriate forums in which to bring such a claim. Even if a court outside the United States agrees to hear a claim, it may determine that the law of the jurisdiction in which the non-U.S. court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the non-U.S. court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders.

The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters.

Our bylaws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our bylaws and French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the European Economic Area, or EEA, Agreement, including from the main French stock exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- under French law, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.;

- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting by a two-thirds majority vote of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can be convened by our chairman, including upon request from our chief executive officer, if any, or, when no board meeting has been held for more than two consecutive months, from directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;
- our shares are registered or bearer, if the legislation so permits, according to the shareholder's choice;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our bylaws can be changed in accordance with applicable French laws and regulations;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the documents referenced in the section of this annual report titled "Item 10. Additional Information—Memorandum and Articles of Association;"
- transfers of shares shall comply with applicable insider trading rules and regulations and, in particular, with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of our Bylaws relating to the number of directors and election and removal of a director from office, may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

A holder of ADSs may instruct the depositary of the ADSs to vote the ordinary shares underlying his or her ADSs. Otherwise, such holder will not be able to exercise voting rights unless he or she withdraws the ordinary shares underlying the ADSs that he or she holds. However, a holder of ADSs may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for a holder of ADSs' instructions, the depositary, upon timely notice from us, will notify him or her of the upcoming vote and arrange to deliver our voting materials to him or her. We cannot guarantee to any holder of ADSs that he or she will receive the voting materials in time to ensure that he or she can instruct the depositary to vote his or her ordinary shares or to withdraw his or her ordinary shares so that he or she can vote them. If the depositary does not receive timely voting instructions from a holder of ADSs, it may give a proxy to a person designated by us to vote the ordinary shares underlying his or her ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that a holder of ADSs may not be able to exercise his or her right to vote, and there may be nothing he or she can do if the ordinary shares underlying his or her ADSs are not voted as he or she requested.

Holders of ADSs are not holders of our ordinary shares.

A holder of ADSs is not treated as one of our shareholders and does not have direct shareholder rights. French law governs our shareholder rights. The depositary is the holder of the ordinary shares underlying ADSs. The deposit agreement among us, the depositary and all persons directly and indirectly holding ADSs sets out ADS holder rights, as well as the rights and obligations of the depositary.

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

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

Under French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis unless they waive those rights at an extraordinary meeting of our shareholders by a two-thirds majority vote or individually by each shareholder. However, ADS holders will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to purchasers of ADSs unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

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

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

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

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

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

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

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

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

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

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

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

We are also exempt from provisions set forth in Nasdaq rules which require an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

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

We are an "emerging growth company" under the JOBS Act and are able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our ADSs less attractive to investors.

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. We have not taken advantage of, and do not intend to take advantage of, the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (2) December 31, 2024; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2023. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (1) the majority of our executive officers or directors are U.S. citizens or residents; (2) more than 50% of our assets are located in the United States; or (3) our business is administered principally in the United States.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described herein and exemptions from procedural requirements related to the solicitation of proxies.

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

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

Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, in the United States, the recently enacted Inflation Reduction Act imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ended December 31, 2022, we believe that we were classified as a passive foreign investment company, or PFIC, for the taxable year ended December 31, 2022. Whether we are a PFIC for any taxable year will depend on our assets and income (including whether we receive certain non-refundable grants or subsidies, and whether such amounts along with reimbursements of certain refundable research tax credits and certain intercompany service payments will constitute gross income for purposes of the PFIC income test) in each year, and because this is a factual determination made annually after the end of each taxable year there can be no assurance that we will not be considered a PFIC in any taxable year. In addition, we hold a substantial amount of cash and cash equivalents. Because the calculation of the value of our assets may be based in part on the value of our ordinary shares or ADSs, the value of which may fluctuate considerably, our PFIC status may change from year to year and it is difficult to predict whether we will be a PFIC for the current year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current taxable year. However, we could continue to be considered a PFIC for the current taxable year or a future taxable year if the current percentage of our passive assets compared to our total assets remains the same or increases. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

Under the Internal Revenue Code of 1986, as amended, or the Code, a non-U.S. company will be considered a PFIC for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. holder (as defined below under "Item 10. Additional Information—Taxation") holds our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above for a particular year, unless the U.S. holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds our ordinary shares or ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. For further discussion of the PFIC rules, the adverse U.S. federal income tax consequences in the event we are classified as a PFIC and the availability of elections that may mitigate such adverse consequences, see the section of this annual report titled "Item 10. Additional Information—Taxation."

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

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Because our group currently includes one U.S. subsidiary, our non-U.S. subsidiaries (and any other non-U.S. subsidiaries we form or acquire in the future) could be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required annually to report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Code. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence and depress the market price of our securities.

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

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. To comply with this obligation, we must maintain an extensive framework of internal control over financial reporting, that we need to regularly update and test. This process is time-consuming, costly, and complicated. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company," which may be through December 31, 2024. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are now applicable to us as a public company listed in the United States.

Management identified no material weakness as of December 31, 2022. See "Item 15—Disclosure Controls and Procedures" of this Annual Report for further discussion of management's assessment of the effectiveness of our internal control over financial reporting.

Assessing our procedures to improve our internal control over financial reporting is an ongoing process. We have identified material weaknesses in our internal control over financial reporting in the past, which were remediated and can provide no assurance that we will not have material weaknesses in the future. Any material weaknesses we identify could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If material weaknesses occur which we are unable to remediate and we conclude that our internal control over financial reporting is ineffective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of the ADSs could decline, and we could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

In December 2019, a new strain of coronavirus, COVID-19, surfaced in Wuhan, China. COVID-19 then spread across the world, including to countries where our facilities are located, countries where our product candidates are being evaluated in ongoing or future clinical trials, and countries where our CROs and CMOs are located.

At the outset of the pandemic, public authorities in most countries where COVID-19 spread to implemented strict containment measures which had a significant impact on our activities.

While as of the date of this annual report, most of the containment measures have been lifted, no assurance can be given that new, similar measures will not be adopted by governments in the light of new peaks in disease activity, in particular epidemics in certain regions of the world, including in the countries or regions where we are active.

The resurgence of the COVID-19 pandemic, including at levels observed in 2020 and 2021 could once again have a negative impact on our activities, that of our current partners and potential future partners, in particular on the conduct of clinical trials in which our product candidates are evaluated, the supply of the active ingredient and the therapeutic units used therein, potential marketing authorizations, and pre-marketing and marketing activities.

As a result, as of the date of this annual report, it is not possible to predict with certainty the economic impact and the extent of the possible recovery from the COVID-19 pandemic. However, a long-lasting pandemic recovery accompanied by the implementation of new restrictive measures in order to limit its spread and, if necessary, contain it could lead to an economic slowdown in one or several markets in which the Group operates, or have disruptions that could have a very significant impact on our activities, our clinical trials, and in particular:

- delays or difficulties manufacturing active ingredients and therapeutic units to be sent to our clinical investigation sites;
- delays or difficulties in enrolling patients in clinical trials in which our product candidates are being evaluated;
- delays or difficulties in recruiting new clinical investigation sites and in starting their activities, in particular for new trials recently launched or future trials, including difficulties in recruiting physician investigators and personnel assigned to trials of the clinical investigation site. In particular, the delays in the launch and in enrollment of patients for the Phase 3 ELATIVE trial evaluating elafibranor in PBC led us to have to revise our forecasts with regard to obtaining clinical results;
- reallocations of resources normally dedicated to the conduct of clinical trials, including the resources of hospitals hosting clinical investigation sites and hospital staff involved in the conduct of our clinical trials or those of our current partners or potential future partners;
- disruptions to key clinical trial-related activities, such as monitoring clinical investigation sites, due to travel restrictions imposed or recommended by governments, employers and other authorities;
- limitations in the human resources that would usually be concentrated on the conduct of our clinical trials, those of our current partners or potential future partners, in particular due to the illness of employees or their families or desire to isolate or avoid contact with large groups of people;
- additional costs related to the implementation of specific protocols within the framework of our clinical trials;
- delays in obtaining authorizations from the regulatory authorities necessary to start clinical or preclinical trials that we, or our current partners, have planned to launch;
- delays in receipt by the clinical investigation sites of the supplies and equipment needed to carry out these clinical trials;
- disruptions in global trade that may affect the transportation of clinical trial materials such as our therapeutic units required in our clinical trials;
- changes in local regulations imposed by a resumption of the COVID-19 pandemic that could require us or our current partners to modify the terms of our clinical trials, which could result in unexpected costs, or lead to the interruption of our clinical trials;
- delays in necessary interactions with local regulatory agencies, particularly the FDA and EMA, Ethics Committees and other important agencies and contractors due to limited human resources or the unavailability or forced leave of public officials;

- delays in interactions with the FDA and the EMA due to the concentration of their efforts and attention on the examination of other treatments or other activities related to the COVID-19 pandemic; and
- refusals by the FDA or the EMA to accept clinical trial data collected in geographical areas affected by the COVID-19 pandemic.

In addition, a resurgence of the COVID-19 pandemic, or new pandemics of this nature, could again disrupt our operations and those of our partners for a significant period of time if management, members of the Board of Directors and/or employees were unable to work due to illness or unable to work remotely, or in case of the Board, unable to meet.

The magnitude of the COVID-19 pandemic may continue to evolve rapidly, and this evolution remains unpredictable. The extent to which COVID-19 may impact our business, that of our current partners and potential future partners, clinical trials and the readiness to market our product candidates will depend on future developments of this pandemic, which are inherently uncertain and cannot be predicted with certainty. This will indeed depend on many factors such as the geographical spread of the disease, the duration and extent of a possible pandemic recovery, any new restrictions on the movement of capital, people and goods at the global level and within the European Union, any further social distancing measures taken by governments, business closures or disruptions, the effectiveness of measures taken in affected countries and globally to contain and treat the disease and the effectiveness, uptake and the speed of vaccination campaigns. In addition, the extent of the negative impact of this possible pandemic recovery on the financial markets, on our share price and therefore on our ability to obtain additional financing is unknown at this time. As of the date of this annual report, the global economy, even if it is in the process of recovering, has been strongly impacted by this pandemic.

Item 4. Information on the Company.

A. History and Development of the Company

GENFIT is a biopharmaceutical group conducting late stage clinical trials dedicated to improving the lives of patients with liver diseases with high unmet medical needs, with a special focus on rare, severe and acute pathologies. Our legal name is "GENFIT SA," or a French société anonyme, and our principal executive office is located at Parc Eurasanté 885, avenue Eugène Avinée 59120 Loos, France. Our telephone number at our principal executive office is +33 (0)3 2016 4000. Our agent for service of process in the United States is Corporation Service Company, located at 19 West 44th Street, Suite 200, New York, NY 10036.

With its rich scientific heritage spanning more than two decades, the Group is a pioneer in the discovery and development of drugs for liver diseases. Our portfolio now covers six therapeutic areas with six drugs at different development stages (preclinical, Phase 1, Phase 2 and Phase 3), with different mechanisms of action: elafibranor in Primary Biliary Cholangitis (PBC), nitazoxanide (NTZ) and VS-01-ACLF in Acute on Chronic Liver Failure (ACLF), GNS561 in cholangiocarcinoma (CCA), VS-02-HE in Hepatic Encephalopathy (HE) and VS-01-HAC in Urea Cycle Disorder (UCD) and Organic Acidemia (OA). We also work on non-invasive diagnostic solutions in nonalcoholic steatohepatitis (NASH) and ACLF, essentially to identify patients eligible for treatment alongside our therapeutic programs in ACLF.

GENFIT was founded in 1999 by Jean-François Mouney, now Chairman of the Board of Directors. Our Chief Executive Officer, Pascal Prigent, took his position on September 16, 2019, following the recommendation of Jean-François Mouney and board of directors' approval. In 2003, GENFIT created GENFIT CORP., our subsidiary in Massachusetts, United States. In 2006, GENFIT was listed on the Alternext Market of Euronext Paris and transferred in 2014 onto the Euronext Market in Paris (compartment B - ISIN : FR0004163111). In March 2019, GENFIT SA listed its American Depositary Shares on the Nasdaq Global Select Market in the United States under the symbol "GNFT". On September 29, 2022, GENFIT completed the acquisition of Versantis AG, a Swiss-based clinical stage biotechnology company focused on providing solutions for increasing unmet medical needs in liver diseases, which has since then become its wholly-owned subsidiary.

We are led by an executive team and board of directors with deep experience at leading biotech companies, large pharmaceutical companies and academic institutions. The chair of our scientific advisory board, Bart Staels, is the other co-founder of our company and a world-renowned expert in metabolic & inflammatory disorders, and nuclear receptors. Our Scientific Advisory Board is composed of world-renowned key opinion leaders in metabolic and inflammatory diseases with a particular focus on hepatic and gastroenterological diseases.

Throughout our company’s history, we have carried out numerous R&D programs through consortiums and co-research agreements with large pharmaceutical companies, and experts from the academic world. The experience and expertise we’ve gained have fueled our own research and development efforts, including the discovery of new therapeutic targets, the development of novel technologies and the identification of drug candidates that have demonstrated potential therapeutic efficacy in clinical trials.

The Group's workforce is spread over 3 sites: Lille and Paris (France), Zurich (Switzerland) and Cambridge (Massachusetts, United States). As of December 31, 2022, we had 148 employees.

Our capital expenditures in the years ended December 31, 2022, 2021, and 2020 totaled €44.9 million, €0.6 million and €1.0 million, respectively, primarily related to our acquisition of Versantis in 2022, and investments in software and scientific equipment in 2021 and 2020. We expect our capital expenditures in 2023 to be primarily financed from our existing cash.

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

The SEC maintains an internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the SEC.

B. Business Overview

i. Our Purpose

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients affected by severe chronic liver diseases that are characterized by high unmet medical needs.

Our purpose supports our long-term commitment with regard to the role we want to play in society, not only as an economic player seeking to create long-term value for our ecosystem and partners but also as an innovative biotechnology company working to improve patients' quality of life, and finally as a civic company striving to promote professional and personal development for its employees.

We intend to create general public benefit by generating a positive and significant social, societal and environmental impact through our activities. As part of this approach, our Board of Directors commits to taking into consideration (i) the social, societal and environmental consequences of its decisions on all of the Company's stakeholders, and (ii) the consequences of its decisions on the environment. As part of this commitment, we have created a dedicated Environmental, Social, Governance, or ESG, Committee of the Board of Directors which meets at least bi-annually, to measure and track our extra-financial performance and communicate to the public through an annual extra-financial performance report.

ii. Our Vision

Our ambition is to capitalize on our scientific, clinical and regulatory expertise acquired during more than two decades in the field of liver disease to build and expand a pipeline of innovative therapeutic and diagnostic solutions targeting rare and severe liver diseases with high unmet medical needs, and representing a significant market potential in order to finance innovation to enable us to sustain excellence in medical innovation, research and development over time.

iii. Our Mission

Our mission is to remain a pioneer in the field of liver diseases, i.e. identify high potential assets to bring them from discovery or early stages up to late development stages, typically the end of Phase 3. Subject to successful development and marketing approval, and depending on the nature of our collaboration and licensing agreements, we would either commercialize the assets ourselves, capitalize on the know-how of our current partners, such as Ipsen, or enter into additional distribution agreements with new partners.

iv. Our Founding Values and Principles

Our employees are driven by common principles that shape their actions:

- **Innovation to serve patients**: We are deeply committed to improving the health and quality of life of patients affected by severe chronic liver diseases. We seek new ways to advance science and medicine, with the goal of optimizing care for patients. With a strong desire to leverage our agility and responsiveness, we and our employees are striving to move our scientific and medical approaches forward, and improve patient management in terms of diagnostics, prevention and care.

- **Respect and diversity**: We bring together talented employees with unique perspectives and experiences, we recognize and value diversity as a great strength, and ensure that all employees and third parties are treated fairly, with dignity and respect.

- **Ethics**: We deliver true and accurate information to our partners and stakeholders and build our business relationships with honesty and transparency. We demand of ourselves and others the highest ethical standards and we conduct our business in a socially and environmentally sustainable manner.

iv. Our Sustainability Journey

GENFIT considers Corporate Social Responsibility, or CSR, a key driver for success, in that extra-financial performance can be considered as closely associated with financial performance. Although we are not yet subject to significant CSR reporting regulations, we strive to be as proactive and transparent as possible, and publish an Extra-Financial Performance Report, or EFPR, on an annual basis.

Our CSR journey pursues several objectives. First is our desire as a company to uphold the principles of our code of ethics and our internal policies. Secondly, we seek to manage risks that could potentially affect our business activity, and to seize opportunities that could potentially contribute to our growth. Third, we engage with key stakeholders in our ecosystem (doctors, patient associations, investors, talents, employees, etc.) in order to capture, understand and address challenges that are material for them and for us. Finally, we attempt to anticipate future regulations that may apply to our organization in the coming years.

With this in mind, at the end of 2021, our Board of Directors created a dedicated ESG Committee which meets at least twice per year and makes recommendations to the Board of Directors. This committee reviews in particular the annual ESG roadmap (specific actions and initiatives conducted or to be launched), and is involved in the drafting and review of the annual EFPR. This report describes our philosophy, our priorities and the nature of our engagement in terms of (1) policies, (2) actions and (3) performance indicators, including criteria related to (1) the environment, (2) social and societal topics and (3) governance matters.

Internally, our CSR approach involves stakeholders at all levels of the Company. At the top of the organization, beyond the ESG Committee, the Audit Committee and the Nominations and Remunerations Committee play a key role. The Economic and Social Council, or Works Council, a statutorily-required council composed of employee representatives, also plays a significant role. In addition, each functional department is responsible for ensuring that E- and/or S- and/or G-related matters are properly addressed. Then at the bottom of the organization, a group of ESG volunteers - or ESG champions - is making sure that CSR remains at the heart of our organization.

In 2022, the independent rating agency Gaïa Research by EthiFinance SAS awarded us a bronze medal and ranked our company in 6th place out of 49 companies in our sector. We also obtained a Prime Status label from Institutional Shareholder Services Inc. In 2022, we also engaged in a series of self-evaluation processes, as part of our dedication to continuous improvement, based on sector-specific tools developed around the IS026000 standard as well as the 17 Sustainable Development Goals (SDGs) from the United Nations, and with regards to environmental standards we referred to ADEME (Agency for the Environment and Energy Management), Science Based Targets initiative (SBTi) and Greenhouse gases (GhG).

In 2023 and beyond, we plan to further strengthen our ESG approach, laying the foundation for a materiality assessment with our relevant stakeholders, in line with emerging regulations.

v. Overview of our main programs

Since its strategic reorientation at the end of 2020, GENFIT has greatly expanded and diversified its portfolio of products under development, which now includes the following programs:

*Upcoming milestones, data announcements and launch dates are anticipated and subject to change. PBC: primary biliary cholangitis ; ACLF: acute on chronic liver failure. CCA: cholangiocarcinoma; HAC: hyperammonemic crises; UCD = urea cycle disorders ; OA = organic acidemias ; HE: hepatic encephalopathy; NASH: non-alcoholic steatohepatitis; POC: Proof of Concept. *elafibranor, VS-01, GNS561, nitazoxanide (NTZ) and VS-02 are investigational compounds that have not been reviewed nor been approved by a regulatory authority in targeted indications. Ipsen has global rights to develop and commercialize elafibranor in PBC (including open-label extension, confirmatory PBC study and life cycle management), with the exception of China, Hong Kong, Taiwan, and Macau (Greater China) where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor. GENFIT has in-licensed the exclusive rights for GNS651 in cholangiocarcinoma in the United States, Canada and Europe, including the United-Kingdom and Switzerland, from Genoscience Pharma. Labcorp has a five-year exclusive license for the development and commercialization of NIS4 technology to power a next-generation NASH diagnostic LDT to identify patients with at-risk NASH in the United States and Canada. NIS2+ is a next-generation technology derived from NIS4.*

vi. Our Strengths

We rely on our strengths to accelerate our research and development efforts over the coming years.

– ***A recognized expertise in bringing earliest stage assets into later development stages***

Over the years, GENFIT has demonstrated its capacity to develop assets from the earliest stages to the pre-commercialization stage. This track record was materialized by the development of elafibranor from discovery to Phase 3 in NASH, and then in PBC, leveraging GENFIT's expertise in several fields: research (target identification, understanding of molecular mechanisms of action, establishing a network of experts, etc.), clinical development (study design and protocol definition, KOL management and Advisory Boards, clinical trial execution from site activation and patient recruitment to data readout and statistical analysis), regulatory (US Food and Drug Administration (FDA)/European Medicines Agency (EMA) interactions for Investigational New Drug (IND) submissions, Breakthrough Therapy/Fast Track/Orphan designations, accelerated pathways such as Subpart H, etc.) and pre-commercialization (disease awareness, patient engagement, forecasting, sales force sizing, market-access ,etc.).

– ***A portfolio focused on disease areas with high unmet needs and high market potential***

In just a few years, GENFIT's portfolio has become widely diversified, expanding from a single asset (elafibranor) and a single indication (PBC) to a portfolio comprised of six assets and six indications. The wide range of mechanisms of action and indications we are targeting allow us to distribute the risk over several programs. The distribution of these programs across multiple development stages (two preclinical and four clinical programs in Phase 1, Phase 2 and Phase 3) provides a dynamic and diverse potential newsflow over the next months and years.

Program		Designation
Elafibranor in PBC	Orphan Drug Designation (FDA, EMA)	Breakthrough Therapy Designation (FDA)
VS-01-ACLF	Orphan Drug Designation (FDA, EMA)	
GNS561 CCA	Orphan Drug Designation (FDA)	
VS-01-HAC*	Orphan Drug Designation (FDA)	Rare Pediatric Designation (FDA)

**VS-01-HAC is also potentially eligible for Priority Review Voucher (PRV) upon approval (FDA)*

– ***Partners with a strong commercial track-record***

Ipsen became an 8% shareholder of GENFIT at the end of 2021. The strategic partnership also provides Ipsen with access to our research capabilities and other clinical programs through rights to first negotiation, therefore becoming a potential natural partner for GENFIT to commercialize any late stage asset successfully developed in the future. Ipsen’s world-class development capabilities, well-established global commercial footprint and excellent track record in delivering therapies to patient populations with unmet medical need indeed makes it an ideal partner for GENFIT. We have also developed partnerships with other stakeholders, creating potential avenues to generate revenues in the future. In 2019, the Company signed a licensing and collaboration agreement with Terns Pharmaceuticals for the development and commercialization of elafibranor in Greater China, and also has agreements with Labcorp, to commercialize NIS4 technology in the US and Canada as a Laboratory Developed Test, as well as with Q2 lab in the clinical research space.

– ***A robust financial situation with a strong cash position***

As of December 31, 2022, the Company’s cash, cash equivalents and current financial assets amounted to €140.2 million (amount is net of cash in transit of €0.3 million, earmarked for payment in early January 2023). Based on current assumptions and without taking exceptional events into account, we believe that our existing cash and cash equivalents as of December 31, 2022, will enable us to fund our operating expenses and capital expenditure requirements until approximately the fourth quarter of 2024. For more information regarding our liquidity and capital resources, see “Item 5.B—Liquidity and Capital Resources.”

vii. Our Strategy

GENFIT's strategy is to make the most of our strengths to become a world leader in the development of innovative therapies and diagnostics in severe liver diseases, prioritizing rare diseases. This strategy is designed to serve our purpose, focused on improving patients' lives.

– ***Targeted therapeutic areas***

The relevance of our positioning in rare, severe liver diseases for which unmet needs remain high is threefold:

- It allows us to act, as a pioneer, for the benefit of patients whose lives are in danger, and who have few, if any, therapeutic options;
- It allows us to apply our know-how, our expertise and experience to try to bring patients satisfactory solutions thanks to the advances enabled by our innovation work in the preclinical and clinical fields and;
- Finally, it allows us to consider potential accelerated approval processes.

– ***Our approach to generate value***

In terms of drug development, our goal is to focus our efforts in one specific area - rare and severe liver diseases - for greater operational efficiency, and to distribute the risk across different programs with different mechanisms of action, with the goal to improve our chances of success.

Our goal is also to reduce development timelines, and we therefore favor two approaches to strengthen our portfolio:

- Repurposing of molecules approved in other indications (e.g. NTZ, an antiparasitic drug, in ACLF); and
- In-licensing and/or acquisition of molecules developed by other companies (e.g. GNS561, from Genoscience Pharma, in CCA, and VS-01-ACLF, from Versantis AG in ACLF).

GENFIT's ambition is to develop drug candidates from the earliest stages up to the latest stages, including Phase 3. Depending on predefined criteria such as the targeted indication or competitive environment, or potential opportunities in terms of partnerships, GENFIT will then choose what we consider to be the best option to commercialize our most promising assets for which the company has not yet licensed the rights:

- Build our own marketing and sales forces to commercialize the asset on our own, or
- Leverage the existing relationship with preferred commercial partner Ipsen which provides a natural path to commercialization, or
- Commercialize via another partner.

We consider the patient journey as a whole and are also looking to continue to be present in the diagnostic field, specifically to determine which populations to treat within the therapeutic areas we are targeting with our drug candidates.

– ***Our corporate priorities in 2023***

To ensure the efficient execution of the previously described strategy in 2023, GENFIT has defined three top corporate priorities:

- to execute our ongoing programs: transition with our partner Ipsen in PBC and to progress our therapeutic programs in ACLF and CCA;
- to capitalize on the excellence of our research, continuing to rely on our pioneering work in ACLF; and
- to continue to strengthen our organization, both on the financial and human aspects.

viii. Our Drug Candidates and Diagnostic Development Programs

We are developing product candidates in six therapeutic programs and two diagnostic programs, as described below.

– ***Elafibranor in Primary Biliary Cholangitis (PBC)***

- **About PBC**

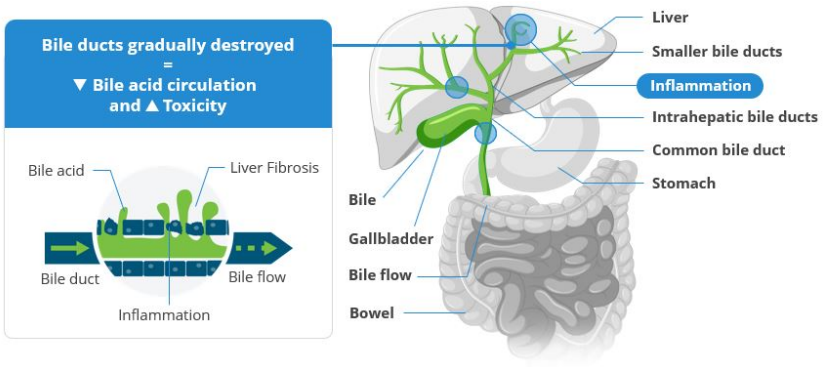
PBC is a rare, chronic, progressive liver disease of autoimmune etiology, characterized by injury of the intrahepatic bile ducts that, in untreated patients or non-responders to existing therapies, may progress to hepatic fibrosis, cirrhosis, hepatic decompensation, and death unless they receive a liver transplant. PBC disproportionately affects women versus men (approximately 10:1) and is typically diagnosed in patients between 40 years to 60 years of age. The incidence and prevalence rates for PBC in Europe, North America, Asia, and Australia are reported as ranging from 0.33 to 5.8 per 100,000 inhabitants and 1.91 to 40.2 per 100,000 inhabitants, respectively. It is estimated that there were 47,000 prevalent cases of PBC in the United States white population and that approximately 3500 new cases are diagnosed each year. Over 60% of the newly diagnosed cases are asymptomatic. The majority of asymptomatic patients become symptomatic within 10 years and the estimates for developing symptoms at 5 and 20 years are 50% and 95%, respectively. Patients with PBC progress at varying rates, some experiencing liver decompensation over a period of several years while others experience liver decompensation over decades. PBC is one of the leading indications for liver transplantation. Despite its rarity, PBC remains an important cause of morbidity in the Western world. PBC has also been identified as an important risk factor for hepatocellular carcinoma.

PBC is characterized by cholestasis caused by autoimmune destruction of biliary ducts with progressive impairment of bile flow in the liver. This results in increased hepatocellular bile acid concentrations, which are toxic to the liver. Such hepatocellular injury is associated with a local inflammatory response resulting early on in an abnormal elevation of serum alkaline phosphatase (ALP) levels, a hallmark of the disease. Antimitochondrial antibody and IgM are specific immunological hallmarks of PBC, and antimitochondrial antibody is a diagnostic marker of the disease in approximately 90% of patients. Liver biopsy, while confirmatory, is no longer the standard of care.

ALP is also routinely used to clinically monitor the disease and serves as a leading indicator of disease progression. ALP increases with disease progression as bilirubin starts to decline in more advanced disease (as the excretory function starts to decline), and both have been shown to be highly predictive of long-term clinical outcomes (e.g., transplant-free survival). There is a near log-linear correlation of both elevated ALP and bilirubin after 1 year of follow-up with long-term liver transplant-free survival.

The most common symptoms of PBC are fatigue and pruritus. The mechanisms underlying these symptoms are not well elucidated and neither correlates with disease stage or clinical outcomes.

The following diagram depicts where and how bile ducts are destroyed.



– *Limitations of Current Treatment Options*

UDCA, an epimer of the primary human bile acid, was the only medicine approved to treat PBC until May 2016. UDCA has been shown to improve ALP and bilirubin, and to delay histological progression, thereby increasing liver transplant-free survival. While UDCA has had a marked impact on clinical outcomes in PBC, a large proportion of patients have an inadequate response. It is estimated that up to 40% of UDCA-treated patients have a suboptimal response to UDCA. ALP levels remain elevated in up to 70% of patients who are currently being treated or are intolerant to UDCA. Such patients remain at risk of disease progression and longer term adverse clinical outcomes.

In May 2016, the FDA approved obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, Inc., for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as a single therapy in adults unable to tolerate UDCA. In September 2017, following the death of 19 PBC patients being treated with Ocaliva, the FDA published a safety announcement for Ocaliva, indicating that some patients with moderate to severe decreases in liver function had been incorrectly dosed, resulting in an increased risk of serious liver injury and death. The FDA also indicated that Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. In February 2018, the FDA issued a Boxed Warning added to the Ocaliva label, the most severe warning required to be included in labeling by the FDA. Concerns remain over pruritus and serious liver injury or liver death caused by administration of Ocaliva. In its Phase 3 clinical trial, severe pruritus was reported in 23% of patients in the Ocaliva 10 mg dose cohort and in 19% of patients in the Ocaliva titration cohort, in which dosing was initiated at 5 mg and titrated up to 10 mg based on clinical response, compared to 7% of patients in the placebo group. In May 2021, the FDA issued a drug safety communication restricting the use of Ocaliva in patients with PBC having advanced cirrhosis. The use of Ocaliva is now contraindicated in advanced cirrhosis due to the risk of liver failure, which may require liver transplant.

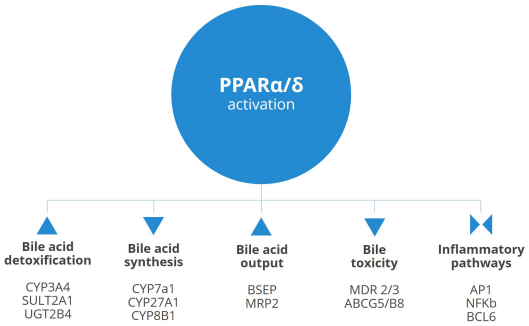
Accordingly, we believe there is still a significant medical need for new therapies, as current treatments either are ineffective for a large portion of PBC patients, cause significant side effects or include safety risks.

- **Our Program: Elafibranor for the Potential Treatment of PBC**

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

– *Elafibranor in PBC: rationale and mechanism of action*

Elafibranor mechanism of action targets PPARα and PPARδ. Targeting PPAR receptors has shown multiple beneficial effects, including the reduction of bile acid synthesis, improved detoxification of bile in the bile duct and anti-inflammatory activity. Patients with PBC often have elevated ALP, a marker of cholestasis, and studies have shown a correlation between elevated ALP levels and increased risk of adverse patient outcomes.



We have observed elafibranor's effect in reducing ALP levels and markers of inflammation in our Phase 2 clinical trial in patients with PBC.

– *Phase 2: positive Phase 2 results published in a renowned scientific journal*

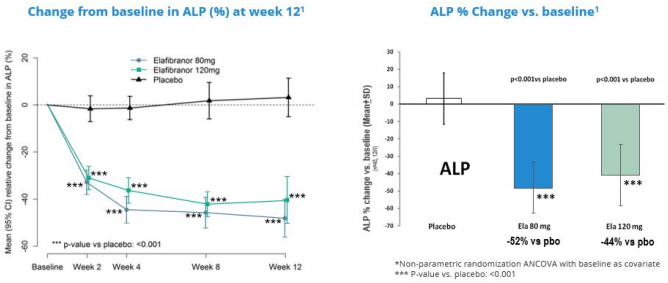
Positive results from our Phase 2 clinical trial of elafibranor in PBC formed the rationale to launch the ELATIVE Phase 3 trial previously described. These results were announced in December 2018 and then presented in April 2019 at the International Liver Congress 2019 organized by EASL (European Association for the Study of the Liver), and then published in The Journal of Hepatology in 2021.

The Phase 2 clinical trial of elafibranor in PBC was a multi-center, double-blind, randomized, placebo-controlled clinical trial evaluating the efficacy and safety of elafibranor after 12 weeks of treatment in patients with PBC and inadequate response to UDCA. The trial was conducted at multiple clinical centers in the United States and in three European countries and enrolled a total of 45 patients. The patients were randomized into one of three treatment arms, receiving either elafibranor 80 mg, elafibranor 120 mg or placebo.

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

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

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



(1) Schattenberg et al. J. of Hepatol. 2021, Vol. 74, Issue 6:1344-1354;

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

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

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

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

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

– *Phase 3 ELATIVE trial: topline data expected towards the end of the second quarter of 2023*

ELATIVE is an international Phase 3 double-blind randomized placebo-controlled study with an open-label long-term extension (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 treatment period, patients were randomized in a 2:1 ratio to receive 80 mg elafibranor (n=100) or placebo (n=50) once daily.

After the variable double-blind treatment period (52 - 104 weeks), 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 as defined by biochemical parameters: ALP < 1.67 x ULN and total bilirubin ≤ ULN and ALP decrease ≥ 15%. Secondary endpoints include response to treatment based on ALP normalization at week 52 and change from baseline in pruritus through week 52 on PBC Worst Itch NRS score.

Enrollment was completed in June 2022. We expect to deliver ELATIVE topline data towards the end of the second quarter of 2023, which, if successful, we plan to use to support regulatory submissions under accelerated approval pathways.

Following announcement of the interim Phase 3 topline results, expected towards the end of the second quarter of 2023, Ipsen will assume responsibility for all additional clinical development. Ipsen owns global rights, and Terns Pharmaceuticals owns rights in Greater China. (See "Item 4.B—Commercialization perspectives—Out-licensing partnerships"). Throughout 2022 GENFIT and Ipsen collaborated closely in preparation of ownership transfer of our program in PBC.

– ***VS-01-ACLF and nitazoxanide (NTZ) in Acute on Chronic Liver Failure (ACLF)***

- **About ACLF**

ACLF is a rare, life-threatening, but potentially reversible condition of varied etiology. ACLF is a syndrome, globally defined by multi-organ dysfunction and failure in patients with chronic liver disease or liver cirrhosis and high short-term mortality within a period of 28 to 90 days. Today, hepatologists recognize ACLF to be a medical entity as a whole.

Patients with cirrhosis may initially be compensated. With progression, many patients will go on to have acute decompensation of cirrhosis characterized by the rapid development of complications such as ascites, hepatic encephalopathy (HE), gastrointestinal hemorrhage, or bacterial infection, which are very common causes of hospitalization. On admission, approximately 30% of these patients will develop liver and/or other organ failure(s) (i.e, brain, kidneys, cardiovascular and respiratory) and will be considered as having ACLF.

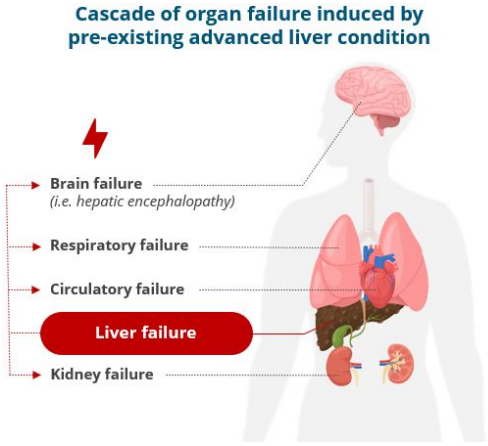
ACLF is an underserved medical condition associated with high short-term mortality (23% to 74% mortality at 28 days, depending on severity grade). Currently, no drugs have been approved in ACLF. In 2021, the prevalence of ACLF is estimated to be approximately 294 thousand across the US, EU4 and UK. This market is expected to grow to approximately 300 thousand patients by 2036 due to an aging population and a higher prevalence of non-alcoholic fatty liver disease (NAFLD)/NASH, diabetes, obesity, alcohol consumption and drug induced liver injuries.

Rising alcohol consumption has already impacted China, the United States, and Denmark, all of which have documented a doubling in alcoholic liver disease hospitalizations over a 10-year period.

In the US, there are over 600,000 hospitalizations per year for decompensated cirrhosis. With a 10-30% ACLF prevalence in this population the annual number of ACLF hospitalizations in the US is estimated to be between 60,000 and 180,000. In the five major European countries, there are about 800,000 hospitalizations for decompensated cirrhosis. With a 20-30% prevalence in this population, the annual number of ACLF hospitalization is estimated to be between 160,000 and 240,000.

Cirrhosis and ACLF represent a substantial health and economic burden. For example, in the United States in 2011, the total inpatient costs for cirrhosis with and without ACLF was estimated to be more than $10 billion. In the same study, the cost per hospitalization was 3.5-fold higher for ACLF patients than for patients with cirrhosis who did not have ACLF.

Such high hospitalization costs for critically ill ACLF patients as compared to cirrhotic patients without ACLF can be easily explained by higher rates of hospitalization in the ICU and, most importantly, by 2-3-fold longer hospital stays: average of 16 days for ACLF patient versus 7 days for patients with cirrhosis who did not have ACLF. Complications are the key drivers impacting the length of patient's hospital stays with renal and infectious complications being associated with the longest hospital stays.



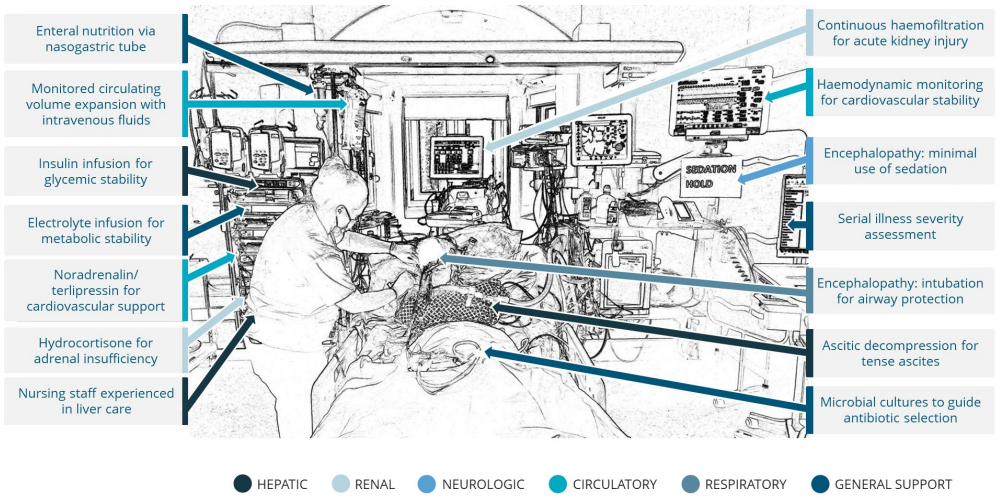
– *A high unmet medical need*

There are no specific therapies currently available for patients with ACLF other than treatment of precipitating events, when identified, and organ failure support (e.g., hemodialysis in the case of kidney failure). The only definitive treatment option is liver transplantation. Due to the emergency setting, limited access to compatible liver donors and, in some cases, no accessible liver transplant capabilities, approximately 15-30% of patients die while awaiting liver transplant.

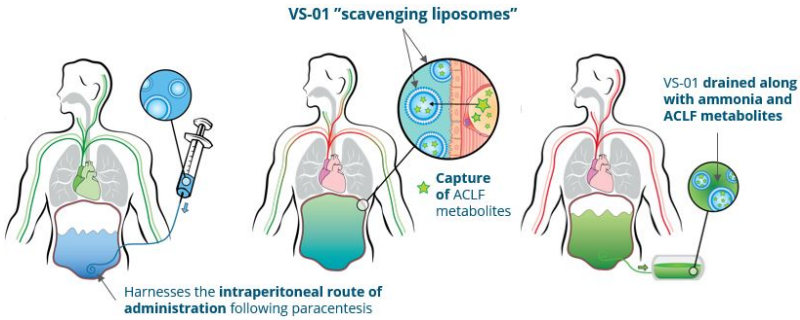
Patients with acute decompensated cirrhosis are generally hospitalized in the regular hepatology ward. Within one week, patients may progress to ACLF and are usually transferred to an intensive care unit where organ support and general care can most effectively be provided. Despite intense efforts to improve the standard of care, the current high short-term mortality rate highlights the critical medical need of new therapies to help patients to rapidly recover and survive an ACLF episode without liver transplantation or bridge them to liver transplant, when appropriate.

The mean survival time in patients with ACLF is 3 – 5 years. In a study of 1,343 hospitalized patients with cirrhosis and acute decompensation, 303 had ACLF when the study began, 112 developed ACLF, and 928 did not have ACLF. The 28-day mortality rate among patients who had ACLF when the study began was 33.9%, among those who developed ACLF was 29.7%, and among those who did not have ACLF was 1.9%. In general, a greater number of organ failures is associated with higher short-term mortality. For example, the 28-day mortality rate for patients having 3 or more organ failures approaches 80%.

– *Bedside management of ACLF patient hospitalized in Intensive Care Unit*



- **Our first program: VS-01-ACLF for enhancing the systemic elimination of ammonia and other ACLF-related metabolites**
  - *VS-01-ACLF: rationale and mechanism of action*



VS-01-ACLF is an innovative, first-in-class, therapeutic drug candidate based on a proprietary scavenging liposomal technology. It is administered directly into the peritoneal (abdominal) cavity following drainage (paracentesis) of ascites, one of the most common complications in patients with ACLF. VS-01-ACLF was granted the Orphan Drug Designation in ACLF by the FDA.

In the setting of ACLF, toxic metabolites build up in the bloodstream due to organ failures. VS-01-ACLF is designed to enhance the clearance of ACLF-related metabolites by extracting them from the blood into the peritoneal cavity by passive diffusion. Toxic metabolites, either captured by the liposomes or in the surrounding fluid, are then drained from the body.

VS-01-ACLF is in clinical development as a first-line therapy for the timely reversal of ACLF. The identification of the toxic metabolites extracted by VS-01 and associated clinical outcomes will be further investigated in the upcoming proof of concept Phase 2a study. Preclinical and clinical pharmacodynamic and metabolomic studies have shown that VS-01-ACLF could be the first drug to use the intraperitoneal route to:

- Simultaneously support the liver, kidney and brain, the organs that most often fail in cirrhotic patients; and
- Reduce inflammation, which is a key driver of ACLF.

More specifically, liposomes in VS-01-ACLF are designed to trap bacterial endotoxins and mediators of inflammation as well as ammonia, one of the main culprits of hepatic encephalopathy and associated brain failure. Overall, we believe VS-01-ACLF will enhance the clearance of hepatic and uremic toxins to support the liver, kidney and brain function.

Thus, VS-01-ACLF may be well suited as a treatment for patients with ACLF, with the potential to improve survival, to increase the probability of success for liver transplant in selected patients, and to reduce healthcare costs.

  - *Evidence supporting further development*

    - *Non-clinical evidence*

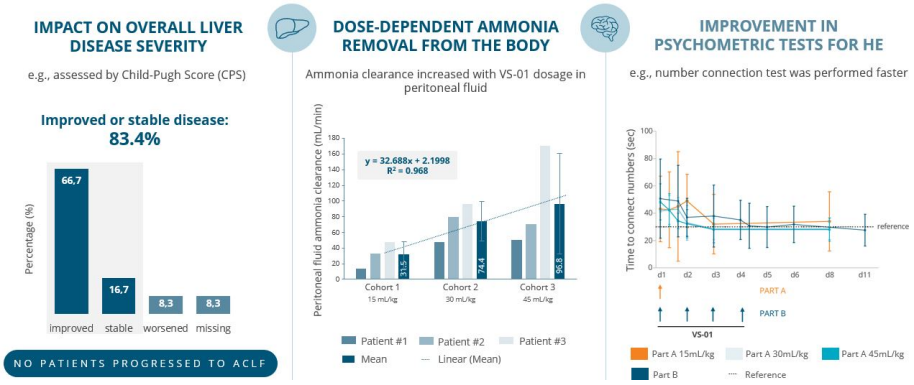
Non-clinical studies evaluated the efficacy of VS-01-ACLF in small and large animal models. VS-01-ACLF was shown to extract kidney and liver toxins (185 extracted metabolites, including ACLF-related metabolites and uremic toxins) as well as inflammation mediators (28 lipophilic compounds identified including fatty acids and bile acids). Moreover, VS-01-ACLF could efficiently capture ammonia. In healthy rats, VS-01-ACLF was shown to remove 20 times more ammonia than a control solution without liposomes. The extraction of ammonia in the peritoneal space led to a decrease in ammonemia in rats and pigs and to a decrease in brain edema in a model of bile duct ligated rats.

In rats, VS-01-ACLF was shown to be safe and well tolerated during a prolonged dwell time (>4h) and during single and multiple doses.

Based on safety pharmacology studies and a GLP repeated dose toxicity study in minipigs receiving a daily session for 10 days, VS-01-ACLF was found to be safe and well tolerated. No immune reactions were observed in pigs which are known to be highly sensitive to colloidal formulation and prone to the so-called CARPA reaction (allergic reaction) following single and daily administration for 10 days.

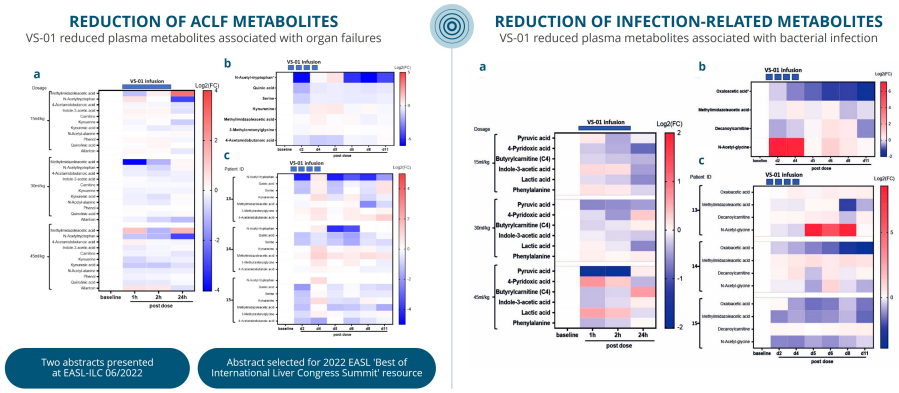
    - *Clinical evidence*

A Phase 1b first-in-human (FIH) open-label study has been completed in 12 cirrhotic patients with ascites and covert hepatic encephalopathy. The study assessed the safety and tolerability of VS-01-ACLF following intraperitoneal administrations of single-ascending doses and multiple doses on top of standard of care (SOC) as a primary objective. The pharmacokinetics and efficacy profile were assessed as a secondary objective. VS-01-ACLF was generally well tolerated. Importantly, >80% of patients demonstrated improvement or stabilization of the severity of their liver disease (as assessed by Child-Pugh score). There was a trend towards dose related increases in the clearance of ammonia removed from the peritoneal cavity as well as improvement in cognitive assessments used in the evaluation of patients with hepatic encephalopathy. Taken together, the benefit risk profile of VS-01-ACLF is supportive of ongoing clinical investigation in patients with ACLF having ascites.



Effect of VS-01-ACLF on metabolites reduction presented at EASL 2022 (2 abstracts):

- Abstract 1 (metabolites associated with organ failure)
- Abstract 2 (metabolites associated with bacterial infection



– *Next milestones*

An international Phase 2, open-label, randomized, controlled, multi-center, proof of concept study will assess the efficacy, safety and tolerability of VS-01 in addition to standard of care (SOC), compared to SOC alone, in approximately 60 adult patients with ACLF grades 1 and 2 and ascites.

It is anticipated that the first patient will be screened in this trial in the second quarter of 2023.

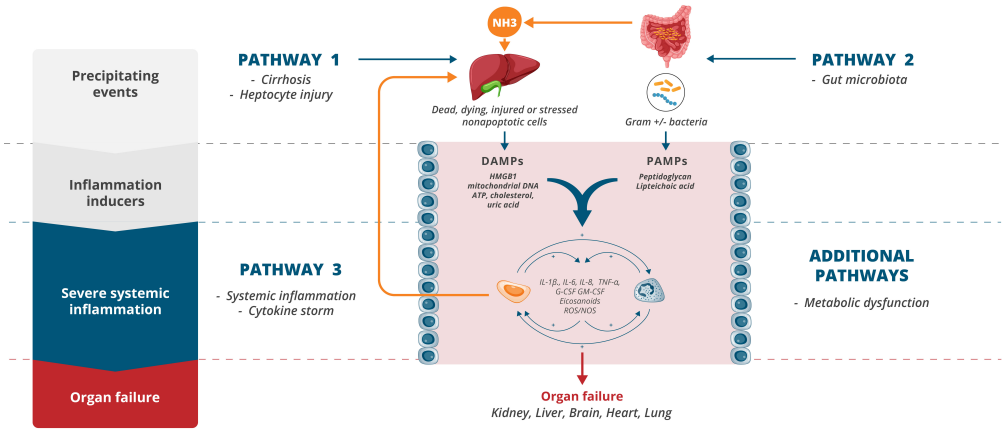
- **Our second program: nitazoxanide (NTZ), as a standalone or in combination treatment**

Our second program aims at developing the repurposed drug nitazoxanide (NTZ).

– *NTZ: rationale and mechanism of action*

The identification of NTZ is the result of our research program initially designed to discover novel anti-fibrotic molecules with a priority given to liver fibrosis.

During further research we have also discovered that NTZ and its circulating metabolite, tizoxanide (TZ), have additional anti-inflammatory effects through the inhibition of inflammatory cell activation. In our preclinical research, the apparent beneficial effects we have observed with NTZ may be explained in part by the anti-infectious properties of NTZ acting on intestinal microbiota dysbiosis/overgrowth and improve the intestinal barrier and direct dose-dependent anti-inflammatory effects on immune cells (macrophages and polymorphonuclear leukocytes).



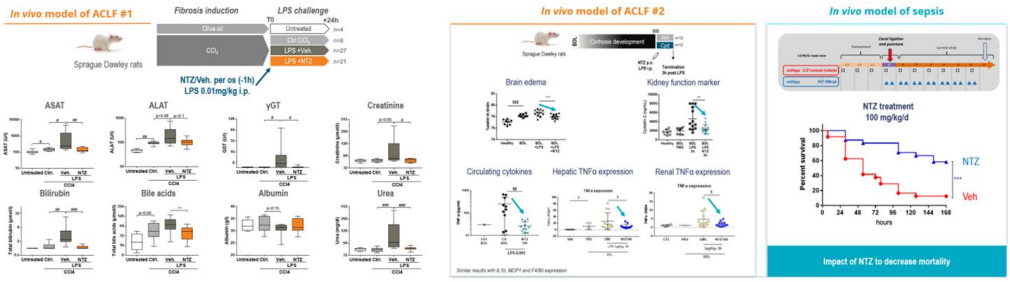
– *Evidence supporting further development*

◦ *Preclinical evidence*

As part of our preclinical program, we have studied NTZ in in vitro and in vivo disease models.

In disease models, NTZ and TZ, its active circulating metabolite, have a wide anti-infectious spectrum acting on bacteria, viruses and parasites commonly encountered in human intestinal flora. Thus, an oral treatment with NTZ is expected to improve bacteria overgrowth and dysbiosis and possibly preserve the intestinal barrier in patients with ACLF. We also observed that, in cultured human liver cells, TZ inhibits a key pathway of programmed cell death (apoptosis) in a dose dependent manner.

- NTZ reduced LPS-induced inflammation in healthy rats: our research has demonstrated that in healthy rats, an oral administration of NTZ concomitant with intraperitoneal injection of LPS significantly reduced the LPS-induced rise in circulating cytokines and inflammatory markers;
- NTZ showed beneficial effects on liver function markers (bilirubin, albumin) in models of cirrhosis: In two distinct rat models of ACLF, we found that NTZ has hepatoprotective effects by reducing ALT and AST while totally preventing LPS-induced rise in GGT and total bilirubin;
- NTZ reduced brain edema in models of ACLF (bile duct ligation);
- NTZ reduced inflammation markers in models of ACLF (bile duct ligation);
- NTZ improved survival in treatment models of Sepsis (cecal ligation puncture, or CLP): the mortality rates in NTZ treated vs vehicle treated group were 53% vs 90% at 72 hours and 67% vs 100% 5 days after CLP surgery; and
- Administration with NTZ also prevented plasma increases in two renal function markers: cystatin C and creatinine.



◦ *Clinical evidence*

Two Phase 1 studies were completed in the fourth quarter of 2022 and the first quarter of 2023 and are expected to provide preliminary insight into NTZ pharmacokinetics and safety in the setting of hepatic impairment or renal impairment.

– *Next milestones*

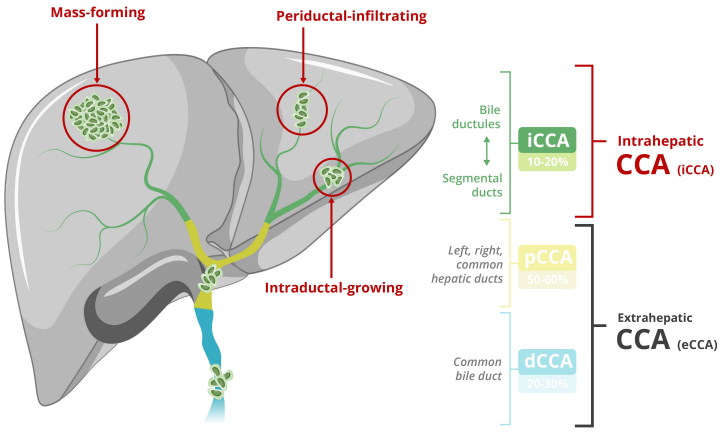
The data for the hepatic impairment study will be presented in a poster presentation during Digestive Disease Week® (DDW) 2023, taking place May 6-9, 2023, at McCormick Place in Chicago, IL, and online. The data from the renal impairment study are currently under review. In both studies, NTZ was generally well tolerated with a safety profile that is supportive of future investigation in patients with ACLF.

A Phase 2a proof of concept study in patients with ACLF grade 1 and 2 is currently under discussion with FDA, and study initiation is targeted for the second half of 2023.

– ***GNS561 in cholangiocarcinoma (CCA)***

• **About Cholangiocarcinoma**

Biliary tract cancer (BTC) is the second most common primary liver malignancy diagnosed globally. Cholangiocarcinoma (CCA) is a type of BTC and represents approximately 15% of all primary liver tumors and 3% of gastrointestinal cancers.



Adapted from Nature Reviews Gastroenterology & Hepatology volume 17, p. 557–588

CCA comprises a heterogeneous group of cancers with pathologic features of biliary tract differentiation and is presumed to arise from the intra- or extrahepatic biliary tract. Gallbladder cancer is distinct from cholangiocarcinoma in epidemiology, pathobiology, clinical presentation and management and is considered as a different type of biliary tract cancer. Based on its anatomical origin, CCA is best classified anatomically as intrahepatic (iCCA) or extrahepatic (eCCA) and comprises perihilar (pCCA) and distal (dCCA) CCA. The incidence of iCCA appears to be increasing and may be as high as 2.1 per 100,000 person years in Western countries.

CCA may occur in normal livers or in the setting of underlying liver disease, and in these cases, it appears as a mixed type hepatocellular-cholangiocarcinoma instead of traditional adenocarcinoma. Several risk factors of chronic inflammatory damage and increased cellular turnover have been established, such as hepatobiliary flukes (Opistorchis viverrini and Clonorchis sinensis), primary sclerosing cholangitis, biliary tract cysts, hepatolithiasis and toxins. Cirrhosis, chronic hepatitis B and C, obesity, diabetes mellitus and alcohol-related liver disease are also emerging as risk factors for CCA.

The clinical presentation of CCA is non-specific and most often insufficient to establish a diagnosis. Early diagnosis is a major challenge as most patients with early-stage disease do not have symptoms due to limited biliary obstruction. Rather, patients characteristically manifest symptoms related to their underlying cirrhosis, a condition present in some patients with CCA.

Taken together, the majority of patients with CCA are diagnosed with advanced disease, often precluding potentially curative therapies. Once symptomatic, CCA is often associated with non-specific complaints, including right upper abdominal or epigastric pain or discomfort, jaundice, weight loss, malaise, hepatomegaly or a palpable abdominal mass. The onset of ascites, encephalopathy, jaundice or variceal bleeding in patients with previously compensated cirrhosis also increases the clinical suspicion for liver tumor. Tumor-related fever may rarely occur, although night sweats are common in advanced disease. CCA should be considered in patients with underlying hepatolithiasis or primary sclerosing cholangitis or PSC with worsening performance status, unexplained loss of weight or failure to thrive.

– A high unmet medical need

There are limited therapeutic options for this aggressive disease. The 5-year survival rates drop to 5-15% in the advanced and unresectable settings. The only potentially curative treatment remains surgical resection. Unfortunately, at time of first diagnosis, only about 25% of the patients are eligible for surgery. Moreover, even after curative intent surgery, the clinical outcomes are disappointing, with 5-year survival rates of 7% to 20%. The role of adjuvant therapies, including systemic chemotherapy and radiotherapy, remains poorly defined yielding only a modest survival benefit. Around 60% to 70% of patients are diagnosed with advanced disease, which is defined as unresectable or metastatic disease. For these patients, palliative treatment with systemic chemotherapy is the only treatment option. Patients progressing on first line chemotherapy often have a rapidly worsening performance status, and only a small number of patients may be suitable for further treatment. The estimated median survival for these patients is 3.7 months.

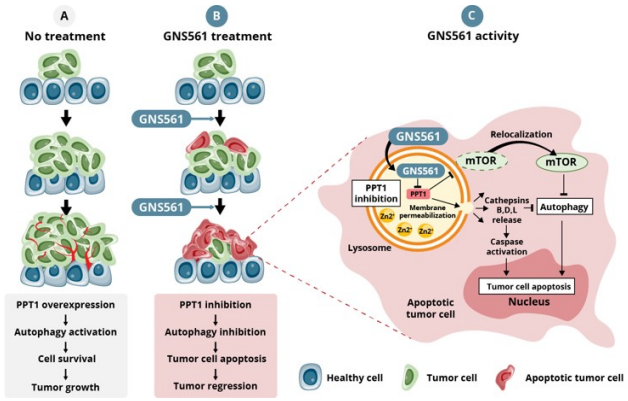
In the advanced setting, the standard of care for first line therapy is a combination of gemcitabine and platinum-based chemotherapy; other gemcitabine- or fluoropyrimidines-based regimens are also commonly used. At time of relapse, patients whose tumor displays fibroblast growth factor receptor 2 (FGFR2) or isocitrate dehydrogenase 1 (IDH-1) alterations may receive approved therapies that target these specific alterations. All other patients are offered second line chemotherapy. The most efficacious regimen is currently a combination of cytotoxics (folic acid, 5-FU/fluorouracil, and liposomal irinotecan (FOLFIRI)) yielding a median overall survival of 8.6 months.

- **Our Program: GNS561**

To address the significant unmet need in patients diagnosed with CCA, GENFIT is developing GNS561 to prolong the overall survival of patients who present with iCCA and eCCA. GNS561 is a Palmitoyl Protein Thioesterase-1 (PPT-1) inhibitor that blocks autophagy, which GENFIT in-licensed in 2021 from Genoscience (See "Item 4.B—Commercialization perspectives—Out-licensing partnerships").

– *GNS561: rationale and mechanism of action*

Autophagy is activated in tumor cells as a survival mechanism in a nutrient poor environment, due to tumor cell growth in advanced cancers. One of the key cellular organelles implicated in the autophagy process is the lysosome. By decreasing the activity of PPT1 in lysosomes, GNS561 may have an important inhibiting activity on late-stage autophagy, which leads to tumor cell death.

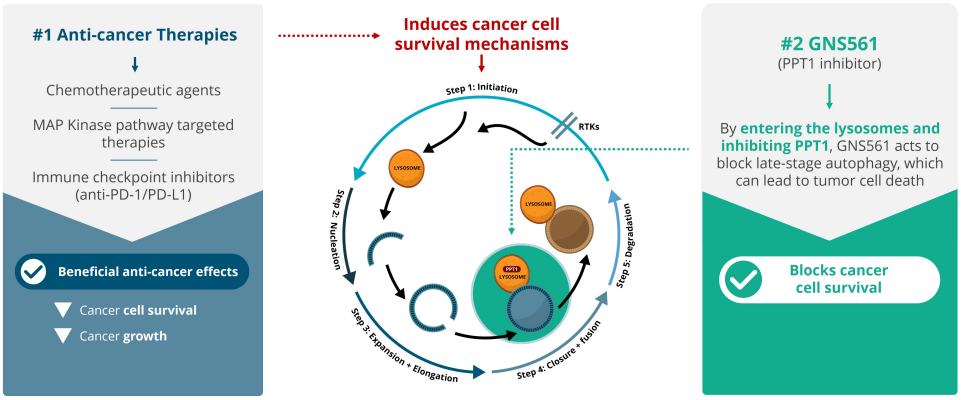


– *Evidence supporting development*

Lysosomal function is an essential element in autophagy, and GNS561 is a lysosomotropic small molecule which inhibits PPT1, a lysosomal enzyme required to maintain lysosome-autophagy function. PPT1 expression is high in most cancer cell lines, increased in tumors compared with paired normal tissue, and in metastases versus primary tumors, and high levels of PPT1 have been associated with shorter overall survival. Thus, these findings, along with the role of PPT1 in maintaining lysosome-autophagy function, establishes the potential of PPT1 inhibition as a strategy in cancer therapy. In addition to its inhibition of PPT1, studies with GNS561 showed that it has high liver tropism when administered orally, significantly reduced cell viability in human iCCA cell lines and induced apoptosis. GNS561-mediated cell death was correlated with inhibition of late-stage autophagy and induction of a dose-dependent build-up of dysfunctional lysosomes. GNS561 was also efficient in vivo against a human intrahepatic CCA cell line in a chicken chorioallantoic membrane xenograft model, with a good tolerance at doses high enough to induce an antitumor effect in this model.

In a first-in-human Phase 1 study in patients with advanced primary (HCC and iCCA) and secondary liver cancer (metastasis from distant carcinomas), GNS561 was observed to have good tolerability, exposure, and preliminary signal of activity. Taken together, the results generated with GNS561 highlight its potential to provide benefit in prolonging survival of patients diagnosed with CCA. In particular, we believe that GNS561, as an inhibitor of autophagy, could potentially be beneficial in combination therapy, including combinations with inhibitors of the MAP kinase pathway or immunotherapy/checkpoint inhibitors.

Cytotoxic chemotherapy drugs as well as multiple targeted therapies such as kinase inhibitors have been proposed to induce autophagy as a survival mechanism in cancer cells. In 2019, the results of two major studies showed that, in the context of a cancer with the KRAS mutation (active RAS leading to activation of the MAP kinase pathway), inhibitors of the MAP kinase pathway can induce autophagy in pancreatic cancer, and combinations of MAP kinase pathway inhibitors with autophagy inhibition can enhance tumor cell killing. Importantly, a significant proportion of CCA patients have mutations including KRAS. Therefore, the combination of therapies targeting the MAP kinase pathway with GNS561 to inhibit autophagy is a potential therapeutic strategy to treat CCA patients.



– *Next milestones*

GNS561 received orphan drug designation for CCA from the FDA in September 2022. Given the high unmet need in this indication and the Orphan Drug Designation obtained from the FDA for GNS561, we believe that the program should qualify for some of the expedited regulatory pathways provided by health authorities.

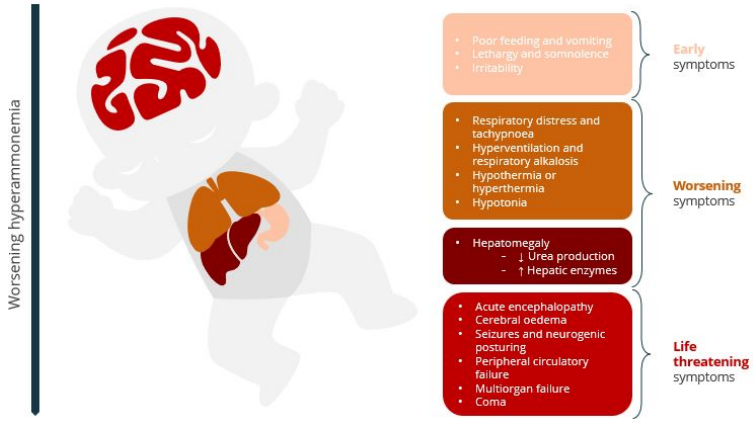
The GNS561 IND was submitted at the end of 2022, and the first patient screening for the Phase 1b/2a clinical trial is expected to occur towards the end of the second quarter of 2023. In Phase 1b of this study, patients with advanced KRAS mutated CCA will be enrolled to evaluate the safety and tolerability of GNS561 when given in combination with a MEK inhibitor and to identify the recommended doses of the combination to be administered in Phase 2a. In Phase 2a, the safety and efficacy of the combination will be assessed in patients with advanced KRAS mutated CCA who have otherwise failed standard-of-care for first line therapy and who do not have an actionable mutation.

– ***VS-01-HAC in urea cycle disorders (UCD) and organic acidemias (OA)***

- **About Hyperammonemic Crisis (HAC) in UCDs and OAs**

Acute hyperammonemia is defined as plasma ammonia levels above 80 µmol/L in newborns up to 1 month of age and above 55 µmol/L in older children. In the mammalian organism, the hepatic urea cycle is the main pathway to detoxify ammonia. Hyperammonemic crisis occurs whenever the load of waste nitrogen exceeds the detoxification capacity.

Inborn errors of metabolism causing HAC comprise a group of hereditary disorders in which a single gene defect results in a clinically significant block of the urea cycle responsible for the metabolic clearance of ammonia from the bloodstream. The accumulation of ammonia, which is continuously produced by the breakdown of protein and other nitrogen-containing molecules, rapidly leads to cerebral edema and the related signs of lethargy, anorexia, hyperventilation or hypoventilation, hypothermia, seizures, neurologic posturing, and coma.



Adapted from Rupesh Raina et al., Nature 2020

Hyperammonemia in Inborn Errors of Metabolism (IEM) is classified as follows:

- Primary hyperammonemia, when the urea cycle is directly affected by a defect of any of the involved enzymes or transporters, defining UCDs; and
- Secondary hyperammonemia, when enzymes of the urea cycle are inhibited due to accumulating metabolites or substrate deficiencies. The most relevant group of disorders associated with secondary hyperammonemia is called Organic Acidemias, or OAs.

Regardless of the underlying genetic disorder, the clinical characteristics, outcome, prognosis and treatment of HACs associated with IEM are similar.

Patients are usually diagnosed shortly after birth via universal newborn screening tests. The clinical presentation of patients with HAC caused by IEM may start as early as the first days of life and as late as adulthood. The most severe cases present in the first week after birth with unspecific symptoms like feeding refusal and vomiting, loss of thermoregulation, neurologic posturing, seizures, hyperventilation and then hypoventilation, and irritability that progress rapidly to somnolence, lethargy, coma, multi-organ failure and death.

While these conditions are ultra-rare with 1,900 acute hyperammonemic crisis in the US and the five major European countries per year, the mortality rate is as high as 75%. Most patients will die after 5 years, and survivors will often have severe brain injuries. Patients with HAC associated to IEM must be transferred to specialized tertiary centers to be treated which increases the costs on the healthcare system.

– A high unmet medical need

The treatment of hyperammonemic crisis typically involves prompt management of the elevated ammonia levels in the blood. This may involve hospitalization, administration of medications such as sodium benzoate and phenylacetate, and intravenous fluids to help remove excess ammonia from the bloodstream. In severe cases, hemodialysis may be necessary to help remove ammonia from the blood. In centers where hemodialysis is not available, hemofiltration or other forms of dialysis should be used.

In practice, pediatric patients presenting HAC must be transferred in highly specialized tertiary centers having devices adapted to their size. Consequently, dialysis in IEM HAC is often initiated late when ammonia levels are above 1000 µmol /L and this may contribute to poor outcomes. Moreover, neonatal hemodialysis is risky, highly invasive and widely unavailable. As many as 45% of UCD patients remain untreated, and no drug is currently approved for treatment of OA.

- **Our Program: VS-01-HAC for Ammonia Clearance and Prevention of HAC**

– *VS-01-HAC: rationale and mechanism of action*

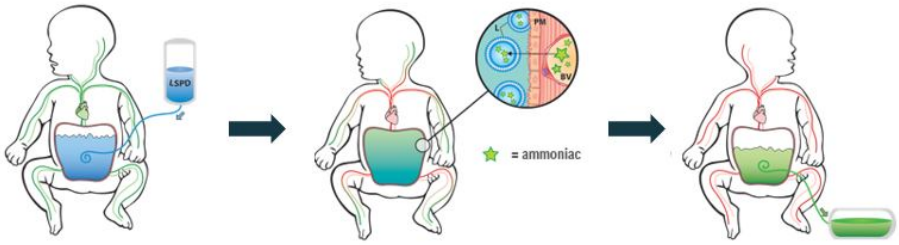
We are developing VS-01-HAC, a potential first-line lifesaving treatment for acute hyperammonemic crisis associated with IEMs.

To reduce high mortality and morbidity associated with HAC in IEMs, early diagnosis and immediate start of treatment are thought to improve the prognosis. Indeed, coma duration and levels of ammonia blood concentration are the main factors for determining mortality and neurologic outcome.

Therefore, a new drug using the peritoneal route with optimized ammonia clearance and a quick implementations time, would allow for the initiation of efficient dialysis immediately after HAC is confirmed and could help in overcoming the crises. Moreover, as the peritoneal route of administration is well adapted to pediatric patients, this treatment could be safely feasible in the hospital setting. Speed of implementation and safety represent tremendous improvements over neonatal hemodialysis, which is only possible in specialized centers and is a long and risky procedure in pediatric patients.

Use of a new treatment before transferring the patient to a tertiary center would save costs to the healthcare system as well as reduce burden on pediatric patients and their parents.

Orphan Drug Designation and Rare Pediatric Disease Designation (RPDD) have been granted to VS-01-HAC by the FDA for this indication. GENFIT is potentially eligible to receive a Priority Review Voucher upon approval of an NDA by the FDA.



– *Evidence supporting further development*

An in vivo feasibility study was performed with OTC-deficient mice (homozygous females (Otcspf-ash/spf-ash) and hemizygous males (Otcspf-ash/Y)), a gold standard model which develops hyperammonemia and presents many characteristics of the human disorder. The results showed that ammonia extracted from blood into the peritoneal cavity was significantly ($p < 0.0006$) higher following single intraperitoneal injection of VS-01 compared to the control solution at all timepoints during the dwell time and led to a significant decrease in blood ammonia.

Our non-clinical and first-in-human clinical data showed that ammonia clearance in the peritoneal fluid increased proportionally with the volume of fluid infused and ranged between 5 and 95 mL/min following treatment with 0.3 L and 3 L VS-01, respectively. These values are in the same range as those reported in UCD patients treated with different extra corporal dialysis modalities.

TYPE OF DIALYSIS	BLOOD FLOW *(ML/MIN)*	DIALYSATE FLOW *(ML/MIN)*	AMMONIA CL *(ML/MIN)*	DIALYSIS DURATION *(H)*	REFERENCES
CPD	NA	NA	1.4 ± 1.1	59 ± 87.2	*Arbeiter et al., 2010*
CAVHD	16	8.3	2.86	33	*Picca et al., 2001*
HD	10	500	9.5	9	*Picca et al., 2001*
HD	15	500	14.4	7.5	*Picca et al., 2001*
CVVHD	40	33.3	21.5	5.5	*Picca et al., 2001*
CVVHD	-	-	18.9 ± 7.7	42 ± 30.4	*Arbeiter et al., 2010*
VS-01 ~ 300 mL *(Minipigs 30 mL/kg)*	NA	NA	6.0 ± 2.8 – 8.0 ± 3.9	3	*Matoori et al., 2020*
VS-01 ~ 1 L *(Patients 15 mL/kg)*	NA	NA	**31.5 ± 16.7**	2	*2021 AASLD abstract*
VS-01 ~ 2 L *(Patients 30 mL/kg)*	NA	NA	**74.4 ± 25.0**	2	*2021 AASLD abstract*
VS-01 ~ 3 L *(Patients 45 mL/kg)*	NA	NA	**96.8 ± 64.3**	2	*2021 AASLD abstract*

– *Next milestones*

Following completion of the non-clinical feasibility study, we plan to develop formulation optimization for specific pediatric implementation and conduct IND-enabling nonclinical studies with a target to complete such studies in 2024 in UCD and OA.

– ***VS-02-HE in hepatic encephalopathy (HE)***

- **About hepatic encephalopathy**

In the setting of chronic liver disease and liver failure, toxins, including ammonia, accumulate in the systemic circulation and can cross the blood-brain barrier. Excess ammonia induces accumulation of glutamine in astrocytes causing osmotic stress and alteration of cell metabolism and can result in brain edema or swelling.

These are features of hepatic encephalopathy, or HE, which is one of the major complications of advanced liver disease and portal hypertension. As many as 45% of patients with cirrhosis will experience at least one episode of HE. HE represents a diverse spectrum of neurologic, psychiatric, and musculoskeletal symptoms, including sleep-wake cycle disturbance, fatigue, concentration difficulty, personality changes, tremor, cognitive deficits, and, in severe cases, coma. Patients with and without ACLF having HE have higher mortality rates compared to patients who do not have HE.

In the US, subclinical HE has been shown to be present in as many as 80% of patients with cirrhosis, and approximately 200,000 patients with cirrhosis had HE in 2018. In Europe (EU-5), the prevalence of HE is close to approximately 90,000 cases. The prevalence of covert HE, based on Psychometric Hepatic Encephalopathy Score (PHES) testing, is 20.3% to 37% in persons with cirrhosis, however, prevalence increases to 54% when minimal hepatic encephalopathy is diagnosed according to the Stroop EncephalApp. The prevalence of overt HE at the time of cirrhosis diagnosis is approximately 10–14%. The estimated annual economic burden associated with HE in the US was $7.2 billion in 2009 and around $12 billion in 2014.

– A high unmet medical need

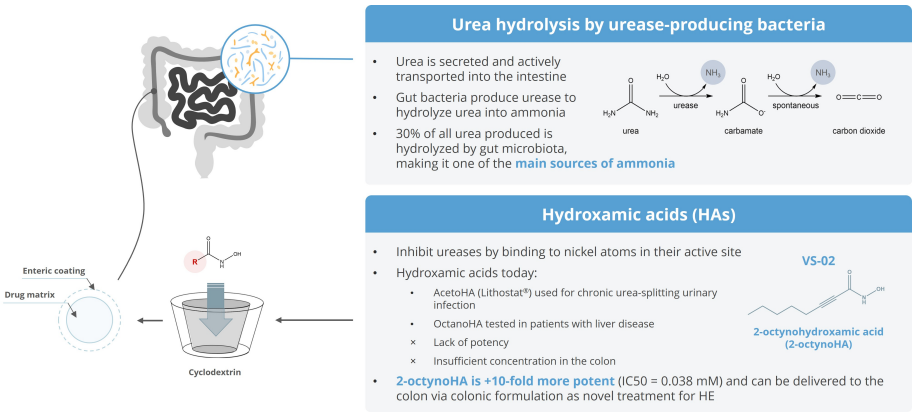
HE is largely underdiagnosed and undertreated and is associated with poor quality of life. Due to its neurotoxic effect, ammonia has been the main target for HE therapy. Current treatment options for HE focus on either reducing ammonia production and absorption (e.g., non-absorbable disaccharides) or on promoting its elimination by eliminating ammonia-producing colonic bacteria (e.g., antibiotics). Non-absorbable disaccharides such as lactulose, however, exhibit various limitations such as persistent side effects leading to poor compliance which indirectly affects overall efficacy. Additionally, antibiotics (e.g., rifaximin), according to the approved label for rifaximin as of the date of this annual report, are limited to the reduction of overt HE recurrence rather to the treatment of overt HE.

- **Our Program: VS-02-HE for the Reduction of Hyperammonemia & the Stabilization of Blood Ammonia**

– *VS-02: rationale and mechanism of action*

As urease-producing bacteria in the gut are one of the main sources of circulating ammonia in humans, urease-inhibitors may represent a promising therapeutic approach for HE.

We are developing VS-02, a urease inhibitor currently in preclinical stage. VS-02 is a hydroxamic acid (HA) derivative, which is designed to inhibit ureases by binding to nickel atoms in their active site. Inspired by earlier studies, the in vitro activity of a series of novel hydroxamic acid (HA) derivatives was investigated on rat caecum content. The lead candidate, VS-02 (2-octynohydroxamic acid (2-octynoHA)), showed a potency largely exceeding that of HA derivatives tested in former clinical trials. It was further found that VS-02 was neither cytotoxic nor mutagenic at up to 1 mM, which makes it an ideal candidate for development as a novel treatment for HE via a colonic formulation.



– *Evidence supporting further development*

In vivo efficacy studies showed that VS-02-HE (30 mg/kg) was able to reduce ammonia blood levels in bile-duct ligated (BDL) rats. Additionally, in vivo 1H MRS measurements performed at 9.4T in the cerebellum (SPECIAL sequence, TE=2.8ms, VOI=2.5x2.5x2.5mm3) showed a significant decrease in brain glutamine levels after 5 days of treatment compared to non-treated BDL rats confirming the therapeutic effects of VS-02-HE. In summary, we believe VS-02-HE represents a promising oral candidate for further evaluation in the treatment of HE.

– Next milestones

We intend to develop VS-02-HE as a unique oral formulation designed to minimize systemic absorption of ammonia and to act where ammonia is primarily produced, while reducing glutamine levels in the brain. The treatment goal is to reduce/stabilize the accumulation of ammonia in the blood and prevent rehospitalization.

Investigational New Drug-enabling nonclinical studies are targeted to be completed in 2025.

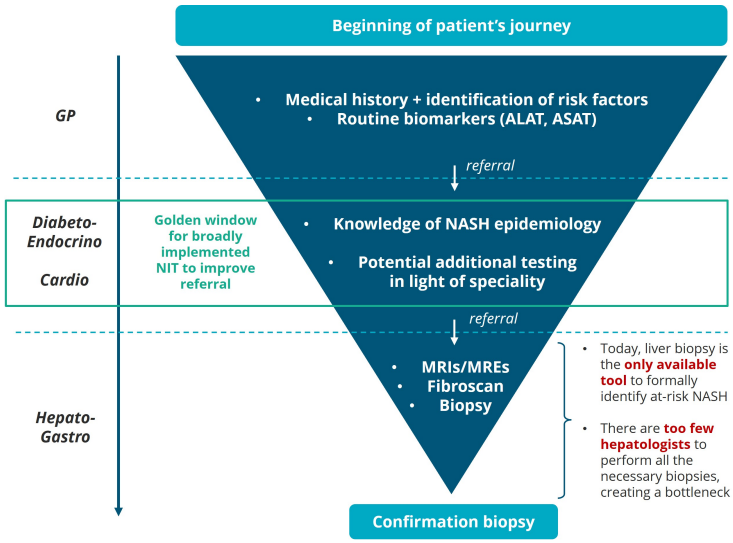
– ***NIS2+™, a next-generation technology derived from NIS4 for the identification of patients with at-risk NASH***

- ***About NASH***

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

– Today's Challenges in Diagnosing NASH

Liver biopsy is the reference standard for the diagnosis of NASH among patients with clinical risk factors for this disease, such as metabolic disorders in the absence of alternative causes for steatosis. The implementation of this diagnostic approach, however, is limited in routine clinical practice by its invasive procedure, cost, attendant risks, variability in interpretation, and the restricted number of professionals able to perform and interpret the test, among other factors. These limitations preclude liver biopsies from being broadly used as the primary diagnostic in such a prevalent disease. Providing a non-invasive alternative to liver biopsy will therefore be critical to facilitate improved patient diagnosis, management, and future treatment access in routine clinical practice, and may eventually reduce the morbidity and mortality associated with this disease.



At the end of 2022, Madrigal Pharmaceuticals announced positive data in its pivotal Phase 3 MAESTRO-NASH clinical trial of resmetirom for the treatment of NASH and liver fibrosis. If this leads to the first-ever approved drug for the treatment of NASH, the incentive to diagnose is expected to increase over the coming years.

The treatment of NASH is a pressing public health challenge and there is a large unmet need for a widely available, non-invasive test, or NIT, to identify patients with at-risk NASH as an alternative to liver biopsy. The availability of such a test would help address the under diagnosis of NASH by supporting physicians in identifying patients with at-risk NASH, who are at higher risk for clinical outcomes and would be eligible for therapeutic intervention.

- **Our Technology: NIS2+ Technology Comprising Our Proprietary Biomarker Algorithm**

As part of our strategy to address unmet needs in NASH, we have an advanced our diagnostic program based on the identification of specific biomarkers that are expressed at different levels in patients with NASH and significant fibrosis (F≥2) as compared to patients with less severe disease. This discovery kicked off a multi-year effort that has resulted in the development of NIS4 technology, a blood-based molecular technology for the identification of patients with NASH (NAS≥4) and significant fibrosis (F≥2), also referred to as "at-risk" NASH, who are at higher risk of disease progression and may be appropriate candidates for therapeutic intervention.

Our first biomarker technology, NIS4, integrated the outputs of four NASH-associated biomarkers (alpha-2-macroglobulin, YKL-40, hemoglobin A1c, and miR-34a-5p) through an algorithm to produce a single score that can be utilized to rule in and rule out at-risk NASH, while minimizing the number of indeterminate test results.

- In August 2020, we announced that pivotal data describing the derivation and validation of NIS4 technology was accepted for publication by The Lancet Gastroenterology & Hepatology.

- In November 2021, NIS4 technology's utility was demonstrated in a biomarker qualification Phase 1 study undertaken by NIMBLE with a strong performance for identifying patients with "at-risk" NASH and the components of "at-risk NASH (NASH, NAS > 4 and fibrosis stage > 2).

We out-licensed our NIS4 technology to Labcorp in 2019 and 2020 in the field of clinical research and for the development of an LDT, respectively. In 2021, we also signed a non-exclusive license with Q Squared Solutions LLC, or Q2, with the objective to broaden access to our NIS4 technology in the clinical research space. See "Item 4.B—Commercialization perspectives—Out-licensing partnerships."

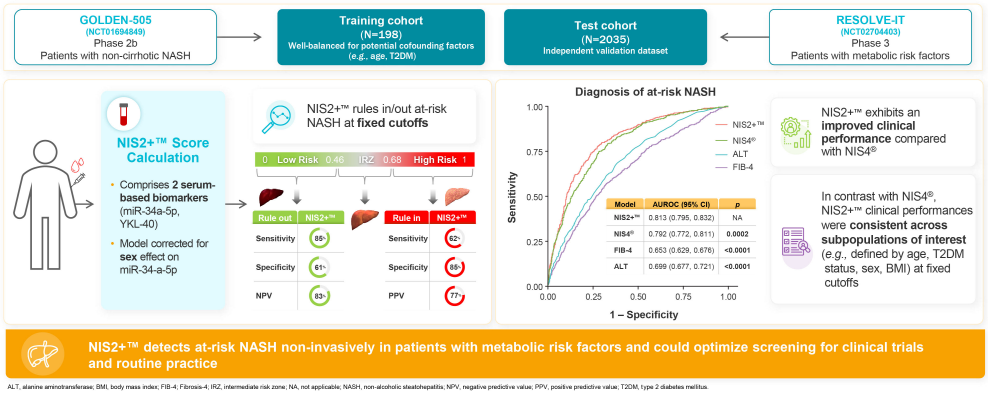
– NIS2+, a next-generation technology for identification of at-risk NASH

In October 2022, we announced the development of NIS2+, a next-generation technology for the diagnosis of at-risk NASH, and the presentation of results on NIS2+'s clinical performance in three poster presentations at The Liver Meeting® 2022 organized by the American Association for the Study of Liver Diseases (AASLD):

- The first poster highlighted NIS2+ as an optimization of NIS4 technology for identifying at-risk NASH. This next-generation technology aims to address the unmet needs for identifying patients with at-risk NASH using non-invasive tests (NITs) that are not impacted by critical patient characteristics. NIS2+ demonstrated strong clinical performance in detecting at-risk NASH, while its composite scores were not impacted by the status of important subpopulations such as Type-2 diabetes, age and sex. While NIS4's performance was compelling, the composite score distributions were significantly impacted in some subpopulations. In addition, the increased robustness and simplicity of NIS2+™ technology (from a 4 to 2-biomarker panel) may allow for a wider and easier application in clinical settings.

- The second poster demonstrated the potential for NIS2+ to be used as an effective screening tool for the enrollment of patients with at-risk NASH in clinical trials, reducing liver biopsy failure rates and associated costs without inflating the number of patients to screen.

- The data in the third poster positioned NIS2+ as a potentially valuable prognostic tool for early detection of fibrosis progression in at-risk NASH patients with significant fibrosis (F2) towards advanced fibrosis (F3) and cirrhosis (F4).



ALT, alanine aminotransferase; BMI, body mass index; FIB-4, Fibrosis-4; IRZ, intermediate risk zone; NA, not applicable; NASH, non-alcoholic steatohepatitis; NPV, negative predictive value; PPV, positive predictive value; T2DM, type 2 diabetes mellitus.

The timely diagnosis of patients with at-risk NASH constitutes a critical unmet medical need, which we intend to address with this new next-generation diagnostic tool, if approved. NIS2+ simplifies the analytical process with only two biomarkers, is more robust in terms of composite scores across critical subpopulations of interest than NIS4 and can be implemented widely in clinical practice. We anticipate that, if approved in clinical practice, NIS2+ could be a diagnostic test of choice to select NASH patients in need for pharmacotherapy, by bypassing the need for liver biopsy – a real progress for patient management. Moreover, there is a need for non-invasive tests to facilitate enrollment in NASH clinical trials, so that the number of liver biopsies, with their many challenges, can be reduced.

Currently, there are four non-invasive diagnostic tests developed to identify at-risk NASH. Three of them involve both imaging and blood-based biomarkers. These are FAST (LSM by VCTE, CAP and AST), MAST (MRI-PDFF, MRE and AST) and MEFIB (MRE and FIB-4). However, NIS2+ is the only blood-based biomarker technology in development for the identification of at-risk NASH, potentially allowing it to be applied for large-scale use in clinical practice as it is more accessible than other tests which are only available at secondary care sites and can be processed in big centralized laboratories .

– *Next milestones*

We began communications with the FDA in 2017 to discuss potential regulatory pathways for an IVD powered by NIS4 technology.

We believe the future of NIS2+ is through an IVD test as a standalone diagnostic with the potential to enable a non-invasive, accessible and validated alternative to the liver biopsy to benefit patients, improve overall clinical care and greatly reduce barriers to entry for innovative therapies.

Prior to obtaining any FDA approval in the United States or CE Certificates of Conformity in the EEA, we, or a partner, will need to finalize the analytical and clinical study designs which are required prior to initiating formal validation studies for both the FDA and Notified Body submissions. Such studies are expensive and require significant investment.

We continue to explore the possibility of initiating and completing validation studies necessary to obtain regulatory approval and CE Certificates of Conformity, alone or with a development and commercial partner, to release an IVD powered by NIS2+ technology on the US and European markets. In the meantime, we will continue to seek the most appropriate ways to optimize on the potential of NIS2+.

– ***TS-01 as a point of care (POC) device for measuring ammonia in blood***

Approximately 90% of hyperammonemia cases in adults are in people who have cirrhosis of the liver. Cirrhosis is the end stage of every chronic liver disease and is the 11th leading cause of death worldwide. Globally, an estimated 112 million people suffer from compensated cirrhosis, claiming more than 1.3 million lives in 2017. Complications of cirrhosis are marked by liver metabolic dysfunctions and the development of clinical signs, of which the most frequent is HE. HE is a serious neurologic condition caused when ammonia accumulates in blood, eventually affecting the brain. Elevated ammonia concentration in blood and brain (hyperammonemia) is associated with high mortality and is the mainstay for pathogenesis and treatment of HE. In patients with cirrhosis, fully symptomatic overt HE leads to hospitalizations and readmissions. HE-related hospitalizations generated charges of approximately US $11.9 billion per year in the United States, a 46% cost increase from 2010 to 2014. Costs are expected to further increase due to disease progression, requiring more complex health care efforts.

Overt HE occurs in 30-45% of patients with cirrhosis, leading to approximately 1 million cases considering 2,828,000 cases of cirrhosis worldwide. There is a need for a reliable point of care devise to measure ammonia in the blood in patients with HE, so that there can be a repeated quantification of ammonia levels to test the efficacy of ammonia-lowering treatments. Furthermore, ammonia levels can predict the onset of new episodes of HE even with mild hyperammonemia, but there are currently logistical challenges to accurately measure ammonia in the blood.

We believe that the ammonia POC diagnosis would complement both VS-01 and VS-02 product candidates and is in line with our business strategy to improve the management of severe liver diseases globally. We believe combining diagnostics with therapeutics under one umbrella synergistically multiplies the value of each product.

– A high unmet medical need

When patients with altered mental status are admitted to the emergency department, HE should be diagnosed as fast as possible to initiate further diagnostic tests, especially in the emergency department, where resources of medical staff and time are limited. Since many of the symptoms of HE also occur in people with other types of brain disease or damage (e.g., stroke, brain tumor, or bleeding inside the skull), an ideal bedside test for fast, precise and accurate ammonia measurements would:

– Allow for the rapid diagnosis of HE. A high ammonia level increases the probability of HE especially in patients who have known liver disease.

– Trigger other diagnostic steps to explore other etiologies of altered mental status (a low ammonia level reduces the probability of HE) or to rule out potential gastrointestinal bleeding if HE confirms (e.g., endoscopy).

– Initiate specific medical treatment (e.g., lactulose/antibiotic therapy). Especially in the emergency department, where resources of medical staff and time are limited.

In addition, self-monitoring of ammonia with an accurate and user-friendly POC device offers the opportunity for early identification of severe HE episodes, timely therapeutic management, and therefore decreasing hospital visits, long-term risks of complications, and global burden on public health. Moreover, close follow-up of the ammonia offers the possibility to better tailor current therapies for HE, which are unfortunately associated with poor compliance due to their side effects. Adapting treatment dose and schedule, can increase compliance and hence reduce occurrence of severe episodes. Finally, HE impacts daily functioning by altering fitness to drive, attention, memory, mood, and psychomotor speed. A tighter control of the disease is expected to increase the quality of life of patients and their families.

Today, serum ammonia testing and interpretation remain logistically challenging. After the sample is collected, erythrocyte and platelet metabolism persist in vitro, and ammonia concentrations increases at room temperature. Therefore, it is recommended that samples are kept on ice and immediately processed after collection, which increases the overall burden on staff.

Despite these challenges, the literature indicate that serum ammonia testing is increasing. Future improved ammonia testing may enhance value-based use of ammonia in patients with cirrhosis and HE. A POC device for ammonia is expected to save time, efforts, and expenses to the health care professionals while supporting caregivers, and family members.

Currently, the only marketed POC device for ammonia measurement is the PocketChem. It is mainly used in research because of its narrow quantification range (7-286 µmol/L), its interference issues and underestimation of ammonia levels in comparison to enzymatic assays.

- **TS-01 for at-home monitoring of ammonia in liver disease patients to help detect HE**

TS-01 is a device based on a "transmembrane pH-gradient polymersome" technology designed to easily measure ammonia levels at home.

The underlying technology behind the Transmembrane pH-gradient polymersomes for ammonia quantification in blood consist of vesicles made of non-biodegradable polymers that form a bi-layer membrane. The aqueous core of the vesicles is loaded with a pH-sensitive dye in an acidic buffer. An alkaline buffer on the outside generates the pH-gradient across the polymersomes' membrane. Uncharged ammonia in blood samples can easily diffuse across the polymeric membrane into the core of the polymersomes, where it is protonated due to the acidic environment. Generated ammonium ions cannot diffuse back due to their charge. Accumulation of protonated ammonia inside the core of the vesicles triggers an increase in pH and consequently an increase in fluorescence intensity of the pH-sensitive dye. The increase correlates with the ammonia concentrations in the sample. When an equilibrium state is reached, fluorescence can be easily measured and thus ammonia concentrations in blood derived. We believe this unique mechanism will allow us to scale polymersome technology from high throughput to single measurements in a POC.

TS-01 was developed and validated by the university, ETH Zurich and we hold an exclusive worldwide license to develop and commercialize TS-01 in all fields, with an option to purchase the intellectual property subject to certain conditions.

- *Next milestones*

The development of TS-01 will be performed in collaboration with ZHAW School of Engineering with expertise in optoelectronics as well as in the development of demanding biomedical instrumentation.

The goal of this project is to build a prototype device which will be fast (≤1.5 min), selective (no interactions or selectivity issues), and sensitive (≤80 µL sample volume) over a wide concentrations range (30 µM–800 µM), covering physiological and pathological levels.

- **Commercialization perspectives**

- ***Out-licensing Partnerships***

  - **Strategic Collaboration with Ipsen**

In December 2021, we entered into a long-term strategic partnership for global collaboration with Ipsen Pharma SAS, or Ipsen, a global, mid-sized biopharmaceutical company focused on transformative medicines in oncology, rare disease and neuroscience. The agreement gives Ipsen an exclusive worldwide (excluding Greater China which is licensed to Terns, see below) license to develop, manufacture and commercialize our investigational treatment elafibranor, for people living with PBC, and in other indications. The partnership also gives Ipsen access to future clinical programs led by GENFIT through rights to first negotiation and combines GENFIT's scientific expertise and proprietary technologies in liver disease with Ipsen's development and commercialization capabilities.

GENFIT remains responsible for the Phase 3 ELATIVE trial until the completion of the double-blind treatment period. Ipsen will assume responsibility for all additional clinical development, including completion of the long-term, open-label extension period of the ELATIVE trial, and global (excluding Greater China) commercialization.

Under the agreement, Ipsen will pay GENFIT up to €480m, comprising an upfront cash payment of €120m, as well as regulatory, commercial, and sales-based milestone payments up to €360m, plus tiered double-digit royalties of up to 20%. In addition, to underscore its long-term commitment, Ipsen also became our largest shareholder through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28m investment. The new shares are subject to a lock-up period ending on the earlier of the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorization of elafibranor in PBC, the date on which the FDA grants approval of elafibranor in PBC or in the event the ELATIVE trial does not meet its primary endpoint.

This agreement will remain in force until the later of either a 10-year period after the first sale of a licensed product in the territory or the expiration of the last patent concerning such a licensed product in the relevant country (determined on a per-country basis).

- **Agreement with Terns Pharmaceuticals**

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

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

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

This agreement will remain in force until the later of either a 10-year period after the first sale of a licensed product in the territory or the expiration of the last patent concerning such a licensed product in the relevant territory (determined on a per-territory basis).

- **Agreements with LabCorp and Q2**

In January 2019, we entered into a worldwide, non-exclusive license agreement with Labcorp, a global life sciences leader specializing in health improvement and patient treatment decision support, to enable them to further develop and deploy NIS4 in the context of clinical research. We believe this agreement will provide expanded access to, and further validation of an LDT powered by NIS4. Initially, we have enabled Labcorp, through its subsidiary Covance, to market and sell an LDT powered by NIS4 test in the context of clinical research studies. Covance processes samples and provides test results to clinical trial sponsors. Covance has made significant progress in the deployment of NIS4 in several clinical trials conducted by leading players in the pharmaceutical industry. Covance is permitted and accredited, and will be responsible for submitting any validation that may be required under applicable state and federal laws.

In September 2020 we and Labcorp announced the signature of a five-year exclusive license agreement for our NIS4 technology, which seeks to enable easier identification of patients with at-risk NASH. Under the license agreement, Labcorp will commercialize a blood-based molecular test based on NIS4 technology in the United States and Canada, thereby making it more widely accessible to health professionals. In April 2021, Labcorp launched the LDT called "NASHnext" powered by the NIS4 technology.

In May 2021, we signed a worldwide, non-exclusive license agreement with Q2 to broaden the availability of NIS4 technology in the clinical research field.

- **In-licensing Partnerships**

- **License and Development Agreement with Genoscience Pharma**

On December 16, 2021, we signed an exclusive license from Genoscience Pharma to develop and commercialize the investigational treatment GNS561 in CCA in the United States, Canada and Europe, including the United Kingdom and Switzerland. Genoscience Pharma is a French clinical-stage biotechnology company developing novel lysosomotropic therapeutics to establish a new standard of care against cancer, autoimmune and infectious diseases.

Under the agreement, Genoscience Pharma is eligible for clinical and regulatory milestone payments of up to €50 million and tiered royalties. The first payable milestone is contingent on positive Phase 2 clinical trial results, and may result in payments of up to €20 million.

In addition, we also have a right of first negotiation with respect to any license or assignment, or option for a license or an assignment, with any third party to develop or commercialize other Genoscience Pharma assets in the field of CCA, to the extent Genoscience Pharma is looking to partner the asset with a third party or receives a spontaneous offer for collaboration.

For the period commencing on the date of the agreement until the first regulatory approval of GNS561 for commercialization, Genoscience Pharma has the right to repurchase the license to GNS561 in CCA at a pre-determined price in the event that Genoscience Pharma receives an offer from a third party to acquire or obtain a license to GNS561 in all indications, provided that GENFIT shall first have the opportunity to negotiate the acquisition or license to GNS561 in all indications.

The agreement shall remain in force, on a country by country basis in the territory until the later of (i) the date on which the last patent rights included in the licensed patents expires, or is otherwise cancelled, withdrawn or abandoned, in such country, or (ii) upon the regulatory approval of a generic product with respect to the licensed product in such country or (iii) the tenth anniversary of the first commercial sale of the licensed product in such country.

GENFIT also purchased a 10% equity stake in Genoscience Pharma through the subscription of new ordinary shares for a total amount of approximately €3.1 million.

- ***Competitive Landscape***

Because we focus on therapeutic areas with high unmet medical needs, characterized by a lack of diagnostic or treatment options, there are relatively few companies with approved products compared with other therapeutic or diagnostic areas where several options are already approved from a regulatory standpoint, and available for healthcare providers and patients.

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

  - **PBC**

Only two drugs are approved in this indication. UDCA, approved by the FDA to treat PBC in 1997, remained the only approved treatment for PBC until 2016, when Ocaliva was approved by the FDA and European Medicines Agency for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

The other molecule that could become a direct competitor of elafibranor is seladelpar, developed by the American company CymaBay, which announced its intention to readout topline data for its Phase 3 (RESPONSE) trial in the third quarter of 2023.

Other companies are developing other less advanced drug candidates and may also become competitors. For instance, Calliditas Therapeutics announced in 2022 that the first patient was enrolled in its Phase 2b/3 TRANSFORM study evaluating setanaxib in patients with PBC.

  - **ACLF**

No drugs have been approved in this indication so far and the only therapeutic option is liver transplantation. Some companies, such as Cellaïon, are investigating the potential of certain technologies, but given known challenges in the space, those would likely become complementary to what GENFIT is developing rather than direct competitors.

  - **CCA**

Current treatment options are limited to chemotherapy. The current pipeline of drugs in development includes anti-PD-(L)1 combinations, FGFR2 and PARP inhibitors. FGFR2 and PARP inhibitors are limited to patients with specific alterations, while the expectations from anti-PD-(L) to work in CCA are currently low. A combination of atezolizumab and cobimetinib (anti-PD-(L)1 and MEKi) is being evaluated but preliminary data do not show a major benefit.

  - **HAC in UCD and OA**

No drugs have been approved for HAC. However, Buphenyl and Ravicti are ammonia scavengers approved in UCD in the US and in the US and Europe, respectively.

  - **HE**

Standard-of-care therapeutics include lactulose (with various brands) and rifaximin (Xifaxan approved in the US and EU, and Rifxima approved in Japan), both oral treatments aiming to reduce ammonia. LOLA (Hepa-Merz approved in the EU) is a third option, but not approved in the US.

  - **NASH Diagnostics**

No blood-based diagnostic solution is validated to identify "at-risk" NASH. In November 2021, our NIS4 technology’s utility was recognized in a Phase 1 study undertaken by NIMBLE as demonstrating a unique performance in identifying patients with “at-risk” NASH versus four other blood-based biomarker panels available for the management of chronic liver disease patients.

  - **At-home ammonia monitoring**

The international state of the art of ammonia quantification in blood is enzymatic assays that are implemented in extremely costly large automatic analyzer machines usually only available at central or hospital clinical laboratories. Considering that ammonia blood samples should be collected on ice and analyzed within the hour, these limitations may delay the results and may add uncertainties to the diagnosis of HE.

These main limitations of the current gold standard can be resolved with a reliable point of care device at the patients' bedside. The current point of care device commercially available (Arkray’s PocketChem BA analyzer) is however limited by its narrow quantification range (7-286 µmol/L), its interference issues and its underestimation of ammonia levels in comparison to enzymatic assays.

Therefore, the need of a fast, accurate, and precise point of care device has not yet been achieved satisfactorily.

- **Other considerations**

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

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

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

– ***Manufacturing and Supply***

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

With respect to our lead drug candidate, elafibranor, we use one supplier for the active ingredient and another manufacturer for the therapeutic units used in our clinical trials. The stock of therapeutic units is sufficient to cover the supply of the part of the ELATIVE Phase 3 clinical trial under our responsibility. The remaining active ingredient and therapeutic units stocks have been sold to Ipsen to meet their short term clinical needs. Thereafter, Ipsen will manage its clinical and commercial needs for elafibranor directly.

Pursuant to our agreement with Genoscience Pharma, Genoscience Pharma will supply our clinical and commercial requirements for GNS561.

NTZ is already approved and commercialized in several jurisdictions in various indications and we therefore purchase our supply of NTZ for clinical purposes in the market through pharmaceutical wholesalers.

VS-01 contains citric acid anhydrous as active ingredient for which a supply agreement covering clinical trials is in place with a third party GMP supplier. VS-01 is a kit containing three intermediate products, supplied by two different GMP suppliers. The kit is to be reconstituted at the pharmacy hospital based on the instructions provided in the pharmacy manual and prior administration to patients.

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

ix. Intellectual Property

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

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

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

– **Patents**

As of April 1, 2023, we own or have rights to 50 issued U.S. patents, over 527 issued foreign patents in force, and 26 pending U.S. applications, and over 366 pending foreign patent applications. Our patent portfolio contains 70 different patent families, which are made up of over 890 patents and patents applications. Twenty-five of our patent families relate to our lead product candidate, elafibranor. Following the acquisition of Versantis AG, three patent families (including two U.S. applications and two issued U.S. patents) were integrated into our patent portfolio.

- **Elafibranor**

Our patent portfolio for elafibranor, a molecule synthesized by us, includes issued patents and pending patent applications directed to compositions of matter, manufacturing methods, and methods of use. As of April 1, 2023, we own three U.S. patents directed to the composition of matter of elafibranor, which are expected to expire in 2024, without taking patent term extensions into account. We also have counterpart patents in various countries and regions, including Australia, Brazil, Canada, China, Europe, Israel and Japan.

In addition, we own two US granted patents and four U.S. patent applications (some of them derivable from PCT applications) directed to the treatment of cholestatic diseases, in particular PBC, which, if issued, are expected to expire in 2037 and 2041, without taking patent term extensions into account. We also have counterpart pending patent applications in various countries or regions, including Australia, Canada, Europe, Israel, China, and Japan.

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

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

- **Repurposing of molecules**

We are pursuing patent protection directed to our repositioning of nitazoxanide for treating cholestatic and fibrotic diseases. As of April 1, 2023, six U.S. patents have been granted for the use of NTZ in the treatment of different fibrotic diseases. Three U.S. patents have been granted for combination of NTZ with other therapeutic agents in the treatment of different fibrotic diseases and one other U.S. patent application is pending. These patents and patent applications, if granted, would be expected to expire in 2037 and 2038 (excluding any patent term extension).

We also filed in 2022 four international patent applications for the use of nitazoxanide and some other proprietary molecules in the treatment of ACLF / sepsis.

We also filed in 2022 one priority patent application on other repurposing compounds for treating ACLF, reinforcing our patent portfolio on ACLF.

- **Diagnostic Tools and Biomarkers**

As of April 1, 2023, we own five U.S. patent applications directed to the diagnosis of NASH, in particular our NIS4 diagnostic technology, using certain biomarkers. The U.S. applications, if issued, would be expected to expire between 2036 and 2041.

We also have filed several US patent applications covering some other NIS4 diagnostic tools and protecting some other research tools. We filed in 2022 an international patent application and three priority patent applications on methods and devices for diagnosis of NASH, liver fibrosis or liver cirrhosis.

- **Patent Term Extension (PTE)**

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

- **Trademarks**

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

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

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

We own more than 500 registered or filed trademarks worldwide.

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

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

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

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

- **Domain names**

It is our policy to file domain names for communicating or giving information on our products or services to patients, prescribers or payers. We own today close to 200 domain names.

- **Know-How and Trade Secrets**

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

x. Government Regulation

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

– **United States Government Regulation**

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

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

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

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

Preclinical and Human Clinical Trials in Support of an NDA

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

Clinical trials involve the administration of the drug candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Each clinical trial must be reviewed and approved by an IRB at each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

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

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

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

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

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

Submission and Review of an NDA

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

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

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

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and clinical trial sites, the FDA will issue either an approval of the NDA or a Complete Response Letter, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the application. Even with submission of this additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval.

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

Fast Track and Breakthrough Designations

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

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

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

Accelerated Approval Pathway

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

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the drug. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Requirements

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

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug. After approval, most changes to the approved drug, such as adding new indications or other labeling claims and some manufacturing and supplier changes are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for marketed drugs, as well as new application fees for certain supplemental applications.

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

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

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including adverse events or AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

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

Section 505(b)(2) NDAs

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

Orphan Drug Designation

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

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

– **FDA Regulation of In Vitro Diagnostics**

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

Device Classification

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

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

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and post market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to either:

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

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

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

The PMA Process

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

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

Laboratory-developed Tests

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

– European Union Regulation for Drug Development and Registration

Privacy and Security

We may be subject to diverse laws and regulations relating to data privacy and security as a result of our employee data or other personal information that we may collect. In addition, if we do collect personal data as part of any clinical trials or other testing, we would be subject to regulatory obligations. This includes, (i) in the European Union, or EU, and the European Economic Area, or EEA, the EU General Data Protection Regulation, or EU GDPR, (ii) in the United Kingdom, or UK, the UK GDPR. EU member states are also able to legislate separately on health and genetic information, and we must comply with these local laws where we operate. For example, in France, the conduct of clinical trials is subject to compliance with reference methodologies (such as MR-001) imposing stringent rules to process health-related information.

Preclinical and Clinical Development

In the European Economic Area (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), our drug candidates are also subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory authorities has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the EEA are subject to significant regulatory controls.

In the EEA, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD, and related national implementing legislation of EEA countries.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the Regulation, which is directly applicable in all EEA countries, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reporting Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EEA countries. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned Member State. Individual EEA countries retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. Sponsors could choose to submit a clinical trial application under either the CTD or the CTR until January 31, 2023. For clinical trials in relation to which application for approval was made on the basis of the CTD before January 31, 2022, the CTD will continue to apply on a transitional basis for three years. If authorized, those clinical trials will be governed by the CTD until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework.

European Union Drug Review and Approval

In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

To obtain an MA for a product in the EEA, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by the Competent Authorities of EEA countries (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EEA countries. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval. Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EEA country in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EEA countries.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EEA country to apply for this authorization to be recognized by the competent authorities in other EEA countries. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of EEA countries of the MA of a medicinal product by the competent authorities of other EEA countries. The holder of a national MA may submit an application to the competent authority of an EEA country requesting that this authority recognize the MA delivered by the competent authority of another EEA country.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EEA country in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of EEA countries may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EEA market (for a centralized MA) or on the market of the authorizing EEA country within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EEA, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

EU Pediatric Development

In the EEA, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EEA countries and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. For other countries outside of the EEA, such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Orphan Drugs in the EU

In the EEA, Regulation (EC) No 141/2000, as implemented by Regulation (EC) No. 847/2000, provides that a drug will be designated as an orphan drug if its sponsor can establish:

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

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

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. If an EU MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, the EMA cannot, for a period of usually 10 years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for orphan drug designation are no longer met, including, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. The exclusivity period may increase to 12 years if, among other things, the MAA includes the results of studies from an agreed pediatric investigation plan. Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the manufacturer for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior. Regulation (EC) No 847/2000 lays down definitions of the concepts 'similar medicinal product' and 'clinical superiority'.

Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan drug designation does not shorten the duration of the regulatory review and approval process.

EU Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving marketing authorization, innovative, medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial contained in the dossier of the reference product when submitting a generic application or biosimilar MAA for eight years from the date of authorization of the reference product. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period will be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity. In the EEA, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an MAA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

EU Regulatory Requirements after Marketing Authorization

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EEA countries. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EEA, the advertising and promotion of medicinal products are subject to both EU and EEA countries' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EEA countries and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EEA. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EEA.

In Vitro Diagnostics

On 26 May 2022, Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDs), or the IVDR, entered into application, repealing and replacing Directive 98/79/EC concerning IVDs, or IVDD. The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs must comply with the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the IVDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of IVD and its classification. Apart from low risk IVDs (Class A which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. After a device is placed on the market, it remains subject to significant regulatory requirements.

French Regulatory Framework on Transfer of Values to Health Care Professionals

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

- The Anti-Benefit regime prohibits companies that produce or market healthcare products or provide services related to healthcare products, or healthcare companies, from offering or promising benefits in cash or kind to healthcare professionals admitted to practice in France (Article L.1453-3 of the French Public Health Code). In certain limited circumstances, benefits may be excluded from this general prohibition. Exceptions include benefits of negligible value (Article L.1453-6 of the French Public Health Code). Additional exceptions apply to benefits such as remuneration, compensation or disbursements to healthcare professionals in relation to scientific research, speaker fees or hospitality provided in the course of scientific event. This includes benefits provided on the basis of a prior written agreement concluded between the parties where, depending on the amount of the benefit, the benefit is either notified to or authorized by the French competent authority prior to granting the benefit (Article L.1453-7 of the French Public Health Code).
- The Transparency or Sunshine regime, set out by Article L.1453-1 of the Public Health Code, requires healthcare companies in France to publicly disclose the benefits and fees paid to healthcare professionals admitted to practice in France where the related amount is 10 euros or above. The related agreements concluded between the parties, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.) must also be disclosed. Information must be submitted to the website https://www.entreprisestransparence.sante.gouv.fr and will be disclosed twice a year through this website.

– ***Reimbursement***

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

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

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

With respect to NASHnext, the LDT powered by NIS4 technology, Labcorp, as the laboratory partner, is responsible for marketing the product to healthcare providers and is responsible for seeking coverage and reimbursement from third party payors, including Medicare and Medicaid. Separately, our strategy is to seek FDA marketing authorization for a kit-based IVD powered by NIS4 or its improvements to allow us to commercialize the test within the United States as a medical device. In parallel, we intend to progress towards submitting an application for a CE Certificate of Conformity to a European Notified Body in the EEA to enable CE marking, alone or with a potential future partner. In Europe, we are still finalizing our plans but are considering, if the appropriate approvals or certifications are obtained, selling the IVD powered by NIS4 through a distributor or commercial partner to independent, smaller laboratories, as there are fewer large central laboratories in these regions. We, or our collaborators, will be required to obtain coverage and reimbursement for this test separate and apart from the coverage and reimbursement we plan to seek for our product candidates, if approved. There is significant uncertainty regarding our ability to

obtain coverage and adequate reimbursement in some or all commercial territories for this test for the same reasons applicable to our product candidates.

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

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

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

In the EEA, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, some EEA countries may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EEA countries allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EEA countries have increased the amount of discounts that pharmaceutical companies are requirement to offer. These efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products onto national markets. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EEA countries, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices.

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EEA country, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA countries. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EEA countries. In December 2021, the EU Parliament adopted the HTA Regulation which aims to harmonize the clinical benefit assessment of HTA across the EEA, the consequences of which remain unknown at this time. The anticipated revenue from and growth prospects for products in the EEA could be negatively affected by the HTA Regulation.

– ***Healthcare Reform***

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

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, enacted in the United States in March 2010, has had a significant impact on the healthcare industry. The ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program.

There have been judicial, executive and Congressional challenges, as well as number of proposed and enacted health reform measures that have impacted certain aspects of the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to additional judicial or Congressional challenges in the future. It is unclear how any such challenges or the health reform measures of the Biden Administration will affect the ACA.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S Presidential Orders, U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, for example, the IRA, among other things (i) directs the Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

– ***Other U.S. Healthcare Laws and Compliance Requirements***

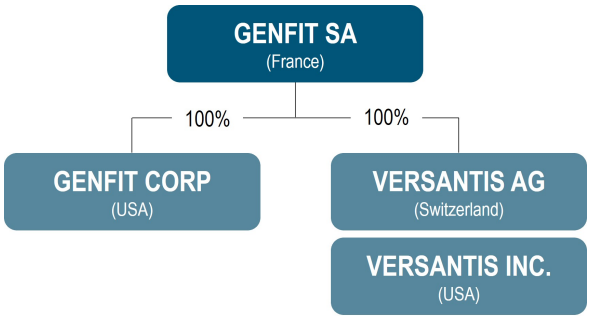
Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients expose us to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, our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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, which can be enforced by private individuals through civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibits individuals and entities from, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (defined to include doctors, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes certain requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their business associates, which are individuals and entities that perform functions or activities on behalf of covered entities that involve protected health information, relating to the privacy, security and transmission of protected health information; and
- State and foreign equivalents of each of the above federal laws and regulations, such as: state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; and state and/or foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

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

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

C. Organizational Structure



In September 2022, we finalized the acquisition of Versantis AG, and its US-based wholly-owned subsidiary, Versantis, Inc. Versantis, Inc. does not currently have any operational activities. For more information about the acquisition, see Note 2.1 to our consolidated financial statements included in this annual report under the caption "Acquisition of the Clinical-stage Biopharmaceutical Company Versantis".

In November 2022, we liquidated GENFIT Pharmaceuticals SAS, a wholly-owned subsidiary which did not have any operational activities.

D. Property, Plants and Equipment

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

Item 4A. Unresolved Staff Comments.

Not applicable.

Item 5. Operating and Financial Review and Prospects.

Overview

We are a late-stage clinical biopharmaceutical company dedicated to the discovery and development of innovative drug candidates and diagnostic solutions targeting liver-related diseases where there is considerable unmet medical need. We are a pioneer in the discovery and development of drugs for liver diseases with a rich history and strong scientific heritage spanning almost two decades. Our portfolio now covers six therapeutic areas with six drugs at different development stages (preclinical, Phase 1, Phase 2 and Phase 3), with different mechanisms of action: elafibranor in Primary Biliary Cholangitis, or PBC, nitazoxanide, or NTZ, and VS-01-ACLF in Acute on Chronic Liver Failure, or ACLF, GNS561 in cholangiocarcinoma, or CCA, VS-02-HE in Hepatic Encephalopathy, or HE, and VS-01-HAC in Urea Cycle Disorder, or UCD, and Organic Acidemia, or OA. We also work on non-invasive diagnostic solutions in nonalcoholic steatohepatitis, or NASH, and ACLF, essentially to identify patients eligible for treatment alongside our therapeutic programs in ACLF. In September 2022, we acquired Versantis AG, a private Swiss-based clinical stage biotechnology company, focused on addressing the growing unmet medical needs in liver diseases. With the acquisition, we added Versantis' assets VS-01, VS-02 and TS-01 to our pipeline.

Elafibranor, our most advanced product candidate, is currently being evaluated as a potential treatment for PBC in a Phase 3 clinical trial, ELATIVE, which began in 2020. We expect topline data from the Phase 3 ELATIVE clinical trial will be available towards the end of the second quarter of 2023.

The worldwide development and commercialization rights in elafibranor for the treatment of PBC and other indications were licensed to Ipsen Pharma SAS, or Ipsen, through a partnership agreement signed in December 2021, with the exception of Greater China, which is licensed to Terns Pharmaceuticals, Inc., or Terns Pharmaceuticals, in NASH and PBC since June 2019.

VS-01-ACLF, our first ACLF program, is currently in a Phase 2a proof of concept study initiated in the fourth quarter 2022 and is expected to recruit its first patient in the second quarter of 2023.

Our second ACLF program is aimed at developing the repurposed drug nitazoxanide (NTZ) either as a standalone treatment or in combination with another treatment. Two Phase 1 studies were completed in the fourth quarter of 2022 and the first quarter of 2023 and are expected to provide preliminary insight into NTZ pharmacokinetics and safety in the setting of hepatic impairment or renal impairment. In both studies, NTZ was generally well tolerated with a safety profile that is supportive of future investigation in patients with ACLF. A Phase 2a proof of concept study in patients with ACLF grade 1 and 2 is currently under discussion with FDA, and study initiation is targeted for the second half of 2023.

We are also developing GNS561 in CCA following the execution in December 2021 of an exclusive license to develop and commercialize GNS561 in the United States, Canada and Europe (including United Kingdom and Switzerland) from Genoscience Pharma. Enrollment for the Phase 1b/2a clinical trial for GNS561 is anticipated to begin in the second quarter of 2023.

A key differentiator of our development strategy is our NASH biomarker-based diagnostic program, called NIS4, a technology which we are developing to power a new in vitro diagnostic, or IVD, test to identify patients with NASH who may be appropriate candidates for drug therapy. In January 2019, we entered into a first license agreement with Labcorp to allow Labcorp to develop and commercialize NIS4 in the clinical research space through their drug development subsidiary, Covance. Since then, Covance has made significant progress in the deployment of NIS4 in several clinical trials conducted by leading players in the pharmaceutical industry. A second exclusive license agreement with Labcorp to allow them to develop and commercialize an LDT powered by NIS4 technology for use in routine clinical diagnostic testing in the United States and Canada was signed in September 2020 and in April 2021, Labcorp launched commercialization of NASHnext, an LDT powered by our NIS4 technology. In May 2021, we signed a worldwide, non-exclusive license agreement with Q Squared Solutions LLC to broaden the availability of NIS4 technology in the clinical research field.

Although we recorded revenue in 2021 from the receipt of an upfront payment under our agreement with Ipsen and again in 2022 in continuation of said agreement and related work, we have never generated significant revenues from product sales. We do not expect to generate material revenue from product sales unless and until we successfully complete clinical development of, obtain marketing approval for and commercialize our drug candidates and LDT and IVD tests. Clinical development, regulatory approval and commercial launch of a product candidate or diagnostic can take several years and are subject to significant uncertainty.

Historically, we have financed our operations and growth through issuances of share capital and convertible bonds, through conditional advances and subsidies from Banque Publique d'Investissement (BPI France), from research tax credits and through the upfront milestone of €120 million from our collaboration and licensing agreement with Ipsen. In 2006, we completed the initial public offering of our ordinary shares on the Alternext market of Euronext in Paris and transferred to the Euronext Paris in April 2014. Between 2010 and 2016, we raised a total of over €220 million in gross proceeds from the issuance of ordinary shares. In October 2017, we issued €180 million in convertible bonds. In March 2019, we completed a global offering consisting of an initial public offering of our American Depositary Shares, or ADSs, in the United States, and a private placement of our ordinary shares in Europe and other countries outside the United States, including France. Aggregate gross proceeds from the global offering, before deducting underwriting discounts and commissions and offering expenses payable by us, were approximately $155.4 million. Additionally, in 2021, Ipsen also became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28 million investment. There have been no subsequent equity raises.

Since our inception, we have incurred significant operating losses. Our net loss was €101.2 million for the year ended December 31, 2020. For the year ended December 31, 2021, our net gain was €67.3 million, primarily due to the upfront payment received from Ipsen in 2021. For the year ended December 31, 2022, our net loss was €23.7 million.

As we continue to advance our current product candidates, conduct preclinical studies and conduct clinical trials, we expect that our cash used in operational activities will amount to €60 million in 2023. This estimate takes into account our projected cash flows from operating activities and government funding of research programs. We have based this estimate on assumptions that may prove to be wrong. Our net losses may fluctuate significantly from quarter to quarter and year to year, notably depending on the timing of our clinical trials and our expenditures on other research and development activities. Also, we could use our available capital resources sooner than we currently expect.

Financial Operations Overview

Revenue and Other Income

For the year ended December 31, 2021, our revenue was €80.1 million. Revenues for 2021 mainly resulted from the receipt of the €120 million upfront payment from Ipsen, out of which €80 million was recognized as revenue in 2021, and €40 million was deducted as deferred revenue. The remainder is recognized gradually as revenue following the completion of the ELATIVE clinical trial evaluating elafibranor in PBC in accordance with both IFRS 15 and the terms of the strategic licensing and collaboration agreement entered into with Ipsen in December 2021.

For the year ended December 31, 2022, our revenue was €20.2 million, which includes €15.9 million attributable to the partial recognition of the €40.0 million deferred income, as described above, €1.0 million in revenue generated from the services we rendered to Ipsen in accordance with the Transition Services Agreement signed in April 2022, which outlines the scope of services to facilitate the transition of certain activities related to the Phase 3 ELATIVE clinical trial and €3.3 million that was recognized as revenue in accordance with the Inventory Purchase Agreement signed with Ipsen in July 2022, pursuant to which Ipsen purchased inventory of the elafibranor active pharmaceutical ingredient and drug product during the second half of 2022 with the prospect of transferring the conduct of the ELATIVE study to Ipsen. Revenue is recognized in accordance with IFRS 15.

In 2019, we entered into two licensing agreements, one with Terns Pharmaceuticals, Inc., or Terns, with respect to the development and commercialization of elafibranor in Greater China, and one with Covance, Labcorp's drug development business, with respect to the development and deployment of a test powered by NIS4 technology in the clinical research space. Pursuant to our agreement with Terns, we received an upfront payment of $35 million in 2019, and are eligible for up to $193 million in clinical, regulatory and commercial milestone payments, as well as mid-teen percentage royalties (For more information see Note 29 - "Commitments" to our consolidated financial statements included in this annual report). In 2020, we entered into a second agreement with Labcorp, for a five-year exclusive licensing agreement with Labcorp to develop and commercialize an LDT powered by NIS4 technology in the clinical diagnostic market. In May 2021, we signed a worldwide, non-exclusive license agreement with Q Squared Solutions LLC, to broaden the availability of NIS4 technology in the clinical research field.

In December 2021, we entered into a long-term strategic partnership for global collaboration with Ipsen granting Ipsen an exclusive worldwide (excluding Greater China which is licensed to Terns) license to develop, manufacture and commercialize elafibranor, for people living with PBC, and in other indications. Under the agreement, Ipsen will pay us up to €480 million, which is comprised of an upfront cash payment of €120 million, as well as regulatory, commercial, and sales-based milestone payments of up to €360 million, plus tiered double-digit royalties of up to 20%. Other than pursuant to these three agreements, we do not expect to receive any revenue from any of our product candidates until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates.

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

CIR Research Tax Credit

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

The main characteristics of the CIR are the following:

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

- the CIR is not included in the determination of the corporate income tax.

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

Exchange Gain on trade receivables and liabilities

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

Operating Expenses

Research and Development Expenses

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

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

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, such as the RESOLVE-IT and ELATIVE trials. We expect that our research and development expenses will increase compared to 2022 for the foreseeable future. As we continue to advance our current product candidates, conduct preclinical studies and conduct clinical trials, we expect that our cash used in operational activities will amount to €60 million in 2023. This estimate takes into account our projected cash flows from operating activities and government funding of research programs. We have based this estimate on assumptions that may prove to be wrong. Our net losses may fluctuate significantly from quarter to quarter and year to year, notably depending on the timing of our clinical trials and our expenditures on other research and development activities. Also, we could use our available capital resources sooner than we currently expect. They may also fluctuate depending on the next steps initiated in the clinical development of our drug candidates, new development programs, which we may decide to start, and progress in the development of our diagnostic tests.

The impact of the RESOLVE-IT study in NASH on our 2022 results was insignificant and is expected to be insignificant in 2023.

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

General and Administrative Expenses

General and administrative expenses include:

- employee-related costs for executive, intellectual property, finance, legal and human resources and communications functions;
- facility-related costs;
- fees for third-party providers of administrative services, including legal, audit and accounting, press relations and communication services, security and reception and recruiting; and
- intellectual property fees for the registration and maintenance of our patents.

Despite cost-saving measures initiated in September 2020 in response to the RESOLVE-IT study outcome, expenses will remain significant over the next several years due to expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and SEC requirements, director and officer insurance premiums, investor relations and litigation costs. In particular, we will continue to incur additional expenses associated with accounting and internal control over financial reporting to comply with the Sarbanes-Oxley Act of 2002 in the United States.

Marketing and Market Access Expenses

Marketing and market access expenses include:

- employee-related costs for marketing, and business development functions;
- facility-related costs; and

- fees for third-party providers of marketing and pre-commercialization services including market surveys, brand strategy, medical communication and market access services.

The cost-saving measures initiated in September 2020 allowed us to decrease our marketing and market access expenses in 2021 and remain stable in 2022. We expect that they will not increase significantly in 2023.

Reorganization and Restructuring Expenses

Reorganization and restructuring expenses include:

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

The impact of the RESOLVE-IT study in NASH on our 2022 results was insignificant.

Financial Income (Expense)

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

Financial expense relates primarily to interest expense on our outstanding convertible bonds as well as interest expense for bank loans and for leases. We also incur foreign exchange losses related to our purchases of services in U.S. dollars, which amounts are recorded as financial expense and interest expenses due to leases in application of IFRS 16.

In 2021, financial income included the one-time buyback bonus of €35.6 million issued from the renegotiation of the OCEANEs completed in January 2021 (See Note 20.1 to our consolidated financial statements included in this annual report under the caption "Breakdown of convertible loan").

A. Operating Results

Our results of operations for the years ended December 31, 2020, 2021 and 2022 are summarized in the table below.

	Notes	Year ended		
(in € thousands, except earnings per share data)		**2020/12/31**	**2021/12/31**	**2022/12/31**
Revenues and other income				
Revenue	7	765	80,069	20,195
Other income	7	6,993	5,510	6,371
Revenues and other income		7,758	85,579	26,566
Operating expenses and other operating income (expenses)				
Research and development expenses	8	(59,097)	(35,166)	(35,818)
General and administrative expenses	8	(14,270)	(16,153)	(16,405)
Marketing and market access expenses	8	(11,216)	(1,539)	(992)
Reorganization and restructuring income (expenses)	8	(5,308)	(142)	11
Other operating expenses	8	(764)	(763)	(652)
Operating income (loss)		(82,897)	31,816	(27,289)
Financial income	10	6,544	44,780	8,212
Financial expenses	10	(25,296)	(7,122)	(4,758)
Financial profit (loss)		(18,752)	37,658	3,453
Net profit (loss) before tax		(101,649)	69,474	(23,836)
Income tax benefit (expense)	11	428	(2,215)	116
Net profit (loss)		**(101,221)**	**67,259**	**(23,719)**

Comparisons for the Years Ended December 31, 2021 and 2022

A discussion and analysis of our financial condition and operating results for the year ended December 31, 2021 as compared to the year ended December 31, 2020 is included in Item 5 of our Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission on April 29, 2022 and is incorporated herein by reference.

Revenue

Revenue amounted to €80.1 million during the year ended December 31, 2021, which was primarily due to the receipt of the €120 million upfront payment from Ipsen, out of which €80 million was recognized as revenue in 2021, and €40 million was deducted as deferred revenue. The remainder will be gradually recognized as revenue following the completion of the ELATIVE clinical trial evaluating elafibranor in PBC in accordance with IFRS 15 and the terms of the strategic licensing and collaboration agreement entered into with Ipsen in December 2021. See Note 7 to our consolidated financial statements included in this annual report under the caption "Revenues and Other Income".

Revenue amounted to €20.2 million during the year ended December 31, 2022, which includes €15.9 million attributable to the partial recognition of the €40.0 million deferred income described above, €1.0 million in revenue generated from the services we rendered to Ipsen in accordance with the Transition Services Agreement signed in April 2022, which outlines the scope of services to facilitate the transition of certain activities related to the Phase 3 ELATIVE clinical trial evaluating elafibranor in PBC and €3.3 million that was recognized as revenue in accordance with the Inventory Purchase Agreement signed with Ipsen in July 2022, pursuant to which Ipsen purchased inventory of the elafibranor active pharmaceutical ingredient and drug product during the second half of 2022 with the prospect of transferring the conduct of the ELATIVE study to Ipsen.

Other Income

Other income for the years ended December 31, 2021 and 2022 consisted of the following:

Other income	Year ended	
(in € thousands)	2021/12/31	2022/12/31
CIR tax credit	5,282	6,017
Other operating income	223	320
Government grants and subsidies	5	34
TOTAL	**5,510**	**6,371**

During the year ended December 31, 2021, other income amounted to €5.5 million.

During the year ended December 31, 2022 other income amounted to €6.4 million.

The increase in other income compared to the previous year is mainly due to:

- Increasing foreign exchange gains related to trade receivables, which is included in other operating income, and amounted to €0.3 million in 2022, compared to €0.2 million in 2021.
- Increasing CIR tax credit (research tax credit granted by the French tax authorities) from €5.3 million for 2021 to €6.0 million for 2022 due to greater research and development activities in 2022.

It should be noted that the research tax credit receivable for the year 2021 amounted to €5.3 million, and the research tax credit receivable for the year 2022 amounts to €11.3 million. This balance includes the 2021 balance as there is currently a tax inspection taking place by the French tax authorities.

Operating Expenses

The tables below summarize our operating expenses for the years ended December 31, 2021 and 2022.

Operating Expenses for the Year Ended December 31, 2022

Operating expenses and other operating income (expenses)	Year ended	Of which :					
(in € thousands)	2022/12/31	Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(35,818)	(1,876)	(17,407)	(10,029)	(5,177)	(1,328)	—
General and administrative expenses	(16,405)	(248)	(71)	(6,772)	(9,168)	(146)	—
Marketing and market access expenses	(992)	(3)	(1)	(565)	(416)	(6)	—
Reorganization and restructuring expenses	11	—	—	—	—	11	—
Other operating income (expenses)	(652)	—	—	—	(667)	—	16
TOTAL	**(53,855)**	**(2,128)**	**(17,479)**	**(17,366)**	**(15,429)**	**(1,469)**	**16**

Operating Expenses for the Year Ended December 31, 2021

Operating expenses and other operating income (expenses) (in € thousands)	Year ended 2021/12/31	Of which : Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(35,166)	(1,305)	(18,808)	(8,192)	(4,593)	(2,247)	(19)
General and administrative income (expenses)	(16,153)	(161)	(85)	(7,379)	(8,003)	(541)	15
Marketing and market access expenses	(1,539)	(1)	(1)	(783)	(741)	(13)	—
Reorganization and restructuring income (expenses)	(142)	(5)	—	—	(2,343)	2,206	—
Other operating income (expenses)	(763)	—	—	—	(338)	4	(429)
TOTAL	**(53,763)**	**(1,472)**	**(18,895)**	**(16,354)**	**(16,019)**	**(591)**	**(433)**

Research and Development Expenses

For the year ended December 31, 2021, research and development expenses totaled €35.2 million, or 65.4% of our total operating expenses. These expenses were comprised of €18.8 million in contracted research and development conducted by third parties, €8.2 million in employee expenses, €4.6 million in other expenses, €2.2 million in depreciation, amortization and impairment charges and €1.3 million in raw materials and consumables.

For the year ended December 31, 2022, research and development expenses totaled €35.8 million, or 66.5% of our total operating expenses. These expenses were comprised of €17.4 million in contracted research and development conducted by third parties, €10.0 million in employee expenses, €5.2 million in other expenses, €1.3 million in depreciation, amortization and impairment charges and €1.9 million in raw materials and consumables.

The decrease of €1.4 million in contracted research and development conducted by third parties is mainly due to:

- Decreasing costs related to the RESOLVE-IT study in NASH of €6.4 million,
- Increasing costs related to the NTZ product candidate and VS-01 product candidate of €4.1 million and €0.7 million, respectively,
- Decreasing costs related to the elafibranor programs in Primary Sclerosing Cholangitis, or PSC, and PBC of €0.6 million and €0.3 million respectively, and
- Increasing costs related to GNS561 of €1.1 million.

The increase of €1.8 million in employee expenses, consisting of wages, salaries, social security, pension costs and share-based compensation paid to employees in the research and development function, relates primarily to the increase in workforce (from 73 to 91 employees at December 31, 2021 and 2022, respectively), which includes a 7 person increase due to the Versantis acquisition.

The increase of €0.6 million in other expenses is mainly due to increasing costs related to consultants of €0.2 million, increasing costs related to maintenance of €0.2 million, increasing costs related to travel of €0.1 million and increasing costs related to recruiting fees of €0.1 million.

The decrease of €0.9 million in depreciation, amortization and impairment charges is mainly due to one-time decreases in property, plant and equipment acquisitions as well as the disposal of two leases in 2021 that were recognized under IFRS 16 and resulted in the to amortization of right of use assets, which did not repeat in 2022.

The increase of €0.6 million in raw materials and consumables used is mainly due to increased utilization of biological reagent products related to preclinical ACLF studies.

We expect our research and development expenses to increase in the foreseeable future compared to 2022, as we continue our efforts to identify potential product candidates, conduct preclinical studies and clinical trials and advance the development of our diagnostic tests. They may fluctuate depending on the next steps initiated in the clinical development of our drug candidates, new development programs, which we may decide to start, and progress in the development of our diagnostic tests.

General and Administrative Expenses

For the year ended December 31, 2021, general and administrative expenses totaled €16.2 million, or 30.0% of our total operating expenses. These expenses were composed primarily of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative function of €7.4 million, as well as €8.0 million in other expenses.

For the year ended December 31, 2022, general and administrative expenses totaled €16.4 million, or 30.5% of our total operating expenses. These expenses were composed primarily of employee-related expenses, consisting of wages, salaries, social security and pension costs and share-based compensation paid to employees in general and administrative function of €6.8 million, as well as €9.2 million in other expenses.

The increase in general and administrative employee expenses was mainly due to the increase in workforce (49 employees in 2021 vs. 57 employees in 2022).

The increase of €1.2 million in other expenses is mainly due to increasing costs related to liability insurance of €0.3 million, increasing costs related to consulting fees of €0.4 million, increasing costs related to maintenance of €0.1 million, increasing costs related to bank charges of €0.1 million, increasing costs related to travel of €0.1 million, and increasing costs related to other various charges of €0.2 million arising out of the ordinary course of business.

The general and administrative expenses will remain significant over the next several years due to expenses associated with being a public company in the United States, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and SEC requirements, director and officer insurance premiums, investor relations and litigation costs. In particular, we will continue to incur additional expenses associated with accounting and internal control over financial reporting to comply with the Sarbanes-Oxley Act of 2002 in the United States.

Marketing and Market Access Expenses

For the year ended December 31, 2021, marketing and market access expenses totaled €1.5 million, or 2.9% of our total operating expenses. These expenses consisted primarily of €0.7 million of other expenses, including market surveys, brand strategy, medical communication and market access services. We also incurred €0.8 million in employee-related expenses, consisting of wages, salaries, social security and pension costs paid to employees in marketing and business development functions.

For the year ended December 31, 2022, marketing and market access expenses totaled €1.0 million, or 1.8% of our total operating expenses. These expenses consisted primarily of €0.4 million of other expenses, including medical communication and market access services. We also incurred €0.6 million in employee-related expenses, consisting of wages, salaries, social security and pension costs paid to employees in marketing and business development functions.

This decrease of €0.5 million was primarily due to:

- Decreasing employee expenses of €0.2 million due to the reduction of marketing activity in the United States, and
- Decreasing consulting expenses of €0.3 million related to reduced marketing activity in France.

We anticipate that our marketing and market access costs will not increase significantly in 2023.

Reorganization and Restructuration Expenses

For the year ended December 31, 2021, reorganization and restructuration expenses totaled €0.1 million, or 0.3% of our total operating expenses. These expenses consisted primarily of renegotiation fees for the OCEANEs for €2.3 million, the reversal of the impairment of rights related to the use of leased premises for €0.7 million, following the relocation of our Paris office, the reversal of the impairment of rights related to leased equipment for €0.4 million, following the sale of certain equipment, the reversal of amortization and impairment loss related to fixed assets for €0.4 million, the reversal of accruals related to employees within the scope of the reduction in force (Plan de Sauvegarde de l'Emploi or PSE) for €0.4 million and the reversal of the provision of €0.4 million previously recognized for some termination costs of the RESOLVE-IT study.

For the year ended December 31, 2022, reorganization and restructuration expenses were not significant. Charges were insignificant as the reorganization following the RESOLVE-IT study is substantially complete.

Financial Income (Expense)

Our net financial income for the year ended December 31, 2021 was €37.7 million, consisting primarily of the financial income of €35.6 million corresponding to a repurchase bonus following the renegotiation of the OCEANEs in January 2021, €4.8 million of interest expense, €8.9 million in foreign exchange gain on cash and cash equivalents, offset partially by €2.3 million of foreign exchange losses, and €0.3 million in interest income.

Our net financial income for the year ended December 31, 2022 was €3.5 million, consisting primarily of €4.3 million of interest expense, €7.5 million in foreign exchange gain on cash and cash equivalents, offset partially by €0.3 million of foreign exchange losses, and €0.7 million in interest income and €0.2 million in other financial expenses.

The foreign exchange result was a net gain of €7.1 million and is notably related to the exchange rate fluctuations on the cash held in US dollars, as we made the decision to keep part of our cash in US dollars. These cash holdings in US dollars are to be used to pay expenses in US dollars directly (natural currency hedge).

B. Liquidity and Capital Resources

Overview

As of December 31, 2021 and 2022, we had €258.8 million and €136.0 million respectively, in cash and cash equivalents. In addition, as of December 31, 2022, we had €4.6 million in other current financial assets which consisted of a single short-term instrument whose term was 180 days. Cash, cash equivalents, and other current financial assets are used to finance key business activities, notably research and developments expenses.

Since our inception, we have financed our operations primarily through the issuance of new ordinary shares and bonds convertible into new ordinary shares in public offerings and private financing transactions, as well as an upfront payment pursuant to our collaboration with Ipsen. In 2006, we completed the initial public offering of our ordinary shares on the Alternext market of Euronext in Paris. The listing of our ordinary shares was transferred to the regulated market of Euronext Paris in 2014. Between 2010 and 2016, we raised a total of over €220.0 million in gross proceeds from the issuance of additional ordinary shares for cash. In October 2017, we issued €180.0 million in bonds convertible into new ordinary shares or exchangeable for existing ordinary shares. In March 2019, we completed a global offering consisting of an initial public offering of our ADSs in the United States, and a private placement of our ordinary shares in Europe and other countries outside the United States, including France. Aggregate gross proceeds from the global offering, before deducting underwriting discounts and commissions and offering expenses paid by us, were approximately $155.4 million. Additionally, in 2021, Ipsen also became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28 million investment. There have been no subsequent equity raises.

We have also financed our operations through collaborative research alliances, such as our licensing and collaboration agreements with Terns Pharmaceuticals and Ipsen. Pursuant to our agreement with Terns Pharmaceuticals, we received an upfront payment of $35 million in 2019. Pursuant to our agreement with Ipsen, we received a €120 million upfront payment in 2021, out of which €80 million was recognized as revenue in 2021, and €40 million was deducted as deferred revenue. We also received €28 million from Ipsen as a result of their purchase of an 8% equity stake in us during 2021. During the year ended December 31, 2022, we recognized €15.9 million of the €40.0 million deferred income from Ipsen.

Additionally, we have financed our operations through the receipt of research tax credits and subsidies granted by various public institutions, such as BPI France, conditional and repayable advances agreements with governmental entities, loans with commercial banks and BPI France and the issuance of convertible bonds.

Following the results of the Phase 3 RESOLVE-IT trial, we implemented a cost savings plan to reduce operational expenses, including a workforce reduction plan and the elimination non-essential expenses, which contributed to reducing our cash flows used in operating activities from €96.4 million in 2020 to €44.0 million in 2021 (excluding the upfront payment received from Ipsen in 2021) to €72.6 million in 2022. We will incur higher expenses and substantial operating losses over the next several years, as we continue our efforts to identify potential product candidates, conduct preclinical studies and clinical trials and advance the development of diagnostic tests based on our NIS4 technology. We expect that our cash flows used in operating activities will amount to €60 million in 2023. This estimate takes into account our projected cash flow from operations and government funding of research programs. We have based this estimate on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect.

Cash Flows

The table below summarizes our cash flows for the years ended December 31, 2020, 2021 and 2022:

	Year ended		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Cash flows provided by (used in) operating activities	(96,371)	99,915	(72,638)
Cash flows provided by (used in) investment activities	(966)	(3,377)	(46,266)
Cash flows provided by (used in) financing activities	(8,256)	(8,916)	(3,786)
	(105,593)	**87,622**	**(122,690)**

Operating Activities

Cash provided by (used in) operating activities was €(96.4) million, €99.9 million and €(72.6) million for the years ended December 31, 2020, 2021 and 2022, respectively.

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

With respect to the 2021 period, this amount primarily resulted from our net profit of €67.3 million largely the result of the receipt of a €120 million initial upfront payment pursuant to a licensing and collaboration agreement with Ipsen, our significant research and development efforts as we incurred significant costs for ELATIVE, our Phase 3 clinical trial of elafibranor in PBC, adjusted by €27.0 million in non-cash and financial income, including the recognition of a €35.6 million repurchase bonus related to the partial buyback of our convertible bonds, and other adjustments of €59.7 million, which includes the recognition of a €40.0 million deferred income and €24.0 million of VAT collected, both of which are related to the initial upfront payment from Ipsen.

With respect to the 2022 period, this amount resulted from our net loss of €23.7 million, in addition to significant research and development efforts including ELATIVE, GNS561, and VS-01, adjusted by €6.0 million in noncash and financial expenses, a decrease in payables and other liabilities of €46.2 million, and an increase in receivables of €8.6 million. Specifically regarding the decrease in payables and other liabilities, this is primarily attributable to a one time payment in early 2022 amounting to €24.0 million of VAT related to the IPSEN upfront initial payment of €120 million from 2021.

Investing Activities

Cash used in investing activities was €1.0 million for the year ended December 31, 2020, and consisted primarily of equipment. Cash used in investing activities was €3.4 million for the year ended December 31, 2021 and consisted primarily of the €3.1 million subscription of new ordinary shares of Genoscience Pharma. Cash used in investing activities was €46.3 million for the year ended December 31, 2022 and consisted primarily of the Versantis acquisition of €41.5 million (net of cash acquired) and short term investments of €5.0 million.

Financing Activities

For the 2020 period, cash used in financing activities was €8.3 million, which consisted primarily of €7.8 million in interest paid on our convertible bonds and €2.2 million in repayments of loans and lease repayments, offset by €1.5 million in interest payments received and €0.1 million in loan reimbursements.

For the 2021 period, cash used in financing activities was €8.9 million, which consisted primarily of €47.5 million used for the partial buy-back of our OCEANEs, €28.0 million of equity investment received from Ipsen, €15.2 million provided by new bank loans, and €4.9 million in interest paid including on on our convertible bonds and €0.3 million in financial interest payments received.

For the 2022 period, cash used in financing activities was €3.8 million, which consisted primarily of €2.2 million in interest paid on our debt and €1.7 million in repayments of loans and lease repayments, offset by €0.1 million in financial interest payments received.

Restriction on use of capital

With the exception of deposits and guarantees (€335 thousand) recognized in non-current and current financial assets as of December 31, 2022, the Company is not faced with any restrictions as to the availability of its capital.

Currencies

GENFIT has expenses and holds cash and cash equivalents in multiple currencies, namely the Euro, the U.S. Dollar and the Swiss Franc (following the acquisition of Versantis in 2022). For further information refer to Note 6.1 to our consolidated financial statements included in this annual report under the caption "Foreign exchange risk."

Operating and Capital Expenditure Requirements

Since our inception, we have incurred significant operating losses. Our net loss was €101.2 million and €23.7 million for the years ended December 31, 2020 and 2022, respectively. For the year ended December 31, 2021 we had net profit of €67.3 million owing to the upfront payment received from Ipsen. Following the results of the Phase 3 RESOLVE-IT trial in May 2020, we implemented a cost savings plan to reduce operational expenses, including a workforce reduction plan and the elimination of non-essential expenses. Nevertheless, we expect to incur higher expenses and substantial operating losses over the next several years, as we:

- conduct our planned preclinical studies and clinical trials of our drug candidates, including ELATIVE, our Phase 3 clinical trial of elafibranor for the treatment of PBC, our Phase 2 clinical trial of VS-01 for the treatment of ACLF, and our Phase 1 clinical trial of NTZ for the treatment of ACLF;
- continue and complete the validation and development of NIS4 for NASH;
- continue the research and development of our other drug candidates, including planned and future preclinical studies and clinical trials, notably the Phase 2 clinical program of GNS561 in CCA;

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

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

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

Until such time, if ever, that we can generate substantial revenue from product sales, we expect to finance these expenses and our operating activities through a combination of our existing liquidity, equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ordinary shares or ADSs. Debt financing, if available, may involve agreements that include covenants that would further limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, which could materially adversely affect our business, financial condition and results of operations.

We believe that our existing cash and cash equivalents as of December 31, 2022, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months at least. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

Disclosure of Contractual Obligations

Our contractual obligations as of December 31, 2022 are disclosed in Note 24 to our consolidated financial statements included in this annual report under the caption "Provisions."

We enter into contracts in the normal course of business with CROs and contract manufacturing organizations, or CMOs, for clinical trials, preclinical studies and clinical manufacturing, and with vendors for pre-commercial activities, research and development activities, research supplies and other services and products for operating purposes. These contracts generally provide for termination upon notice. Such agreements may be terminated at will.

We have entered into a licensing agreement with Genoscience Pharma whereby we are obligated to pay royalties and milestone payments based on future events that are uncertain and therefore they constitute contingent liabilities not recognized in our consolidated financial statements for the period ending December 31, 2022.

We have entered into a share purchase agreement with the former shareholders of Versantis AG whereby we are obligated to pay milestone payments based on future events that are uncertain and therefore they constitute contingent liabilities not recognized in our consolidated financial statements for the period ending December 31, 2022.

Subsidies and Refundable and Conditional Advances

We have received financial assistance from BPI France, and other governmental organizations in connection with the development of our product candidates. Such funding, in the form of refundable and conditional advances, is intended to finance our research and development efforts and the recruitment of specific personnel. We account for non-refundable subsidies as other income ratably over the duration of the funded project. Funds received in the form of refundable advances are recognized as financial liabilities, as we are obligated to reimburse BPI France for such refundable advances in cash based on a repayment schedule if specified conditions are met.

As of December 31, 2021 and 2022, we had one outstanding repayable advance from BPI France with an aggregate remaining balance of €3.2 million. This advance, in an amount of €3.2 million, is a conditional advance we received in our capacity as leader of a research consortium initiated in 2008 called IT-DIAB to follow patients at risk for type 2 diabetes. The program ended on December 31, 2014. The conditional advance is not refundable except in the event of technical or commercial success of the consortium's activities, defined as the sale of related drugs or diagnostic devices developed using research results. We would then be required to repay the advance, plus an additional specified amount, based on a percentage of any revenues generated from the licensing of such products over a 10-year period. The maximum amount that we would be required to pay under this arrangement is €14.8 million, inclusive of the €3.2 million advance to be repaid. As provided in the contract, we sent a letter to BPI France in December 2019 in order to notify it of our Labcorp and Terns contracts while indicating that elafibranor was now aimed at treating hepatic diseases and no longer type 2 diabetes as provided for in the agreement. We proposed to BPI France to acknowledge the failure of the IT-DIAB project. Following this letter, the parties met in March 2020 for the presentation of our arguments, and were in contact again in June 2020 following the results of the RESOLVE-IT trial. We sent another letter in November 2020. We are awaiting a proposal from BPI France on new financial terms related to this situation and a draft amendment to the repayable advance agreement. Refer to Note 20.2.1 to our consolidated financial statements included in this annual report under the caption to our consolidated financial statements included in this annual report under the caption "Refundable and conditional advances" for further information.

Convertible Bonds

In October 2017, we issued convertible bonds (OCEANEs) for gross proceeds of €180.0 million, with a maturity date initially of October 16, 2022.

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

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

At the Shareholders' and Bondholders' Meetings on January 25, 2021, the shareholders and bondholders approved this renegotiation offer and we completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) per bond for a total buyback cost of €47.48 million on January 29, 2021. We then cancelled the repurchase of OCEANEs. Following the renegotiation, the OCEANEs bear interest at an annual nominal rate of 3.50% payable semi-annually in arrears on April 16 and October 16 of each year (or the following business day if this date is not a business day). The OCEANEs will be redeemed at par on October 16, 2025 (or the following business day if this date is not a business day). The effective interest rate is 8.8%.

The nominal unit value of the OCEANEs was set at €29.60. The OCEANEs conversion ratio is 5.5 shares for one OCEANE, subject to any subsequent adjustments.

The OCEANEs may be redeemed early at the option of the Company, under certain conditions. Specifically, the OCEANEs may be redeemed early at the option of the Company from November 3, 2023 onward if i) the mathematical average of the volume-weighted average price of GENFIT shares on the regulated market of Euronext in Paris and ii) the conversion ratio of the shares in force (over a period of 20 trading days) exceeds 150% of the nominal value of the OCEANEs bonds.

As of December 31, 2022, there were 1,923,662 OCEANEs outstanding, and the maximum dilution to GENFIT's current share capital in the event of full conversion would be 21.29%, with approximately €56.9 million nominal amount outstanding.

The OCEANEs are admitted to trading on Euronext Access (the free market of Euronext in Paris).

For more information see Note 20.1 to our consolidated financial statements included in this annual report under the caption "Breakdown of convertible loan.".

Bank Loans

We have borrowed under multiple bank loans primarily intended to finance the acquisition of scientific and information technology equipment. As of December 31, 2021 and 2022, the total principal amount outstanding was €15.9 million and €15.2 million, respectively. These bank loans carry fixed interest rates of between 0.40% and 2.25% and are generally payable over periods ranging from three to five years from the original date of the loan.

In 2021, we entered into three new bank loans for a total nominal amount of €15.2 million, granted in the context of the COVID-19 pandemic, including:

- A €11.0 million loan in June 2021 by a pool of four French commercial banks,
- A €2.0 million loan in July 2021 by BPI France,
- A €2.2 million subsidized loan in November 2021 by BPI France,

the June 2021 and July 2021 bank loans are 90% guaranteed by the French government (State-Guaranteed Loans or Prêts Garantis par l'Etat "PGE") and carry an initial term of one year with repayment options up to six years, and the November 2021 bank loan carries an initial term of six years.

In 2022, we did not enter into any additional loan agreements.

For further information, refer to Note 20.2.2 to our consolidated financial statements included in this annual report under the caption "Bank loans."

Leases

As of December 31, 2022, leases subject to IFRS 16 consist of real estate leases for our offices located in Loos, France and Zurich, Switzerland, and lease agreements for scientific equipment. Additionally, we rent coworking spaces in Paris, France and Cambridge, MA which are not considered leases pursuant to IFRS 16.

For further information, refer to Note 15 to our consolidated financial statements included in this annual report under the caption "Property, Plant and Equipment.".

Pension and Employee Benefits

French law requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement. Benefits do not vest prior to retirement. The amount presented in the table included in Note 25 to our consolidated financial statements included in this annual report under the caption "Employee Benefits" represents the present value of the estimated future benefits to be paid, applying a number of assumptions, including dates of expected retirement, life expectancies, salary growth rates and a discount rate.

C. Research and Development, Patents and Licenses, etc.

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

D. Trend Information

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

E. Critical Accounting Estimates

For a discussion of our critical accounting estimates, see Note 4.1 to our consolidated financial statements included in this annual report under the caption "Use of estimates and judgements."

Item 6. Directors, Senior Management and Employees.

A. Directors and Senior Management

In March 2022, we appointed two new members to the Executive Committee, Emilie Desodt, Executive Vice-President, Human Resources, and John Brozek, Executive Vice-President Data & Information Technology.

The May 25, 2022 annual shareholders meeting confirmed the appointment of Ipsen, represented by Dr. Steven Hildemann, to the Board of Directors. It also renewed the appointments of Jean-François Mouney, Jean-François Tiné, Xavier Guille des Buttes, Anne-Hélène Monsellato, Catherine Larue, and Biotech Avenir SAS, as represented by Florence Séjourné.

Finally, in connection with the acquisition of Versantis AG, in December 2022, we appointed Meriam Kabbaj to the Executive Committee, as Chief Technology Officer in charge of CMC, Analytical Chemistry and Non-Clinical Development activities.

The following table sets forth information concerning our senior management and directors as of April 1, 2023. Unless otherwise stated, the address for our senior management and directors is c/o GENFIT S.A., Parc Eurasanté, 885 avenue Eugène Avinée, 59120 Loos, France.

Name	Age	Position(s)
Senior Management		
Pascal Prigent	55	Chief Executive Officer
Carol Addy, M.D.	63	Chief Medical Officer
Thomas Baetz	49	Chief Financial Officer
John Brozek	46	EVP, Data & Information Technology
Pascal Caisey	55	Chief Operating Officer
Emilie Desodt	40	EVP, Human Resources
Dean Hum, Ph.D	61	Chief Scientific Officer
Laurent Lannoo	53	Corporate Secretary, Director of Legal Affairs
Stefanie Magner, J.D.	42	Chief Compliance Officer, EVP International Legal Affairs
Jean-Christophe Marcoux	45	Chief Corporate Affairs Officer, Head of Investor Relations, Head of ESG
Meriam Kabbaj, Ph.D.	49	Chief Technology Officer
Non-Employee Directors		
Jean-François Mouney (1)(7)(9)	67	Chairman of the Board of Directors
Xavier Guille des Buttes (2)(3)(8)(9)	81	Vice-Chairman of the Board of Directors
Eric Baclet (1)(2)	63	Director
Katherine Kalin (8)	60	Director
Catherine Larue, Ph.D (1)(10)	67	Director
Anne-Hélène Monsellato (4)	55	Director
Philippe Moons (11)	71	Board observer (censeur)
Florence Séjourné (5)	51	Director
Steven Hildemann, M.D. (6)	61	Director
Jean-François Tiné (8)	66	Director

(1) Member of the Nomination and Compensation Committee.

(2) Member of the Audit Committee.

(3) Chair of the Nomination and Compensation Committee.

(4) Chair of the Audit Committee.

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

(6) As representative of IPSEN, the legal entity that holds this board seat.

(7) Chair of the Strategy and Alliances Committee

(8) Member of the Strategy and Alliances Committee

(9) Member of the Environmental, Social, Governance Committee

(10) Chair of the Environmental, Social, Governance Committee

(11) Resigned as Director of the Board of Directors on February 26, 2021, now serves as board observer, and attends ESG committee meetings.

Senior Management

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

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

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

John Brozek was appointed to the Executive Committee in March 2022 as Executive Vice-President, Data & Information Technology. He holds three master's degrees respectively in Cell and Molecular Biology from Lille University, Bioinformatics from Paris 7 University and Information Technology from Amiens University. He started his career in 2001 as Bioinformatician with IT-omics, a startup specializing in Information Systems design and data mining for biotech companies. In 2005, he joined GENFIT where he progressively took the lead of In Silico activities providing support in bioinformatics, biostatistics and Information Systems design. Since 2016, in addition to managing the In Silico activities, he leads the IT Department as Vice-President Data & Information Technology where he has been focusing on a global Information System renewal project while continuing to develop data related projects (data science and business intelligence).

Pascal Caisey joined GENFIT in September 2019 as Executive Vice President of Commercial Development, becoming Chief Commercial Officer in January 2021 and was appointed Chief Operating Officer in March 2022. He has vast pharmaceutical business experience, holding roles with GSK, BMS, Pfizer, Schering Plough and most recently Boehringer Ingelheim, where he oversaw, as the European Business Manager, the commercial launch of empagliflozin in Europe. Mr. Caisey is a registered nurse and holds an MBA from École des Hautes Études Commerciales (HEC) in Paris.

Emilie Desodt joined GENFIT in January 2018 as Human Resources Director and was appointed to the Executive Committee in March 2022 as the Executive Vice-President, Human Resources. Ms. Desodt has been working in Human Resources for the past 18 years in various operational and strategic positions. Prior to joining GENFIT, she was in charge of HR activities, first at regional level (Americas & Middle East) then at global level at the Lesaffre Group. She has also held various HR roles of increasing responsibilities within General Electric. Ms. Desodt holds a bachelor's degree in computer sciences (MIAGE) and a master's degree in HR Development.

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

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

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

Jean-Christophe Marcoux has served as our Chief Corporate Affairs Officer, Head of Investor Relations, Head of ESG (previously titled Chief Strategy Officer) since 2016. He joined our company in 2015 to play a cross-disciplinary role regarding tactical, strategic and operational matters. He is an engineer and graduated from INSA Lyon in France, having spent part of his time at the University of Leeds in England. In addition, he also holds a degree in Strategic Management and Economic Intelligence from EGE in France. From 2000 to 2015, he led international projects and programs in a variety of industrial sectors, in Europe and Asia, and with clients and colleagues in the United States. In 2012, he joined IQVIA (formerly known as IMS Health), a global information and technology services company for clients in the healthcare industry, where he led projects in healthcare systems, such as patient longitudinal studies, forecasting, targeting, profiling, prospective analyses, digital healthcare and innovation. Since 2021, he is responsible for the company's extra-financial reporting and activities, covering the challenges of corporate social and environmental responsibility.

Meriam Kabbaj, Ph.D has served as our Chief Technology Officer since December 2022. She is pharmacist by training (University of Geneva) and received her Master and PhD in Pharmaceutical Sciences from the University of Montreal. She acquired clinical drug development experience and was exposed to quality assurance and regulatory affairs in a leading Contract Research Organization (Celerion, formerly MDS Pharma Sciences) specialized in applied translational medicine, where she held many key operational and leadership positions. After a 10 year deep dive in the pharmaceutical industry, she co-founded Versantis where she successfully led the development of VS-01 from an academic prototype to a clinical lead compound and supported the fundraising activities. As a result of the acquisition of Versantis by GENFIT in September 2022, Meriam joined the Executive Committee as Chief Technology Officer in charge of CMC, Analytical Chemistry and Non-Clinical Development activities.

Non-Employee Directors

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

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

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

Katherine Kalin joined our board of directors in 2020. She brings more than 25 years of experience as a senior executive in healthcare and professional services. Her healthcare industry experience spans pharmaceuticals, medical devices, diagnostics and digital health. From 1990 to 2002, Katherine was a partner in the global healthcare practice of McKinsey & Company, where she served clients across a range of healthcare disciplines. In 2002, Katherine joined Johnson & Johnson where she held leadership roles in marketing, sales and new business development, until 2011. From 2012 to 2017, Katherine led corporate strategy at Celgene Corporation. She began her career as an investment banker in Corporate Finance at Nomura in Tokyo, Japan and London, UK. Ms. Kalin currently serves as a non-executive director of Sellas Life Sciences,, a publicly-traded, late-stage clinical biopharmaceutical company, and as a member of the board of directors of Brown Advisory LLC, an independent investment and strategic advisory firm and FemHealth Ventures, a women’s health venture capital firm. She has a B.A. from Durham University, U.K., and an M.B.A. from Harvard Business School.

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

Anne-Hélène Monsellato has served as a member of our board of directors and the chair of our Audit Committee since 2017. From May 2015 to March 2023, she was an independent member of the Supervisory Committee and the Chairman of the Audit and Risk Committee of Euronav, a Belgian crude oil tanker company listed on the New York Stock Exchange and Euronext Brussels. In addition, she serves as the Vice President and Treasurer of the Board of Trustees of the American Center for Art and Culture, a U.S. private foundation based in New York, which operates the American cultural center in Paris, France. From 2005 until 2013, Ms. Monsellato served as a Partner with Ernst & Young (now EY), Paris, after having served as Auditor and, Manager for the firm starting in 1990. During her time at EY, she gained extensive experience in financial communication, IFRS, cross border listing transactions, in particular with the United States, internal control over financial reporting and risk management, as well as financial statements audits and audits of internal control over financial reporting. She was involved with several companies in the pharmaceutical and biotechnology sector. Ms. Monsellato is an active member of the French association of Directors (IFA) since 2013 in particular with the Club of Audit Committee' Chairs, and the ESG Committee, and the European Confederation of Directors' Association (ecoDa). She was a member of the Consultative Working Group for the ESMA Corporate Reporting Standing Committee for 2019-2020, and she is a member of the EFRAG community for the development of the listed SMEs standards (LSME ESRS). Ms. Monsellato has been a Certified Public Accountant in France since 2008 and received a board member certification from IFA-Sciences Po in 2014. She graduated from EM Lyon in 1990 with a degree in Business Management.

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

Florence Séjourné has served as a member of our board of directors since June 2017 as representative of SAS Biotech Avenir. She was a member of our former Supervisory Board from 1999 until the change in our management and administration in June 2017. Ms. Séjourné co-founded our company and served as our chief operating officer, business development director, industrial alliances coordinator and member of our former Executive Board from 1999 to 2008. From 2008 to 2022, she has been the Chairwoman and CEO of Da Volterra, a clinical-stage biotechnology company developing novel Microbiota Protective therapies for protection against antibiotics residues, in particular in cancer and blood disorders. Since September 2022, Ms. Séjourné has been appointed CEO of a newly formed biopharmaceutical company founded as a joint venture by Boehringer Ingelheim, Evotec SE and bioMérieux, named AUROBAC THERAPEUTICS, to create the next generation of antimicrobials along with actionable diagnostics to fight AntiMicrobial Resistance. Ms. Séjourné graduated from the Ecole des Mines of Paris with a degree in Biotechnology and holds a master's degree in Pharmacy from the University of Illinois in Chicago.

Steven Hildemann, MD., Ph.D, has served as a member of our board of directors since May 2022 as representative of Ipsen. He has been serving as Executive Vice President, Chief Medical Officer, Head of Global Medical Affairs and Pharmacovigilance at Ipsen since March 1, 2020. With over 20 years of service in the pharmaceutical industry and 10 years as a physician-scientist in academic medicine, he has been leading, since his appointment in this role, Ipsen activities related to global medical affairs, pharmacovigilance, and patient relations. As a member of the Executive Leadership team, he actively contributes to the overall management and strategic leadership of Ipsen. Prior to joining Ipsen, Dr. Hildemann held leadership roles in science-based bioethics and built an innovative digital health startup in cancer care. He previously served for five years as Chief Medical Officer, Senior Vice President, Head of Global Medical Affairs and Global Patient Safety at Merck. He also held several strategic leadership positions with biopharmaceutical companies such as Pharmacia-Pfizer and Schering-Plough-MSD. Dr. Hildemann is board certified in internal medicine and cardiology with broad clinical training across internal medicine including medical oncology, gastroenterology, rheumatology and pulmonary oncology at university hospitals in Munich, Germany. Throughout his career, he has engaged in part-time clinical practice, late-stage pharmaceutical research and medical teaching. Dr. Hildemann received his MD-PhD at the Albert Ludwig University of Freiburg, Germany, where he continues to serve as an adjunct Professor of Medicine.

Jean-François Tiné joined the Board of Directors in 2021. He was a senior investment banking executive until 2022, having most recently served since 2017 as Chairman of Equity Capital Markets at Natixis Corporate & Investment Banking after joining Natixis in 2005 as Global Head of Equity Capital Markets. He began his career in various sales, trading and syndication positions in the London and Paris capital markets at Union Bancaire Privée, Crédit Suisse, First Boston and Bank of America. In 1993, he became an associate at MC Securities in London, before being appointed three years later as Global Head of Equity Syndicate at Société Générale in Paris.

Family Arrangements and Selection Arrangements

There are no family relationships between any of the members of our senior management or board of directors. Except as described below, there are no arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any member of our senior management or board of directors was selected as such.

Pursuant to an investment agreement entered into with Ipsen on December 16, 2021 pursuant to which Ipsen became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, our shareholders, at the annual shareholders meeting held on May 25, 2022, appointed Ipsen as board member, represented by Steven Hildemann, M.D.

B. Compensation

Director Compensation

At our general meeting of shareholders held on May 25, 2022, shareholders renewed the total annual attendance fees (*jetons de présence*) to be distributed among non-employee directors at €600,000 for the period beginning with the shareholders' general meeting of May 25, 2022 until the next shareholders' general meeting, currently expected to occur on May 24, 2023. The following table sets forth information regarding the compensation earned by our non-employee directors for service on our board of directors during the year ended December 31, 2022, which consisted solely of attendance fees, with the exception of our Chairman, Jean-François Mouney.

NAME	(€)
Jean-François Mouney(1)	368,545
Eric Baclet	60,000
Xavier Guille des Buttes	96,250
Frédéric Desdouits(2)	15,035
Katherine Kalin	46,250
Catherine Larue, Ph.D.	53,125
Anne-Hélène Monsellato	52,500
Philippe Moons(3)	13,750
Florence Séjourné, as representative of SAS Biotech Avenir	—
Steven Hildemann, MD., Ph.D., as representative of IPSEN	—
Jean-François Tiné	43,750

(1) Mr. Mouney's compensation includes his fixed compensation, directors' fees and social security charges. See below "Chairman of the Board Compensation" for more details.
(2) Mr. Desdouits resigned from the Board of Directors effective May 25, 2022. He received a pro-rated annual compensation due to his mid-year departure.
(3) Philippe Moons is an observer on the Board of Directors

We compensate all the members of the Board of Directors, with the exception of the permanent representatives of Biotech Avenir and Ipsen, both shareholders of the Company. Director compensation includes a fixed part for each director and a variable part depending on their attendance. The fixed part varies according to:

- the role played by each director on the Board of Directors and the Committees;
- the function of Vice-Chairman of the Board of Directors or Chairman of a specialized committee.

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

Directors fees are allocated as follows:

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

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

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

The Board of Directors, in accordance with the Articles of Association, decided on March 11, 2021 to appoint Philippe Moons as an observer. Mr. Moons' compensation is deducted from the overall budget of €600,000 allocated by the Shareholders Meeting to directors, at the rate of €1,250 per meeting of the Board of Directors and the ESG Committee in which he attends.

Chairman of the Board Compensation – Jean-François Mouney

The components of the overall annual compensation of Mr. Mouney for his duties within the GENFIT group during the fiscal year ended December 31, 2022 are summarized below:

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

Fixed Compensation

Mr. Mouney received a gross fixed compensation of €210,000.

Attendance Fees

Mr. Mouney also received gross compensation of €40,625 as Chairman of the Board of Directors, which amount includes directors' fees for his participation in certain Board committees (Compensation and Nominations Committee, Strategy and Alliances Committee and ESG Committee).

Other Compensation

The benefits in kind granted to Mr. Mouney for the year ended December 31, 2022 consisted of the use of a company car valued at €7,200 and eligibility for the Group's life insurance and health insurance benefits.

Chief Executive Officer Compensation – Pascal Prigent

Our only executive officer under French law is our chief executive officer. The following table sets forth information regarding compensation earned during the year ended December 31, 2022 by Mr. Prigent.

	FIXED COMPENSATION	VARIABLE COMPENSATION (1)(2)	EQUITY AWARDS (1)	ALL OTHER COMPENSATION	TOTAL
NAME AND PRINCIPAL POSITION	**(€)**	**(€)**	**(€)**	**(€)**	**(€)**
Pascal Prigent, Chief Executive Officer	375,000	169,500	73,890	14,044	632,434

(1) Variable compensation and equity awards subject to "Say-on-Pay" approval of the Shareholders' Meeting to be called to approve the financial statements for the year ended December 31, 2022.

(2) Including variable compensation and exceptional bonus.

The various components of the overall annual compensation of Mr. Prigent for his duties as Chief Executive Officer of the GENFIT group during the fiscal year ended December 31, 2022 are summarized below:

Fixed Compensation

Through his executive officer contract (*contrat de mandat social*), Mr. Prigent received a gross fixed compensation of €375,000.

Variable Compensation

After evaluating the performance conditions relating to the variable compensation of the Chief Executive Officer, the Board of Directors has determined that the Chief Executive Officer's variable compensation will be €142,500. This amount represents 38% of the Chief Executive Officer's fixed compensation.

The Board of Directors has determined that 76% of the Chief Executive Officer's objectives were achieved in 2022.

The 2022 objectives of the Chief Executive Officer and their weighting in the annual assessment of his performance were defined at the beginning of the financial year by the Board of Directors around the following three pillars/assessment criteria:

– Strengthening of the Company's portfolio of R&D programs by acquiring the rights to new innovative molecules or through advances in internal research programs (representing a relative weight in the performance assessment of 35%);

– Execution of R&D programs (representing a relative weight in the performance evaluation of 35%);

– Improvement in the valuation of the Company (representing a relative weight in the performance assessment of 30%).

The Board of Directors evaluated the performance of the Chief Executive Officer as follows:

– Strengthening the Company's R&D portfolio: 100% of the objective achieved, considering the addition to the portfolio of the new programs (VS-01-ACLF, VS-01-HAC, VS-02-HE and TS-01);

– Execution of R&D programs: 100% of the objective achieved considering the completion of the recruitment of patients in the ELATIVE trial evaluating elafibranor in PBC despite the delays caused by COVID-19, obtaining Orphan Drug Designation for GNS561 and the execution of the Phase 1 clinical studies evaluating NTZ in ACLF;

– Improvement of the valuation of the Company: 20% of the objective achieved, considering the evolution of the stock market valuation of the Company and the Corporate Social Responsibility actions carried out during the 2022 financial year.

The Chief Executive Officer was not present during the Board of Directors discussion of his performance.

Considering, moreover, that the acquisition of Versantis AG constitutes an exceptional performance, the achievement of which was not fully taken into account in the definition of the objectives of the Chief Executive Officer at the beginning of the 2022 financial year, the Board of Directors, on the proposal of the Nomination and Compensation Committee, has decided to award the Chief Executive Officer an exceptional bonus of €27,000 (i.e. approximately 7% of the gross annual fixed compensation of the the Chief Executive Officer).

All variable compensation is subject to approval at the upcoming Shareholders' Meeting scheduled on May 24, 2023 called to approve the financial statements for the year ended December 31, 2022.

Equity Awards

During the year ended December 31, 2022, Mr. Prigent received a grant of 35,000 stock options (SO C 2022) and 20,000 free shares (AGA D 2022) with vesting subject to performance conditions. The performance conditions attached to the stock options and free shares granted in 2022 are linked to internal and external conditions, in particular, the acquisition of new programs in accordance with the Group's strategy, clinical and regulatory advances in R&D programs and stock price. The performance conditions are detailed hereafter. The grant of these instruments is subject to approval at the upcoming Shareholders' Meeting called to approve the financial statements for the year ended December 31, 2022.

In September 2022, after the recognition of the fulfillment of the presence condition and the assessment of the performance conditions of the free share and stock option plans of which the Chief Executive Officer is one of the beneficiaries:

– 4 free shares linked to the AGA D 2019 out of the 6 free shares allocated subject to performance conditions were definitively acquired by the Chief Executive Officer, i.e. the maximum amount provided for by the plan regulations in respect of the achievement of the so-called internal performance condition; and considering the signatures of the license agreements with the companies Labcorp and Ipsen that we entered into during the period of measurement of the performance conditions. The assessment of the achievement of the external performance criterion linked to the evolution of the share price did not give rise to any definitive vesting.

– 6,667 SO 2019 stock options out of the 10,000 stock options granted subject to performance conditions have been definitively acquired by the Chief Executive Officer, i.e. the maximum amount provided for by the plan regulations in respect of the achievement of the so-called internal performance criteria; and considering the license agreements with the companies Labcorp and Ipsen that we entered into during the period of measurement of the performance conditions. The assessment of the achievement of the external performance condition linked to the evolution of the share price did not give rise to any definitive vesting.

The details of the performance conditions of the AGA D 2019 plan and the SO 2019 plan which was adopted by the Board of Directors in 2019 are detailed below.

Other Compensation

Mr. Prigent received use of a company car valued at €4,423, and was eligible for the Group's life insurance and healthcare plans and the payment of premiums for unemployment insurance Social Security for Business Managers (GSC), which guarantees the payment of compensation in the event of unemployment (up to 55% of net professional tax income for the uncapped share for 12 months following the loss of the position) given that corporate officers are not eligible for standard French unemployment benefits, valued at €9,621.

Change of Control and Severance Benefits

Mr. Prigent also benefits from a severance payment falling within the scope of Article L.225-42-1 of the French Commercial Code equal to 18 months' gross compensation, calculated on the basis of the last 12 months, increased, where applicable, by the amount of annual variable compensation due for the previous fiscal year and it would be paid if, and only if, one of the following three performance conditions is achieved at the time that his post is terminated:

- elafibranor has been granted marketing authorization by the FDA or EMA in PBC;
- a license agreement for NTZ, GNS561, VS-01 or VS-02 has been signed for the US market and / or for at least two of the five major European markets (Germany, France, Italy, United Kingdom, Spain and / or for Japan); or
- there is a takeover of the Company.

Mr. Prigent also benefits from a non-compete indemnity equal to 12 months of gross fixed compensation, calculated on the basis of the gross amounts due for the past twelve months end, and where applicable, by the amount of the annual variable compensation due for the previous year. The amounts which he may receive under a non-compete indemnity are not cumulative with his severance payment and vice-versa. The non-compete covenant would not apply to the Chief Executive Officer if he leaves the Company, for whatever reason, either by decision of the Board of Directors or at his initiative, following a takeover of the Company.

Compensation recovery policy

In October 2022, the SEC adopted rules, pursuant to Section 10D-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requiring national securities exchanges and national securities associations, such as Nasdaq, to amend their relevant listing standards no later than November 28, 2023 to require listed companies to adopt a written compensation recovery (clawback) policy providing for the recovery, in the event of a required accounting restatement, of incentive-based compensation received by the Chief Executive Officer and certain other "executive officers" as defined in Rule 10D-1(d) under the Exchange Act that is wholly or partially contingent on the attainment of financial performance criteria based on reported financial information that has been determined to be erroneous and has required restatement of the financial statements for accounting purposes. In February 2023, Nasdaq published a proposal to amend its listing rules, pending public comment and SEC approval. However, as of the date of publication of this annual report, Nasdaq listing standards have not yet been amended pursuant to Section 10D-1 of the Exchange Act. In anticipation of Nasdaq's adoption of its amended listing standards, our Board of Directors adopted at its meeting on March 28, 2023 a written compensation recovery policy, or the Recovery Policy, which will take effect as described below and be included as an exhibit to our Annual Report on Form 20-F for the year ended December 31, 2023. In accordance with French law, the compensation policy of the Chief Executive Officer for the year ended December 31, 2023, including the Recovery Policy, will be presented to our shareholders for approval at our Annual General Meeting to be held on May 24, 2023. If approved, the Recovery Policy will enter into force with respect to the Chief Executive Officer no later than 60 days following the effective date of the final amended rules adopted by Nasdaq. The Recovery Policy will apply to other executive officers, subject to compliance with applicable local laws and the amended rules adopted by Nasdaq, within the same timeframe.

Limitations on Liability and Indemnification Matters

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

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

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

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

Equity Incentives

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

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

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

We have two outstanding share-based compensation plans for our senior management, certain directors and employees, the AGA plan and the SO plan. In general, vesting of our stock options and free shares is subject to continued employment or service of the holder and all vested stock options must be exercised within post-termination exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants.

As of April 7, 2023, share warrants, stock options and free shares were outstanding allowing for the potential purchase and/or free allocation of an aggregate of 1,170,751 ordinary shares.

Share Warrants (BSA)

In the past, share warrants were granted to the independent members of the former supervisory board and of the board of directors and scientific consultants. Similar to options, share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary share on the date of grant. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants.

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

As of December 31, 2022, only the BSA 2019 share warrants plan is outstanding, whose beneficiaries are exclusively outside consultants. The two BSA 2017 plans expired without any warrants having been exercised.

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

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

Free Shares (AGA)

Free shares may be granted to any individual employed by us or by any affiliated company. Free shares may also be granted to our chairman of the board of directors, chief executive officer (directeur général) and deputy executive officers (directeurs général délégué). During the year ended December 31, 2022, Mr. Prigent, our chief executive officer, received a free share grant. Mr. Mouney our chairman of our board, did not receive any free shares. We currently do not have any deputy executive officers. However, under French law, the maximum number of shares that may be granted shall not exceed 10% of the share capital as at the date of grant of the free shares (30% if the allocation benefits all employees).

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

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

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

As of April 1, 2023, our free shares plans will vest, subject to performance conditions and continued employment, as follows:

	MEETING DATE	DATE OF ALLOCATION	NUMBER OF FREE SHARES GRANTED	VESTING DATE (SUBJECT TO CONDITIONS)(1)	STOCK PRICE ON ALLOCATION DATE	FREE SHARES VESTED	REMAINING TO VEST
AGA D and S 2016-1	June 21, 2016	December 15, 2016	20,520	December 16, 2019	€20.78	17,484	—
AGA D and S 2016-2	June 21, 2016	December 15, 2016	10,189	December 16, 2019	€20.78	7,796	—
AGA D and S 2017-1	June 16, 2017	November 21, 2017	27,468	January 1, 2021	€21.95	19,400	—
AGA D and S 2017-2	June 16, 2017	November 21, 2017	13,728	January 1, 2021	€21.95	8,021	—
AGA D and S 2018	June 15, 2018	November 7, 2018	35,800	January 1, 2022	€20.02	21,737	—
AGA D and S 2019	June 15, 2018	July 18, 2019	36,626	September 17, 2022	€17.06	19,494	—
AGA D and S 2021	November 27, 2019	March 30, 2021 (S) March 17, 2021 (D)	47,400	April 1, 2024	€4.00 (S) €4.15 (D)	—	41,400
AGA D and S 2022	May 25, 2022	October 14, 2022	58,900	October 17, 2025	€4.08	—	39,200
AGA D and S 2023	May 25, 2022	March 10, 2023	40,100	March 14, 2026	€4.05	—	40,800

Subject to meeting performance conditions and continued employment with us.

Stock Options (SO)

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

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

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

Stock options issued pursuant to these plans provide the holder with the right to purchase a specified number of ordinary shares from us at a fixed exercise price payable at the time the stock option is exercised, as determined by our board of directors. The plans generally provide that the exercise price for any stock option will be no less than 80% of the volume weighted average price of the 20 market trading days prior to the day of the board of directors' decision to grant the options. Starting from 2020, stock options granted to the Chief Executive Officer are granted without discount. The vesting of the stock options is subject to performance conditions and the continued presence in our Company. These conditions are evaluated over a period of three years and reflect our mid-term objectives. Incentive stock options and non-statutory stock options may be granted under the SO plans.

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

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

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

The main terms of the SO plans are as follows:

Plan title	SO 2016-1	SO 2016-2	SO 2017-1	SO 2017-2	SO 2018	SO 2019	SO US 2019-2	SO 2020	SO 2021	SO 2022	SO 2023
Meeting date	June 21, 2016	June 21, 2016	June 16, 2017	June 16, 2017	June 15, 2018	June 15, 2018	November 27, 2019	November 27, 2019	June 30, 2021	May 25, 2022	May 25, 2022
Dates of allocation	December 15, 2016	December 15, 2016	November 21, 2017	November 21, 2017	November 7, 2018	July 18, 2019	November 27, 2019	December 11, 2020	October 18, 2021 / October 19, 2021	October 14, 2022	March 10, 2023
Exercise conditions(1)	1 option / 1 share										
Total number of SOs granted	48,917	24,458	72,830	36,420	139,500	138,500	13,350	195,000	201,875	209,375	190,200
Start date for the exercise of the SOs	December 16, 2019	December 16, 2019	January 1, 2021	January 1, 2021	January 1, 2022	September 17, 2022	January 17, 2023	January 1, 2024	October 21, 2024 / October 21, 2024	October 18, 2025 / December 3, 2025	March 14, 2026
SO expiry date	December 16, 2026	December 16, 2026	January 1, 2027	January 1, 2027	January 1, 2028	September 17, 2029	January 17, 2030	January 1, 2031	October 20, 2031 / October 20, 2031	October 17, 2032 / December 3,2032	March 14, 2026-March 13, 2033
SO exercise price per share	€15.79/€21.12(2)	€15.79/€21.12	€17.91/€22.54(3)	€17.91/€22.54	€16.00/€21.65(4)	€13.99/€16.90(5)	€14.31	€3.50/€4.38/€4.52(6)	€2.61/€3.26/€3.22(7)	€3.12/€3.91/€3.94/€2.95(8)	€3.26/€4.05/€4.07(9)
Number of SO exercised as of December 31, 2022	—	—	—	—	—	—	—	—	—	—	—
SO voided or lapsed	14,519	9,150	29,619	18,655	61,458	82,044	13,350	28,750	17,500	—	—
SO vested as of December 31, 2022	34,398	15,308	43,212	17,765	78,042	56,456	—	—	—	—	—
SO remaining to vest as of December 31, 2022	—	—	—	—	—	—	—	166,250	184,375	209,375	190,200

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

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

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

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

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

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

(7) Exercise price at €2.61 for the SO 2021, €3.22 for the SO US 2021 and €3.26 for the SO 2021 granted to Pascal Prigent.

(8) Exercise price at €3.12 for the SO 2022, €3.94 for the SO US 2022, €2.95 for the SO SU 2022 and €3.91 for the SO 2022 granted to Pascal Prigent.

(9) Exercise price at €3.26 for the SO C 2023, €4.05 for the SO US 2023, €3.26 for the SO SU 2023 and €4.07 for the SO D granted to Pascal Prigent.

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

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

Plans	Nature of performance conditions
SO 2017-2 ***SO US 2017-2*** ***AGA D 2017-2*** ***AGA S 2017-2***	**Internal conditions -** 66 2/3% of the instruments SO 2017-2/SO US 2017-2/AGA D 2017-2 will be exercisable or definitively vest, and 100% of the Free Shares for the AGA S 2017-2 will vest, regardless of the evolution of the stock market price if at least one of the three following conditions is met: (i) if an application for marketing authorization for a product (elafibranor for NASH) is examined by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA); or (ii) if the launch of at least one clinical trial among the following is authorized by the EMA or the FDA, either: Phase 3 clinical trials which aim to record a new product (NTZ program) or a new indication for Elafibranor (PBC); or clinical trials with a product in Phase 2 (Elafibranor) within a NASH subpopulation; or (iii) if we enter into at least one licensing agreement for our product candidates in one or several territories.
Evaluation date for performance conditions: 12/31/2020	**External conditions -** 33 1/3% of the instruments SO 2017-2/SO US 2017-2/AGA D 2017-2 will be exercisable or definitively allocated in proportion to the evolution of the stock market price, as follows: (a) if the Final Price is strictly lower than the Initial Price, the number exercisable or definitively allocated is equal to 0; (b) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number exercisable or definitively allocated is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of instruments; or (c) if the Final Price is equal to or higher than the Ceiling Price, the number exercisable or definitively allocated is equal to the entire one-third of the instruments granted. The notions of “Final Price”, “Initial Price” and “Ceiling Price” are defined in the plan regulations.

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

Plans	Nature of performance conditions
SO 2019 ***SO US 2019*** ***AGA D 2019*** ***AGA S 2019***	**Internal conditions -** 66 2/3% of the instruments SO 2019/SO US 2019/AGA D 2019 will be exercisable or definitively vest, and 100% of the Free Shares for the AGA S 2019 will vest, regardless of the variation of the stock market price of our shares, if at least one of the three following conditions is fulfilled: (i) if marketing authorization is granted or an application for marketing authorization is examined by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA) for elafibranor for NASH; or by the U.S. Food and Drug Administration (FDA)/the competent European authorities in the field of IVD for NIS4 for NASH; or (ii) if at least two of the four clinical trial among the following trials have delivered their principal results or are ongoing: Phase III clinical trials for elafibranor for PBC; or clinical trial evaluating elafibranor’s efficacy in NASH pediatric patients; or Phase 2b clinical trial or clinical trial aimed at registration for NTZ in fibrosis; or clinical trial evaluating elafibranor or NTZ in combination therapy for NASH or for hepatic fibrosis; or: (iii) if we enter into at least one new licensing agreement for our product candidates in one or several territories.
Evaluation date for performance conditions: 7/31/2022	**External conditions -** 33 1/3 % of the instruments SO 2019/SO US 2019/AGA D 2019 will be exercisable or definitively vest, in proportion to the variation of our stock market price as per the following breakdown: (a) if the Final Price is strictly lower than the Initial Price, the number of instruments exercisable or definitively vested is equal to 0; (b) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number of instruments exercisable or definitively vested is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of instruments; or (c) if the Final Price is equal to or higher than the Ceiling Price, the number of instruments exercisable or definitively vested is equal to the entire one-third of the instruments allocated. The notions of “Final Price”, “Initial Price” and “Ceiling Price” are defined in the plan regulations.

Plan	Nature of performance conditions
SO US 2019-2 *Evaluation date for performance conditions: 1/9/2023*	**Internal conditions -** 66 2/3 % of the Stock Options will be exercisable if at least if at least one of the three following conditions is fulfilled: (i) if elafibranor has been granted marketing authorization by the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA) in NASH or PBC or NIS4 has been authorized by FDA or received CE marking from the EMA; (ii) a licensing agreement pertaining to elafibranor or NTZ has been signed for the U.S. market and/or for at least two of the five major European markets (Germany, France, Italy, United Kingdom, Spain) and/or Japan; or (iii) at least two clinical trials for drug registration are underway. **External conditions -** 33 1/3 % of the Stock Options will be exercisable, in proportion to the variation of our stock market price as per the following breakdown: (a) if the Final Price is strictly lower than the Initial Price, the number of the Stock Options exercisable is equal to 0; (b) if the Final Price is between (i) a value equal to or higher than the Initial Price and (ii) a value lower than the Ceiling Price, the number of Stock Options exercisable is equal to: [(Final Price / Initial Price)-1]/2 x 1/3 of number of Stock Options; or (c) if the Final Price is equal to or higher than the Ceiling Price, the number of Stock Options exercisable is equal to the entire one-third of the Stock Options allocated. The notions of "Final Price", "Initial Price" and "Ceiling Price" are defined in the plan regulations.

Plans	Nature of performance conditions
SO D 2020 ***SO C 2020*** ***SO US 2020*** *Evaluation date for performance conditions: 12/31/2023*	a) 50% of the Stock Options will be exercisable if at least one of the following three conditions relating to PBC and ELATIVE is fulfilled: (i) "Last Patient Visit" in ELATIVE in the fourth quarter of 2022 or earlier; (ii) If the results of ELATIVE are released to the market before or during the first half of 2023; (iii) if a registration request is filed for elafibranor in PBS with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in 2023. b) 25% of the Stock Options will be exercisable if at least one of the following two conditions relating to the NIS 4 diagnostic is fulfilled: (i) if a research and development partnership agreement with at least one major NASH player ("big pharma", biotech company, institution, etc.) is entered into by the Company; (ii) the NIS 4 diagnostic is used in at least 20 clinical studies. c) 25% of the Stock Options will be exercisable if at least one of the following two conditions relating to the product pipeline of the Company is fulfilled: (i) initiation of a clinical study for a new indication with elafibranor or NTZ; (ii) if the Company develops or acquires the rights to a new molecule.

Plans	Nature of performance conditions
SO D 2021 ***SO C 2021*** ***SO US 2021*** *Evaluation date for performance conditions: 10/20/2024*	a) 50% of the Stock Options will be exercisable if at least one of the following three conditions relating to the development of elafibranor in PBC and to the ELATIVE clinical trial is fulfilled: (i) ELATIVE topline results are released to the market before or during the second quarter of 2023; (ii) a new drug application is filed for elafibranor in PBC with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in the second half of 2023 or before; (iii) elafibranor is approved by a regulatory authority in 2024. b) 15% of the Stock Options will be exercisable if at least one of the following two conditions relating to the development of NTZ and the ACLF franchise is fulfilled: (i) a Phase 2 clinical study or a more advanced clinical study evaluating NTZ is in ongoing or was carried out; (ii) the Company develops or acquires the rights to a new molecule (including through repositioning) for development in ACLF. c) 15% of the Stock Options will be exercisable if at least one of the following two conditions relating to the NIS4 diagnostic technology is fulfilled: (i) if a research and development partnership agreement relating to the implementation of the NIS4 diagnostic technology into an IVD test with at least one major NASH player ("big pharma", biotech company, institution, etc.) is entered into by the Company; (ii) Labcorp's NASHnext LDT is reimbursed by at least three payers in the United States (insurance, integrated system, etc). d) 20% of the Stock Options will be exercisable if at least one of the following two conditions relating to the development of the product pipeline of the Company is fulfilled: (i) At least one new molecule (excluding elafibranor and NTZ) is developed by the Company or the Company has acquired development rights to a new molecule outside of the ACLF franchise (performance already covered by b(ii) above); (ii) At least two Phase 2 clinical studies or more advanced clinical studies are ongoing or have been completed; not including a Phase 2 clinical study or more advanced clinical study in NTZ (performance already covered by b(i) above).

Plans	Nature of performance conditions
AGA S 2021 ***AGA D 2021*** *Evaluation date for performance conditions: 3/31/2024*	**Internal conditions -** a) 50% of the Free Shares AGA S 2021 will be exercisable, and 7,500 of the Free Shares AGA D 2021 will be exercisable, if at least one of the following three conditions relating to PBC and ELATIVE is fulfilled: (i) “Last Patient Visit” in ELATIVE in the fourth quarter of 2022 or earlier; (ii) If the results of ELATIVE are released to the market before or during the first half of 2023; (iii) if a registration request is filed for elafibranor in PBS with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in 2023. b) 25% of the Free Shares AGA S 2021 will be exercisable, and 3,750 of the Free Shares AGA D 2021 will be exercisable, if at least one of the following two conditions relating to the NIS4 diagnostic is fulfilled: (i) if a research and development partnership agreement with at least one major NASH player (“big pharma”, biotech company, institution, etc.) is entered into by the Company; (ii) the NIS4 diagnostic is used in at least 20 clinical studies. c) 25% of the Free Shares AGA S 2021 will be exercisable, and 3,750 of the Free Shares AGA D 2021 will be exercisable, if at least one of the following two conditions relating to the product pipeline of the Company is fulfilled: (i) initiation of a clinical study for a new indication with elafibranor or NTZ; (ii) if the Company develops or acquires the rights to a new molecule. **External conditions -** Each applicable portion of all 15,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, is then subject to the External Condition according to the methods described below. The degree of fulfillment of the External Condition relating to the Company's stock market price will be determined according to the relative performance of GENFIT shares. Each applicable portion of all 15,000 Free Shares under the AGA D 2021 plan, as each Internal Conditions above is met, will be definitively acquired per the following conditions: (a) No AGA D 2021 shall vest if the Final Price is strictly lower than the Initial Price; (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value lower than the Ceiling Price, the number of AGA D 2021 definitively allocated will be equal to:[(Final Price / Initial Price) -1] x 1/2 of the number of AGA D 2021 instruments (c) All AGA D 2021 if the Final Price is equal to or higher than the Ceiling Price. The notions of “Final Price”, “Initial Price” and “Ceiling Price” are defined in the plan regulations.

Plans	Nature of performance conditions
SO D 2022 ***SO C 2022*** ***SO US 2022*** ***SO SU 2022*** ***AGA S 2022*** ***AGA D 2022*** *Evaluation date for performance conditions:* *- 10/17/2025 for SO D 2022/SO C 2022/SO US 2022/AGA S 2022/ AGA D 2022* *- 12/3/2025 for SO SU 2022*	**Internal conditions -** a) 50% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 10,000 of the Free Shares for the AGA D 2022 will vest, if during the 2022 financial year and then at any time during the Vesting Period, 3 new R&D programs (at the rate of one third of these 2022 instruments per new program) complete the Company's R&D program portfolio (as it was at 12/31/2021); that these programs are at the so-called clinical development stage when this addition is made or that they reach this stage afterwards and that this addition originates: (i) a business-development operation (licensing-in, M&A, etc.), or (ii) the identification of new opportunities resulting from internal research (repositioning). b) 25% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 5,000 of the Free Shares for the AGA D 2022 will vest, if at least one of the following three conditions relating to the development of the elafibranor development program is fulfilled: (i) obtaining the main results of the first part of the ELATIVE trial in the second quarter of 2023; (ii) filing of a Marketing Authorization Application for elafibranor in the second half of 2023; (iii) marketing authorization for elafibranor in 2024. c) 15% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 3,000 of the Free Shares for the AGA D 2022 will vest, if at least one of the following two conditions relating to the development of the NTZ program in the ACLF is fulfilled: (i) First clinical results in 2022; (ii) start of a Phase 2 clinical trial in the first half of 2023. d) 10% of instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 2,000 of the Free Shares for the AGA D 2022 will vest, if as part of the development of the GNS561 program, a Phase 2b trial starts in the first half of 2023. **External conditions -** Each applicable portion of all 20,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, is then subject to the External Condition according to the methods described below. The degree of fulfillment of the External Condition relating to the Company's stock market price will be determined according to the relative performance of GENFIT shares. Each applicable portion of all 20,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, will be definitively acquired per the following conditions: (a) No AGA D 2022 shall vest if the Final Price is strictly lower than the Initial Price; (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value lower than the Ceiling Price, the number of AGA D 2022 definitively allocated will be equal to:[(Final Price / Initial Price) -1] x 1/2 of the number of AGA D 2022 instruments (c) All AGA D 2022 if the Final Price is equal to or higher than the Ceiling Price. The notions of “Final Price”, “Initial Price” and “Ceiling Price” are defined in the plan regulations.

Plans	Nature of performance conditions
SO D 2023 ***SO C 2023*** ***SO US 2023*** ***SO SU 2023*** ***AGA S 2023*** ***AGA D 2023***	**Internal conditions -** a) 50% of the instruments SO D 2023/SO C 2023/SO US 2023/ SO SU 2023/AGA S 2023 will be exercisable or definitively vest, and 5,000 of the Free Shares for the AGA D 2023 will be vest, if during 2023 and then at any time during the Vesting Period, 2 new R&D programs (at the rate of one-half of these 2023 instruments per new program), join the Company's R&D pipeline (as evaluated at December 31, 2022) ; and that these programs are at the clinical development stage at the time they join the pipeline or that they later enter this stage, following: (i) A business development transaction (in-licensing, M&A, etc.) or, (ii) Identification of new opportunities resulting from in-house research (program going from preclinical development stage to clinical development stage). b) 25% of the instruments SO D 2023/SO C 2023/SO US 2023/ SO SU 2023/AGA S 2023 will be exercisable or definitively vest, and 2,500 of the Free Shares for the AGA D 2023 will vest, if at least one of the two following conditions related to development of elafibranor in PBC is met: (i) Filing of the Marketing Authorization Application in the fourth quarter of 2023 (in Europe or the United States); (ii) Marketing Authorization obtained in 2024 (in Europe or the United States). c) 15% of the instruments SO D 2023/SO C 2023/SO US 2023/ SO SU 2023/AGA S 2023 will be exercisable or definitively vest, and 1,500 of the Free Shares for the AGA D 2023 will vest, if at least one of the two following conditions related to the development of the ACLF program is met: (i) VS-01 in ACLF: top-line results from the Phase 2 study obtained in 2024 or communication of final results on the Phase 2 study in 2025; (ii) NTZ : start of a Phase 2 clinical trial in the second half of 2023. d) 10% of the instruments SO D 2023/SO C 2023/SO US 2023/ SO SU 2023/AGA S 2023 will be exercisable or definitively vest, and 1,000 of the Free Shares for the AGA D 2023 will vest, if intermediate results in the Phase 1b/2 of GNS561 are obtained in the fourth quarter 2024 or final results obtained in 2025.
Evaluation date for performance conditions: *3/13/2026*	**External conditions -** Each applicable portion of all 10,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, is then subject to the External Condition according to the methods described below. The degree of fulfillment of the External Condition relating to the Company's stock market price will be determined according to the relative performance of GENFIT shares. Each applicable portion of all 10,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, will be definitively acquired per the following conditions: (a) No AGA D 2022 shall vest if the Final Price is strictly lower than the Initial Price; (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value lower than the Ceiling Price, the number of AGA D 2022 definitively allocated will be equal to:[(Final Price / Initial Price) -1] x 1/2 of the number of AGA D 2022 instruments (c) All AGA D 2022 if the Final Price is equal to or higher than the Ceiling Price. The notions of "Final Price", "Initial Price" and "Ceiling Price" are defined in the plan regulations.

C. Board Practices

Board Composition

Under French law and our bylaws, our board of directors must be comprised of between three and 18 members. Their term of office, in accordance with our bylaws, is five years. Directors are appointed, reappointed to their position, or removed by the company's ordinary general meeting. Directors chosen or appointed to fill a vacancy must be elected by our board of directors for the remaining duration of the current term of the vacant director. The appointment must then be ratified at the next shareholders' general meeting. In the event the board of directors would be comprised of less than three directors as a result of a vacancy or removal, the remaining directors shall immediately convene a shareholders' general meeting to elect one or several new directors so there are at least three directors serving on the board of directors, in accordance with French law.

Our board of directors currently consists of nine members, one of which is a citizen or resident of the United States, and one board observer. As permitted by French law, two of our directors, SAS Biotech Avenir, and Ipsen, are legal entities. These entities have designated, respectively, individuals, Florence Séjourné, and Dr. Steven Hildemann, to represent them and to act on their behalf at meetings of our board of directors. Ms. Séjourné and Dr. Hildemann have the same responsibilities to us and to our shareholders as they would have if they had been elected to our board of directors in their individual capacity. None of our directors serve pursuant to a service contract providing benefits upon termination of service as a director.

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

	CURRENT POSITION	YEAR OF INITIAL APPOINTMENT	TERM EXPIRATION YEAR
Jean-François Mouney	Chairman	1999 (1)	2027
Xavier Guille des Buttes	Vice Chairman	2006 (2)	2027
Eric Baclet	Director	2020	2025
IPSEN, represented by Dr. Steven Hildemann	Director	2022	2027
Katherine Kalin	Director	2020	2025
Catherine Larue	Director	2017	2027
Anne-Hélène Monsellato	Director	2017	2027
Philippe Moons	Observer	2015 (3)	2027
SAS Biotech Avenir represented by Florence Séjourné	Director	2010 (4)	2027
Jean-François Tiné	Director	2020 (5)	2027

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

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

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

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

(5) Appointed by the Board of Directors on February 26, 2021 to replace Philippe Moons on the Board of Directors. His appointment was approved by the Shareholders' Meeting on June 30, 2021 to serve out the remainder of the term of Philippe Moons which ended at the shareholders meeting called to approve the financial statements for the year ended December 31, 2021 held on May 25, 2022. His appointment was renewed by the May 25, 2022 shareholders' meeting.

In 2022, the Board of Directors met nine times, with an average participation rate of 93 % of Board members.

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

Mr. Jean-François Mouney : 100 % ;

Mr. Eric Baclet : 100%

Mr. Xavier Guille des Buttes: 89 % ;

Mr. Frédéric Desdouits (until May, 25, 2022) : 75%;

IPSEN (represented by Dr. Steven Hildemann) (since May 2022): 100%

Ms. Katherine Kalin: 89%;

Ms. Catherine Larue : 89 % ;

Ms. Anne-Hélène Monsellato : 100 % ;

Mr. Philippe Moons : 100 %;

SAS Biotech Avenir (represented by Ms. Florence Séjourné) : 89 %.

Mr. Jean-François Tiné: 89%.

Board Diversity

Since January 1, 2017, under French law, the number of directors of each gender may not be less than 40% of the total number of directors. Any appointment made in violation of this limit that is not remedied within six months of this appointment will be null and void. Any appointment which remedies a violation of the 40% gender limit must be ratified by our shareholders at the next ordinary general meeting.

The Nominations and Compensation Committee endeavors to seek nominees representing diverse experience in the drug development and diagnostics business, finance and other areas that are relevant to our activities. Furthermore, our board of directors is committed to actively seeking out highly qualified women and individuals from minority groups to include in the pool from which Board nominees are chosen.

Pursuant to Nasdaq Listing Rule 5605(f) the table below provides certain highlights of the composition of our board members to the extent we are permitted to disclose such information under French law.

Board Diversity Matrix as of December 31, 2022

Country of Principal Executive Offices:				France
Foreign Private Issuer:				Yes
Disclosure Prohibited under Home Country Law:				No
Total Number of Directors:				9
Part I: Gender Identity				
	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	4	5	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction				-
LGBTQ+				-
Did Not Disclose Demographic Background				9

Director Independence

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

Role of the Board in Risk Oversight

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

Corporate Governance Practices

As a French *société anonyme*, we are subject to various corporate governance requirements under French law. When we listed our shares on Euronext Paris in 2014, we elected to refer to the Middlenext Governance Code providing guidance to mid and small cap companies. In addition, as a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq corporate governance listing standards. However, the corporate governance standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq rules, with certain exceptions. We rely on these exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, which would otherwise require that (1) a majority of our board of directors consist of independent directors; (2) we establish a nominating and corporate governance committee; and (3) our remuneration committee be composed entirely of independent directors.

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

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

Board Committees

The board of directors has established an audit committee, a nomination and compensation committee, a strategy and alliances committee, and an ESG committee, in accordance with the Middlenext Code requirements. Subject to available exemptions, the composition and functioning of all of our committees complies with all applicable requirements of the French Commercial Code, the Exchange Act, the Nasdaq Global Select Market and SEC rules and regulations.

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

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

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

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

In 2022, the audit committee met five times, with an average participation rate of 100% of committee members.

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

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

- ensure the professionalism and objectivity of the appointment procedure for senior executives and corporate officers and senior management of the company. In particular, it is in charge of making any proposal regarding the size and the desirable balance of the composition of the board of directors in view of the structure and evolution of the shareholding of our company, as well as the requirements for good corporate governance, including the proportion of independent directors at our board of directors, examine board committee membership, including in relation to the new ESG committee. Its mission is to research and assess potential candidates as well as the opportunity to renew mandates; and reviews the future succession of our company's chairman and chief executive officer;
- assess the status of each of its board members relative to other relations they might have with our company, which may compromise his or her free judgment or trigger potential conflicts of interest with us; the nomination and compensation committee must also organize a procedure to select future independent members of the Board of Directors; and

- make proposals to the board of directors concerning the elements of compensation or benefits granted to senior executives, corporate officers and senior management, including directors' attendance fees and salaries, allowances or remuneration of any kind that such persons may receive under an employment contract or company contract with our company, the indemnities and benefits due upon termination of their employment, function or subsequent to this, the allocation of warrants, stock options or free shares, or any form of long-term incentive in the capital of the company. In this respect, the nomination and compensation committee assesses the scale of the compensation offered by the company in comparison with those practiced on the market and gives its recommendations to the board of directors on the remuneration levels and the breakdown between the various elements of the compensation, as well as the changes in compensation that may be proposed by the company to its senior management and corporate officers.

In 2022, the Nomination and Compensation Committee met four times, with an average participation rate of 94% of committee members.

Strategy and Alliances Committee.

Mr. Jean-François Mouney, Mr. Xavier Guille des Buttes, Ms. Katherine Kalin and Mr. Jean-François Tiné currently serve on our strategy and alliances committee. Mr. Jean-François Mouney is chairman of our strategy and alliances committee.

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

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

In 2022, the strategy and alliances committee met seven times, with an average participation rate of 93% of committee members. In particular, in 2022, the committee examined the Versantis AG acquisition as well as reviewed and provided recommendations regarding the Ipsen and Genoscience collaborations.

ESG Committee

Ms. Catherine Larue, Mr. Xavier Guille des Buttes and Mr. Jean-François Mouney currently serve on our ESG committee. Ms. Catherine Larue is the chairwoman of our ESG committee.

The ESG Committee was created in October 2021, in accordance with the R8 recommendation of the Middlenext Code, with the mission of ensuring that the Company adequately addresses the economic and societal challenges related to its corporate purpose of proposing therapeutic and diagnostic solutions intended to address unmet medical needs of patients around the world.

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

- review the Company's strategy, ambitions, policies and commitments in terms of social responsibility (Ethics and compliance, Human Rights, Hygiene / Health / Safety of people, Environment);
- ensure the Company's level of commitment to non-financial performance, ethics and social and environmental responsibility in relation to stakeholders' expectations;
- ensure implementation of actions in these areas; and
- make recommendations in this regard to the Board of Directors.

The ESG Committee works in conjunction with the Nomination and Compensation Committee to define the components of social responsibility to be integrated into compensation policies and the development of diversity criteria within the Company as well as with the Audit Committee to manage the risks specific to the social responsibility of the Company.

In 2022, the ESG committee met three times, with a participation rate of 100% of committee members.

D. Employees

As of December 31, 2022, we had 148 employees. Of these employees, 91 were engaged in research and development and services related to research and development activities, 55 were engaged in administration and management, which includes finance, investor relations, information systems, human resources and legal, and 2 were engaged in marketing and commercial activities.

Of these 148 employees, 127 were employed by GENFIT S.A., 13 were employed by our U.S. subsidiary, GENFIT Corp, and 8 were employed by our Swiss subsidiary, Versantis AG. Employees employed by GENFIT S.A. are mainly based in France, employees employed by GENFIT Corp. are mainly based in our Cambridge, Massachusetts office and employees employed by Versantis AG are mainly based in Zurich, Switzerland. As of April 14, 2023, Versantis Inc does not have any activities and therefore has no employees.

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

E. Share Ownership

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

F. Disclosure of a registrant's action to recover erroneously awarded compensation

Not applicable.

Item 7. Major Shareholders and Related Party Transactions.

A. Major Shareholders

The following table sets forth, as of April 1, 2023, information regarding beneficial ownership of our ordinary shares by:

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

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including free shares that vest by June 1, 2023 the date that is 60 days after April 1, 2023, and stock options and warrants that are currently exercisable or exercisable by June 1, 2023. Shares subject to options and warrants currently exercisable or exercisable by June 1, 2023 are deemed to be outstanding for computing the percentage ownership of the person holding these options or warrants and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person.

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

Our calculation of the percentage of beneficial ownership is based on 49,834,983 of our ordinary shares outstanding as of April 1, 2023.

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

Name of Beneficial Owner	Number of Ordinary Shares	Percentage
Significant Shareholders:		
Biotech Avenir SAS(1)	1,888,618	3.79%
Ipsen Pharma SAS(2)	3,985,239	8.00%
Directors and Senior Management:		
Jean-François Mouney(3)	1,966,539	3.95%
Pascal Prigent(4)	34,074	*
Dean Hum, Ph.D(5)	43,686	*
Carol Addy	—	—
Jean-Christophe Marcoux(6)	19,575	*
Laurent Lannoo(7)	29,084	*
Thomas Baetz	—	—
Pascal Caisey	—	—
Meriam Kabbaj	—	—
Stefanie Magner(8)	16,021	*
Emilie Desodt (9)	3,986	*
John Brozek (10)	9,990	*
Xavier Guille Des Buttes(11)	1,842	*
Catherine Larue, Ph.D	—	—
Anne-Hélène Monsellato	—	—
Steven Hildemann(2)	—	—
Florence Séjourné(1)	—	—
Philippe Moons(12)	310	*
Katherine Kalin (13)	5,000	*
Eric Baclet (14)	1,200	*
Jean-François Tiné	—	—
All directors and senior management as a group (21 people)(15)	2,117,331	4.25%

* Represents beneficial ownership of less than 1%

(1) Biotech Avenir SAS is our holding company. Mr. Mouney, the Chairman of our board of directors, is also the Chief Executive Officer and Chairman of the Management Committee of Biotech Avenir and holds 17.1% of its share capital. Florence Séjourné, who represents Biotech Avenir on our board of directors, is also a member of the Management Committee of Biotech Avenir and holds 9.9% of its share capital. Dean Hum holds 6.2% of its share capital, Laurent Lannoo, who is a member of the Management Committee of Biotech Avenir, holds less than 0.03% of its share capital and John Brozek holds 0.13% of its share capital.

(2) Steven Hildemann represents Ipsen Pharma SAS (through Ipsen) on our board of directors. The Ipsen shares are subject to a lock-up period ending, on the earlier of the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorization of elafibranor in PBC, the date on which the U.S. FDA grants approval of elafibranor in PBC or in the event the ELATIVE trial does not meet its primary endpoint.

(3) Consists of 1,925,212 ordinary shares, of which 1,888,618 shares are held directly by Biotech Avenir, and 41,327 stock options that are exercisable within 60 days of April 1, 2023.

(4) Consists of 20,708 ordinary shares and 13,366 stock options that are exercisable within 60 days of April 1, 2023.

(5) Consists of 8,804 ordinary shares and 35,482 stock options that are exercisable within 60 days of April 1, 2023.

(6) Consists of 2,620 ordinary shares and 16,955 stock options that are exercisable within 60 days of April 1, 2023.

(7) Consists of 9,736 ordinary shares and 19,348 stock options that are exercisable within 60 days of April 1, 2023.

(8) Consists of 1,540 ordinary shares and 14,481 stock options that are exercisable within 60 days of April 1, 2023.

(9) Consists of 608 ordinary shares and 3,158 stock options that are exercisable within 60 days of April 1, 2023, and 220 ordinary shares underlying OCEANEs convertible bonds.

(10) Consists of 2801 ordinary shares and 7,189 stock options that are exercisable within 60 days of April 1, 2023.

(11) Consists of 1,842 ordinary shares.

(12) Consists of 310 ordinary shares. Philippe Moons is an observer on the Board of Directors.

(13) Consists of 5,000 ADS.

(14) Consists of 1,200 ordinary shares.

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

Significant Changes in Percentage Ownership

There were no significant changes in the percentage ownership held by our principal shareholders during the year ended December 31, 2022.

Voting Rights

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

Shareholders in the United States

As of March 31, 2023, to the best of our knowledge, 4,422,717 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) or approximately 8.87%% were held by 17 shareholders of record in the United States, including The Bank of New York Mellon, the depositary of our ADR program. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Since January 1, 2022, we have engaged in the following transactions with our directors, senior management and holders of more than 5% of our outstanding voting securities and their affiliates, which we refer to as our related parties.

Directors

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

Chief Executive Officer

Mr. Prigent benefits from a severance payment falling within the scope of Article L.225-42-1 of the French Commercial Code equal to 18 months' gross compensation, calculated on the basis of the last 12 months, increased, where applicable, by the amount of annual variable compensation due for the previous fiscal year and it would be paid if, and only if, one of the following three performance conditions is achieved at the time that his post is terminated:

- elafibranor has been granted marketing authorization by the FDA or EMA in PBC;
- a license agreement for NTZ, GNS561, VS-01 or VS-02 has been signed for the US market and / or for at least two of the five major European markets (Germany, France, Italy, United Kingdom, Spain and / or for Japan); or
- there is a takeover of the Company.

Mr. Prigent also benefits from a non-compete indemnity equal to 12 months of gross fixed compensation, calculated on the basis of the gross amounts due for the past twelve months end, and where applicable, by the amount of the annual variable compensation due for the previous year. The amounts which he may receive under a non-compete indemnity are not cumulative with his severance payment and vice-versa. The non-competition covenant would not apply to Mr. Prigent if he leaves the Company, for whatever reason, either by decision of the Board of Directors or at his initiative, following a takeover of the Company.

Biotech Avenir

Biotech Avenir SAS, our holding company, holds 3.79% of our share capital and 7.16% of our voting rights, as of April 1, 2023. Mr. Mouney, the Chairman of our board of directors and, until September 2019, our Chief Executive Officer, is also Chairman of the Management Committee of Biotech Avenir and holds 17.1% of its share capital. Florence Séjourné, who represents Biotech Avenir on our board of directors, is also member of the Management Committee of Biotech Avenir and holds 9.9% of its share capital. Dean Hum holds 6.2% of its share capital, Laurent Lannoo, who is a member of the Management Committee of Biotech Avenir, holds less than 0.03% of its share capital and John Brozek holds 0.13% of its share capital. The registered office of Biotech Avenir is located at the same address as our principal executive offices, without charge to Biotech Avenir.

Shareholders' Agreement

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

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

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

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

Ipsen Pharma SAS

Collaboration and license agreement

On December 16, 2021, we entered into an exclusive collaboration and license agreement with Ipsen for the development and commercialization of elafibranor in PBC and other indications (the Ipsen Collaboration and License Agreement). On the same date, we also entered into an investment agreement pursuant to which Ipsen became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance and, following approval by our shareholders at the shareholders' meeting on May 25, 2022, Ipsen became a member of our Board of Directors, represented by Dr. Steven Hildemann. Ipsen therefore qualifies as a related person.

See also "Item 10.C—Material Contracts" herein for more information.

Transition Services Agreement

The Transition Services Agreement (the "TSA") signed between the Company and Ipsen on April 6, 2022, pursuant to the Ipsen Collaboration and License Agreement, was approved by the Board of Directors on April 6, 2022 in accordance with the Company's Related Party Transactions policy.

The TSA governs the performance of a number of transition services by the Company in relation to the ongoing ELATIVE trial, the Phase 3 clinical trial evaluating elafibranor in PBC and the financial conditions thereof. These services are mainly related to preparing the second phase of the ELATIVE trial as well as certain regulatory tasks such as preparation of the conditional marketing authorization application for elafibranor in PBC. The services are being performed on an arms-length basis.

In 2022, €1.0 million in revenue was generated from the services rendered by GENFIT to Ipsen pursuant to the TSA.

Inventory Purchase Agreement

The Inventory Purchase Agreement (the "IPA") signed between the Company and Ipsen on July 13, 2022, pursuant to the Ipsen Collaboration and License Agreement, was ratified by the Board of Directors on September 27, 2022 in accordance with the Company's Related Party Transactions policy.

The IPA defines the conditions under which the Company sold and Ipsen purchased almost all of the Company's remaining stock of elafibranor active ingredient and drug product for the ELATIVE Phase 3 clinical trial. The sale was conducted on an arms-length basis.

In 2022, €3.3 million was recognized as revenue from the sale of said inventory in accordance with said agreement.

Related Person Transaction Policy

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

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

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

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

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

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

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

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information.

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

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

Dividend Distribution Policy

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

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

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations, including those described in Note 27 of our consolidated financial statements for the year ended December 31, 2022 appended to this annual report.

On May 14, 2020, following our announcement that elafibranor had not achieved the primary or key secondary endpoints of the RESOLVE-IT trial, a purported shareholder class action complaint, captioned Schwartz v. GENFIT S.A. et al., was filed in state court in the Commonwealth of Massachusetts, naming us, our board of directors and certain members of our senior management as defendants. The complaint alleged that we made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws. The complaint sought unspecified compensatory damages. In October 2020, the plaintiff voluntarily withdrew its action filed in state court in the Commonwealth of Massachusetts.

However, in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering. In August 2021, the Supreme Court of the State of New York, New York County, dismissed the complaint with prejudice. The plaintiff appealed, and in December 2022, the Supreme Court, Appellate Division, First Department affirmed the dismissal of the complaint, except that it deleted the phrase "with prejudice" from the Supreme Court's judgment. The time to appeal the decision of the Appellate Division has expired.

Other than the legal proceeding described above, we are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

B. Significant Changes

Not applicable

Item 9. The Offer and Listing.

A. Offer and Listing Details

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

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth in the final prospectus dated March 27, 2019 as part of our Registration Statement on Form F-1 (File No. 333-229907), declared effective by the SEC on March 26, 2019, under the heading “Limitations Affecting Shareholders of a French Company” and the information in Exhibit 2.3 "Description of Securities" hereto is incorporated herein by reference.

C. Material Contracts

Collaboration and License Agreement with Ipsen Pharma SAS

On December 16, 2021, we entered into an exclusive collaboration and license agreement with Ipsen Pharma SAS or Ipsen, a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience, as well as Consumer Healthcare products. Under the agreement, Ipsen has an exclusive worldwide (excluding Greater China which is licensed to Terns) license to develop, manufacture and commercialize elafibranor, our proprietary investigational compound, for people living with PBC, and in any other indications.

Under the terms of the agreement, we received an upfront cash payment of €120m, and are eligible for regulatory, commercial, and sales-based milestone payments up to €360m, plus tiered double-digit royalties of up to 20%.

We remain responsible for the Phase 3 ELATIVE trial until the completion of the double-blind period. Ipsen will assume responsibility for all additional clinical development, including completion of the long-term extension period of the ELATIVE trial, and global commercialization (excluding Greater China which is licensed to Terns). This newly established strategic partnership will also provide Ipsen with access to our research capabilities and other clinical programs through rights to first negotiation.

In addition, pursuant to an investment agreement entered into on the same date as the collaboration and licensing agreement, Ipsen also became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28m investment. The new shares are subject to a lock-up period ending, on the earlier of the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorization of elafibranor in PBC, the date on which the U.S. FDA grants approval of elafibranor in PBC or in the event the ELATIVE trial does not meet its primary endpoint. Following approval by our shareholders at the shareholders' meeting on May 25, 2022, Ipsen became a member of our Board of Directors.

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

Collaboration and License Agreement with Terns Pharmaceuticals, Inc.

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

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

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

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

Share Purchase Agreement for the Acquisition of Versantis AG

On September 19, 2022, we announced we had signed an exclusive agreement to acquire all the shares and voting rights of Versantis AG, or Versantis, a private Swiss-based clinical stage biotechnology company, and its U.S. subsidiary, Versantis, Inc., focused on addressing the growing unmet medical needs in liver diseases.

With this acquisition, we acquired Versantis' pipeline, which includes Versantis' main asset VS-01, a liposomal-based therapeutic product candidate currently in clinical development as a potential therapy for ACLF and HAC. In addition, it's second asset, VS-02 is a pre-clinical oral and colon-active, drug candidate being developed for the chronic management of HE. Finally, TS-01, a point-of-care diagnostic device in prototype development for at-home measurement of ammonia in the blood, is in-licensed by Versantis from ETH Zurich.

The deal included an initial consideration of CHF40.0 million due at closing plus a CHF2.8 million cash adjustment, with contingent consideration of up to CHF65 million upon positive Phase 2 results for VS-01 and VS-02 and regulatory approval of VS-01. In addition, the former owners of Versantis are eligible to receive 1/3 of the net proceeds resulting from the sale of VS-01's pediatric review voucher to a third party, or 1/3 of the fair market value of this pediatric review voucher if we opt to apply it to one of our own programs.

The transaction closed effective September 29, 2022.

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

For additional information on our material contracts, please see "Item 4—Information on the Company," "Item 6—Directors, Senior Management and Employees," and "Item 7.B—Related Party Transactions" of this annual report.

Convertible Bonds (OCEANEs)

In October 2017, we issued convertible bonds (OCEANEs) for gross proceeds of €180.0 million, with a maturity date initially of October 16, 2022.

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

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

At the Shareholders' and Bondholders' Meetings on January 25, 2021, the shareholders and bondholders approved this renegotiation offer and we completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) per bond for a total buyback cost of €47.48 million on January 29, 2021. We then cancelled the repurchase of OCEANEs. Following the renegotiation, the OCEANEs bear interest at an annual nominal rate of 3.50% payable semi-annually in arrears on April 16 and October 16 of each year (or the following business day if this date is not a business day). The OCEANEs will be redeemed at par on October 16, 2025 (or the following business day if this date is not a business day). The effective interest rate is 8.8%.

The nominal unit value of the OCEANEs was set at €29.60. The OCEANEs conversion ratio is 5.5 shares for one OCEANE, subject to any subsequent adjustments.

The OCEANEs may be redeemed early at the option of the Company, under certain conditions. Specifically, the OCEANEs may be redeemed early at the option of the Company from November 6, 2020 onward if i) the mathematical average of the volume-weighted average price of GENFIT shares on the regulated market of Euronext in Paris and ii) the conversion ratio of the shares in force (over a period of 20 trading days) exceeds 150% of the nominal value of the OCEANEs bonds.

As of December 31, 2022, there were 1,923,662 OCEANEs outstanding, and the maximum dilution to GENFIT's share capital in the event of full conversion would be 21.29%, with approximately €56.9 million nominal amount outstanding.

The OCEANEs are admitted to trading on Euronext Access (the free market of Euronext in Paris).

For more information see Note 20.1 to our consolidated financial statements included in this annual report under the caption "Breakdown of convertible loan."

D. Exchange Controls

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

E. Taxation

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

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a "hedging," "integrated", "wash sale" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- certain former citizens or long term residents of the United States;
- persons that received ADSs as compensation for the performance of services;
- persons acquiring ADSs in connection with a trade or business conducted outside of the United States, including a permanent establishment or a fixed base in France;
- holders subject to special tax accounting rules under Section 451(b) of the U.S. Internal Revenue Code of 1986, as amended, or the Code;
- holders that elect to apply the provisions of Section 1400Z-2 of the Code to any gain realized upon a disposition of our ADSs;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ADSs and shares or, in the case of the discussion of French tax consequences, 5% or more of the voting stock or our share capital; and
- holders that have a "functional currency" other than the U.S. dollar.

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

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

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

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

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

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

Material French Tax Considerations

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

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

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

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

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

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

Estate and Gift Taxes

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

Financial Transactions Tax and Registration Duties

Pursuant to Article 235 ter ZD of the French tax code (Code général des impôts, the "FTC"), purchases of shares or ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the French Financial Market Authority (AMF) are subject to a 0.3% French tax on financial transactions provided that, broadly, the issuer's market capitalization exceeds 1 billion euros as of December 1 of the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the taxation year within the meaning of Article 235 ter ZD of the FTC is published by the French tax authorities on an annual basis in their official guidelines. Pursuant to the official guidelines BOI-ANNX-000467 issued on December 21, 2022, we are currently not included in such list.

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

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

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

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

Tax on Sale or Other Disposals

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

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

Taxation of Dividends

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

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

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

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

- such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000) in accordance with French guidelines (BOI-INT-DG-20-20-20-20 dated September 12, 2012); or
- the depositary or other financial institution managing the securities account in the U.S. of such holder provides the French paying agent with a document listing certain information about the U.S. holder and its ordinary shares or ADSs and a certificate whereby the financial institution managing the U.S. holder's securities account in the United States takes full responsibility for the accuracy of the information provided in the document.

Otherwise, dividends paid to a U.S. holder, if such U.S. holder is a legal person, will be subject to French withholding tax at the rate of 25%, or 75% if paid in certain non-cooperative States or territories (as defined in Article 238-0 A of the FTC - except for those mentioned in paragraph 2 bis-2°), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides through the French paying agent, the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the calendar year following the year during which the dividend is paid (due to recent case law regarding status of limitation for filing a withholding tax claim; U.S. holders are advised to consult their own tax advisors in this respect).

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

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

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

Wealth Tax

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

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

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

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

Material U.S. Federal Income Tax Considerations

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

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

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

Passive Foreign Investment Company Considerations.

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

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

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

The fair market value of our assets may be determined in large part by reference to the market price of the ADSs and our ordinary shares, which is likely to continue to fluctuate. Fluctuations in the market price of our ordinary shares or ADSs may result in our being a PFIC for any taxable year. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from our offerings. Based on our analysis of our income, assets, activities and market capitalization for our taxable year ended December 31, 2022, we believe that we were classified as a PFIC for the taxable year ended December 31, 2022. Whether we are a PFIC for any taxable year will depend on our assets and income (including whether we receive certain non-refundable grants or subsidies, and whether such amounts along with reimbursements of certain refundable research tax credits and certain intercompany service payments will constitute gross income for purposes of the PFIC income test) in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year. In addition, we hold a substantial amount of cash and cash equivalents. Our PFIC status may change from year to year and it is difficult to predict whether we will be a PFIC for the current year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current taxable year. However, we could continue to be considered a PFIC for the current taxable year or a future taxable year if the current percentage of our passive assets compared to our total assets remains the same or increases. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

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

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

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

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

Notwithstanding our belief that we were classified as a PFIC for the taxable year ended December 31, 2022, we do not currently intend to provide the information necessary for U.S. holders to make qualified electing fund elections for such taxable year or any other taxable year for which we are treated as a PFIC. U.S. holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

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

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

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

Distributions.

Subject to the discussion under "— Passive Foreign Investment Company Considerations," above, the gross amount of any distribution (including any amounts withheld in respect of foreign tax) actually or constructively received by a U.S. holder with respect to ADSs will generally be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will generally be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder's adjusted tax basis in the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we may not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) and qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for such purposes and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. Our ADSs are currently listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance in this regard. The Company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under "— Passive Foreign Investment Company Considerations," above, such dividends will generally be "qualified dividend income" in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days

of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

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

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

Sale, Exchange or Other Taxable Disposition of the ADSs.

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

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

Medicare Tax.

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

Backup Withholding and Information Reporting.

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

Foreign Asset Reporting.

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

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

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

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

I. Subsidiary Information

Not required.

J. Annual Report to Security Holders

If we are required to provide an annual report to security holders in response to the requirements of Form 6-K, we will submit the annual report to security holders in electronic format in accordance with the EDGAR Filer Manual.

Item 11. Quantitative and Qualitative Disclosures About Market Risk.

Foreign Currency Exchange Risk

We use the euro as our functional currency and the majority of our operations are denominated in euros. However, a portion of our operating expenses is denominated in U.S. dollars and Swiss Francs (notably due to the acquisition of Versantis in 2022), as well as a significant portion of our cash and cash equivalents. As result, we may be exposed to foreign currency risk.

Our overall exposure to the foreign exchange risk depends, in particular, on:

- the currencies in which we receive our 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 our co-contracting parties to indirectly transfer foreign exchange risk to us;
- our foreign exchange risk policy; and
- the fluctuation of foreign currencies against the euro.

For the years ended December 31, 2021 and December 31, 2022, expenses in U.S. dollars totaled $12.6 million and $14.9 million respectively, based on the exchange rate in effect at December 31, 2021 and December 31, 2022. As a result, an adverse 10% change in the exchange rate for the U.S. dollar against the euro would have resulted in a foreign exchange rate loss of approximately €1.0 million and €1.3 million for the years 2021 and 2022 respectively.

For the year ended December 31, 2022, expenses in Swiss Francs totaled CHF2.0 million, based on the exchange rate in effect at December 31, 2022. As a result, an adverse 10% change in the exchange rate for the Swiss Franc against the euro would have resulted in a foreign exchange rate loss of approximately €0.2 million for the year 2022.

As of December 31, 2021 and December 31, 2022, cash and cash equivalents in U.S. dollars totaled $81.7 million and $34.2 million respectively, based on the exchange rate in effect at December 31, 2021 and December 31, 2022. As a result, an adverse 10% change in the exchange rate for the U.S. dollar against the euro would have resulted in a foreign exchange rate loss of approximately €6.6 million and €2.9 million for the years 2021 and 2022 respectively.

As of December 31, 2022, cash and cash equivalents in Swiss Francs totaled CHF2.3 million, based on the exchange rate in effect at December 31, 2022. As a result, an adverse 10% change in the exchange rate for the Swiss Franc against the euro would have resulted in a foreign exchange rate loss of approximately €0.2 million for the year 2022.

For the year ended December 31, 2021, we recorded a total net foreign exchange gain of €6.7 million (cumulating operating and financial exposure), including a realized gain of €0.8 million. For the year ended December 31, 2022, we recorded a total net foreign exchange gain of €7.1 million (operating and financial), including a realized gain of €7.5 million. Any such historical gains or losses do not predict the future impact of foreign exchange rate risks.

We maintain a balance between euros, US dollars and Swiss Francs in line with the projected outflows of expected resources in order to naturally cover the risk and therefore hold a significant portion of our cash in US dollars and Swiss Francs. Given the significant portion of our operations denominated in US dollars and Swiss Francs, we decided to limit the conversions into euros of our US dollar denominated cash and the conversions into euros of our Swiss Franc denominated cash. We do not use any specific hedging arrangements. However, as the majority of our expenses are denominated in euros, we could be required to convert U.S. Dollars into euros or Swiss Francs into euros, and are therefore exposed to a foreign exchange risk. As of December 31, 2022, we did not have foreign exchange rate hedging tools or contracts in place.

In the future, and in particular with respect to our clinical trials and the funding of our US subsidiary and our Swiss subsidiary, we will continue to have a significant portion of transactions denominated in currencies other than the euro or indirectly exposed to currency risk, and as a result, we will continue to have exposure to this risk.

See also Note 6.1 to our consolidated financial statements included in this annual report under the caption "Foreign Exchange Risk."

Interest Rate Risk

We believe we have low exposure to interest rate risk.

Our financial liabilities, which consist primarily of convertible bonds, bank loans and government refundable or conditional advances, that carry no interest or fixed interest rates, and therefore are not subject to interest rate risk, with the exception of the state-guaranteed loans (PGE), the interest rates of which may be revised in case of their extension beyond their current maturity, which in turn could lead to an increase in interest in the future.

With respect to our financial assets, which consist primarily of cash and cash equivalents, our exposure is also limited, as these assets are held on euro and US dollar denominated demand deposits, term deposits with progressive rates, or invested in euro and US dollar denominated medium-term negotiable notes or in euro denominated UCITs (Undertakings for the Collective Investment of Transferable Securities). While these interest-earning instruments carry a degree of interest rate risk, historical fluctuations in interest income in comparison to the average balance have not been significant.

Credit Risk

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

Liquidity Risk

We had €145.5 million in cash and cash equivalents and other financial assets, including €136.0 million in cash and cash equivalents, as of December 31, 2022 and as a result, do not believe that we are exposed to short-term liquidity risk. In addition, our loans and borrowings mainly consist of bonds convertible or exchangeable into new or existing shares (OCEANEs), repayable for a nominal amount of €56.9 million on October 16, 2025 (see Note 20.1 to our consolidated financial statements included in this annual report under the caption "Breakdown of convertible loan").

We estimate that we will be able to fund our operating expenses and capital expenditure requirements for the next 12 months at least based on our existing cash and cash equivalents and the reimbursement of research tax credits. This estimate is based on our current business plan and does not include any potential milestones payable to or from us, nor any additional expenditures resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development we may pursue. We have based this estimate on assumptions that may be incorrect and we may use our capital resources sooner than anticipated.

We may need to seek additional funds, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other partnerships, strategic alliances and licensing arrangements or a combination of these approaches. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

Detail of calculation of net cash	**As of**		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Cash and cash equivalents	171,029	258,756	136,0
Current convertible loans	1,312	415	4
Other current loans and borrowings	3,035	1,773	4,6
Non-current convertible loans	169,470	47,682	49,8
Other non-current loans and borrowings	11,873	24,365	20,3
Net cash	**(14,662)**	**184,521**	**60,7**

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations in 2022. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs, as we do not generate significant revenue from product sales. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 11C. Interim Periods.

Not applicable.

Item 11D. Safe Harbor

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

Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

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

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

Fees and Charges

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

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

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

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

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

Payment of Taxes

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

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

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

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

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

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

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

Following the shareholders' and bondholders' decisions, GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. The settlement operations occurred on January 29, 2021. The repurchased OCEANEs were then cancelled by GENFIT. The convertible bonds carry a fixed interest rate of 3.5%, with an effective interest rate of 8.8%, payable semi-annually in arrears in April and October.

Following conversion of the OCEANEs into shares up until April 1, 2023, which led to the creation of 6,941,875 new shares, the residual nominal convertible debt, initially reduced to a nominal amount of €94.3 million through the partial buyback transaction, was further reduced by a nominal amount of €37.4 million, with approximately €56.9 million nominal amount outstanding as of April 1, 2023.

For more information please see Note 20.1 to our consolidated financial statements included in this annual report under the caption "Breakdown of convertible loan."

Item 15. Disclosure Controls and Procedures.

A. Disclosure Controls and Procedures

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

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2022, have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2022 based on the framework in "Internal Control - Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management has concluded that, as December 31, 2022, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of

effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

C. Attestation Report of the Registered Public Accounting Firm

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

D. Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert.

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

Item 16B. Code of Business Conduct and Ethics.

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

Item 16C. Principal Accountant Fees and Services.

Ernst & Young et Autres, or E&Y, served as our independent registered public accounting firm for 2021 and 2022. Our accountants billed the following fees to us for professional services in each of those fiscal years :

	As of	
(in € thousands)	**2021/12/31**	**2022/12/31**
Audit fees	337	420
Audit-related fees	6	5
Tax fees	—	—
Other fees	—	—
TOTAL	**343**	**425**

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

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

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

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

There were no "Tax Fees" or "Other Fees" billed or paid during 2021 or 2022.

Auditor Name	Auditor Location	Auditor Firm ID
Ernst & Young et Autres	Paris, France	1704

Audit and Non-Audit Services Pre-Approval Policy

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

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

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

Not applicable.

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

Not applicable.

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

Not applicable.

Item 16G. Corporate Governance.

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

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

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

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

Item 16H. Mine Safety Disclosure.

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 17. Financial Statements.

See pages F-1 through F-56 of this annual report.

Item 18. Financial Statements.

Not applicable.

Item 19. Exhibits.

		Incorporation by Reference			
Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
1.1*	Articles of Association of GENFIT S.A. (English translation)				
2.1	Form of Deposit Agreement	F-6	333-230265	4.1	3/14/2019
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)	F-6	333-230265	4.1	3/14/2019
2.3*	Description of Securities				
4.1†	Summary of 2017 BSA Plan	F-1	333-229907	10.1	2/27/2019
4.2†	Summary of 2019 BSA Plan	20-F	001-38844	4.3	5/27/2020
4.3†	Summary of 2019 Free Shares (AGA) Plan	20-F	001-38844	4.5	5/27/2020
4.4†	Summary of 2021 Free Shares (AGA) Plan	20-F	001-38844	4.5	4/29/2022
4.5†*	Summary of 2022 Free Shares (AGA) Plan				
4.6†*	Summary of 2023 Free Shares (AGA) Plan				
4.7†	Summary of 2016, 2017 and 2018 Share Option Plans	F-1	333-229907	10.3	2/27/2019
4.8†	Summary of 2019 Share Option Plans	20-F	001-38844	4.7	5/27/2020
4.9†	Summary of 2020 Share Option Plans	20-F	001-38844	4.8	4/23/2021
4.10†	Summary of 2021 Share Option Plans	20-F	001-38844	4.9	4/29/2022
4.11†*	Summary of 2022 Share Option Plans				
4.12†*	Summary of 2023 Share Option Plans				
4.13	Summary of Lease Agreement (English translation)	F-1	333-229907	10.5	2/27/2019
4.14#	Collaboration and License Agreement between the registrant and Terns Pharmaceuticals, Inc., dated June 24, 2019	20-F	001-38844	4.9	5/27/2020
4.15#	Collaboration and License Agreement between the registrant and Ipsen Pharma SAS, dated December 16, 2021	20-F	001-38844	4.12	4/29/2022
4.16*#	Share Purchase Agreement among the registrant, certain sellers of Versantis AG, as representative of the sellers, dated September 29, 2022				
4.17*	Amended and Restated Terms and Conditions of the OCEANE convertible bonds dated January 21, 2021				
8.1*	Subsidiaries of GENFIT S.A.				
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
13.2**	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				

101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

SIGNATURES

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

GENFIT S.A.

By: /s/ Pascal Prigent

Pascal Prigent

Chief Executive Officer

Date: April 18, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of GENFIT S.A.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Genfit S.A. (the Group) as of December 31, 2022 and 2021, the related consolidated statements of operations, other comprehensive income (loss), cash flows and changes in equity for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Group at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board.

Basis for Opinion

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

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

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

/s/ Ernst & Young et Autres

Ernst & Young et Autres has served as the Group's auditor since 1999

Paris-La Défense, France

April 18, 2023

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(amounts in thousands of euros)

ASSETS	Notes	As of	
(in € thousands)		2021/12/31	2022/12/31
Current assets			
Cash and cash equivalents	13	258,756	136,001
Current trade and others receivables	16	7,236	15,906
Other current financial assets	18	—	4,550
Other current assets	19	2,101	1,998
Inventories	—	4	4
Total - Current assets		268,097	158,459
Non-current assets			
Intangible assets	14	174	43,957
Property, plant and equipment	15	9,015	8,210
Non-current trade and other receivables	16	3	—
Other non-current financial assets	18	4,431	4,914
Deferred tax assets	11	—	—
Total - Non-current assets		13,623	57,081
Total - Assets		**281,720**	**215,540**

SHAREHOLDERS' EQUITY AND LIABILITIES	Notes	As of	
(in € thousands)		2021/12/31	2022/12/31
Current liabilities			
Current convertible loans	20	415	415
Other current loans and borrowings	20	1,773	4,665
Current trade and other payables	22	40,988	14,845
Current deferred income and revenue	23	14,298	14,479
Current provisions	24	313	61
Other current tax liabilities	11	5,051	4,906
Total - Current liabilities		62,837	39,370
Non-current liabilities			
Non-current convertible loans	20	47,682	49,861
Other non-current loans and borrowings	20	24,365	20,334
Non-current trade and other payables	22	450	448
Non-current deferred income and revenue	23	25,821	9,706
Non-current employee benefits	25	864	782
Deferred tax liabilities	11	602	510
Total - Non-current liabilities		99,786	81,641
Shareholders' equity			
Share capital	26	12,454	12,459
Share premium	—	444,438	444,683
Retained earnings (accumulated deficit)	26	(405,076)	(337,550)
Currency translation adjustment	—	22	(1,344)
Net profit (loss)	—	67,259	(23,719)
Total - Shareholders' equity		119,097	94,528
Total - Shareholders' equity & liabilities		**281,720**	**215,540**

The accompanying notes form an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

(in € thousands, except earnings per share data)	Notes	Year ended 2020/12/31	2021/12/31	2022/12/31
Revenues and other income				
Revenue	7	765	80,069	20,195
Other income	7	6,993	5,510	6,371
Revenues and other income		7,758	85,579	26,566
Operating expenses and other operating income (expenses)				
Research and development expenses	8	(59,097)	(35,166)	(35,818)
General and administrative expenses	8	(14,270)	(16,153)	(16,405)
Marketing and market access expenses	8	(11,216)	(1,539)	(992)
Reorganization and restructuring income (expenses)	8	(5,308)	(142)	11
Other operating expenses	8	(764)	(763)	(652)
Operating income (loss)		(82,897)	31,816	(27,289)
Financial income	10	6,544	44,780	8,212
Financial expenses	10	(25,296)	(7,122)	(4,758)
Financial profit (loss)		(18,752)	37,658	3,453
Net profit (loss) before tax		(101,649)	69,474	(23,836)
Income tax benefit (expense)	11	428	(2,215)	116
Net profit (loss)		**(101,221)**	**67,259**	**(23,719)**
Attributable to owners of the Company		(101,221)	67,259	(23,719)
Basic and diluted earnings (loss) per share				
Basic earnings (loss) per share (€/share)	12	(2.60)	1.51	(0.48)
Diluted earnings (loss) per share (€/share)	12	(2.60)	1.23	(0.48)

The accompanying notes form an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE INCOME (LOSS)

(amounts in thousands of euros)

(in € thousands)	Notes	Year ended 2020/12/31	2021/12/31	2022/12/31
Net profit (loss)		**(101,221)**	**67,259**	**(23,719)**
Actuarial gains and losses net of tax	25	196	216	258
Other comprehensive income (loss)				
that will never be reclassified to profit or loss		196	216	258
Exchange differences on translation of foreign operations		(106)	113	(1,366)
Other comprehensive income (loss)				
that are or may be reclassified to profit or loss		(106)	113	(1,366)
Total comprehensive income (loss)		**(101,131)**	**67,589**	**(24,827)**
Attributable to owners of the Company		(101,131)	67,589	(24,827)

The accompanying notes form an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands of euros)

(in € thousands)	Notes	Year ended 2020/12/31	Year ended 2021/12/31	Year ended 2022/12/31
Cash flows from operating activities				
+ Net profit (loss)		(101,221)	67,259	(23,719)
Reconciliation of net loss to net cash used in operating activities				
Adjustments for:				
+ Depreciation and amortization on tangible and intangible assets		3,559	2,742	1,832
+ Impairment and provision for litigation	24	3,015	(1,996)	(179)
+ Expenses related to share-based compensation	9	1,236	470	245
- Gain on disposal of property, plant and equipment		80	420	(16)
+ Net finance expenses (revenue)		10,335	4,663	2,042
+ Income tax expense (benefit)	11	(428)	2,215	(116)
+ Other non-cash items	10	(1,818)	(35,538)	2,210
including Income incurred by renegotiating the convertible bond debt OCEANE				
Operating cash flows before change in working capital		**(85,242)**	**40,235**	**(17,702)**
Decrease (increase) in trade receivables and other assets	16	318	4,344	(8,565)
(Decrease) increase in trade payables and other liabilities	22	(11,447)	55,335	(46,226)
Change in working capital		**(11,129)**	**59,680**	**(54,791)**
Income tax paid		—	—	(145)
Net cash flows provided by (used in) in operating activities		**(96,371)**	**99,915**	**(72,638)**
Cash flows from investment activities				
- Acquisition net of cash acquired	2.1		—	(41,525)
- Acquisition of property, plant and equipment	14. / 15.	(900)	(537)	251
+ Proceeds from disposal of / reimbursement of property, plant and equipment	14. / 15.	—	309	20
- Acquisition of financial instruments	18	(66)	(3,148)	(5,012)
Net cash flows provided by (used in) investment activities		**(966)**	**(3,377)**	**(46,266)**
Cash flows from financing activities				
+ Proceeds from issue of share capital (net)	26	7	27,972	5
+ Proceeds from subscription / exercise of share warrants		—	—	—
+ Proceeds from new loans and borrowings net of issue costs	20	—	15,270	—
- Repayments of loans and borrowings	20	207	(48,436)	(628)
- Payments on lease debts	20	(2,150)	(1,887)	(1,120)
- Financial interests paid (including finance lease)		(7,762)	(2,109)	(2,180)
+ Financial interests received		1,442	274	137
Net cash flows provided by (used in) financing activities		**(8,256)**	**(8,916)**	**(3,786)**
Increase (decrease) in cash and cash equivalents		**(105,593)**	**87,622**	**(122,690)**
Cash and cash equivalents at the beginning of the period	13	276,748	171,029	258,756
Effects of exchange rate changes on cash		(126)	105	(66)
Cash and cash equivalents at the end of the period		**171,029**	**258,756**	**136,001**

The accompanying notes form an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

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

(in € thousands)	Share capital		Share premium	Treasury shares	Retained earnings (accumulated deficit)	Currency translation adjustment	Net profit (loss)	Total shareholders' equity
	Number of shares	Share capital						
As of January 01, 2020	**38,858,617**	**9,715**	**377,821**	**(478)**	**(237,862)**	**14**	**(65,144)**	**84,065**
Net profit (loss)							(101,221)	(101,221)
Other comprehensive income (loss)					196	(106)		90
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**196**	**(106)**	**(101,221)**	**(101,131)**
Allocation of prior period profit (loss)					(65,144)		65,144	—
Capital increase	29,762	7	—		(7)			—
Share-based compensation			1,236					1,236
Treasury shares				(333)				(333)
Other movements			—		(268)			(268)
As of December 31, 2020	**38,888,379**	**9,722**	**379,057**	**(811)**	**(303,086)**	**(92)**	**(101,221)**	**(16,430)**
Net profit (loss)							67,259	67,259
Other comprehensive income (loss)					216	113		330
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**216**	**113**	**67,259**	**67,589**
Allocation of prior period profit (loss)					(101,221)		101,221	—
Capital increase	10,927,110	2,732	62,600		—			65,332
Equity component of OCEANE net of deferred taxes			2,311					2,311
Share-based compensation			470					470
Treasury shares				(174)				(174)
As of December 31, 2021	**49,815,489**	**12,454**	**444,438**	**(986)**	**(404,090)**	**22**	**67,259**	**119,097**
Net profit (loss)							(23,719)	(23,719)
Other comprehensive income (loss)					258	(1,366)		(1,108)
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**258**	**(1,366)**	**(23,719)**	**(24,827)**
Allocation of prior period profit (loss)					67,259		(67,259)	—
Capital increase	19,494	5	—		(5)			—
Share-based compensation			245					245
Treasury shares				8				8
Other movements			—		5			5
As of December 31, 2022	**49,834,983**	**12,459**	**444,683**	**(978)**	**(336,573)**	**(1,344)**	**(23,719)**	**94,528**

The accompanying notes form an integral part of these consolidated financial statements.

1. THE COMPANY

Founded in 1999 under the laws of France, GENFIT S.A. (the "Company") is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative drugs and diagnostic tools in therapeutic areas of high unmet need due in particular to the lack of effective treatments or diagnostic solutions and/or the increase in patients worldwide.

The Company focuses its research and development (R&D) efforts on the potential marketing of therapeutic and diagnostic solutions to combat certain metabolic, inflammatory, autoimmune and fibrotic diseases affecting in particular the liver (such as Primary Biliary Cholangitis or PBC) and more generally gastroenterological diseases. The head office address is : 885 Avenue Eugène Avinée – 59120 Loos, France.

The consolidated financial statements of the Company include the financial statements of GENFIT S.A. and those of its wholly-owned subsidiaries: GENFIT CORP. (U.S. subsidiary), Versantis AG (Swiss subsidiary), Versantis, Inc. (U.S. Subsidiary), and GENFIT PHARMACEUTICALS SAS (French subsidiary, liquidated prior to December 31, 2022) (together referred to in these notes to the consolidated financial statements as "GENFIT" or the "Group" or “we “ or “us”). There are no non-controlling interests for any period presented herein.

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

2.1. Acquisition of the Clinical-stage Biopharmaceutical Company Versantis

On September 19, 2022, the Company announced it had signed an exclusive agreement with Versantis AG ("Versantis") to acquire all the shares and voting rights of Versantis, a private Swiss-based clinical stage biotechnology company focused on addressing the growing unmet medical needs in liver diseases. This acquisition aims at:

1. Consolidating GENFIT’s position as a leader in acute-on-chronic liver failure (ACLF)
2. Significantly expanding GENFIT’s pipeline with VS-01-ACLF, a Phase 2 ready program based on first-in-class scavenging liposomes technology, VS-01-HAC, a pediatric program focused on urea cycle disorder (UCD), and VS-02-HE, an early-stage program focused on hepatic encephalopathy (HE), and
3. Combining Versantis’ expertise with GENFIT’s know-how in conducting complex development programs in liver diseases, to strengthen and accelerate research and development

The deal closed effective September 29, 2022.

Total purchase price and contingent milestone payments

This transaction includes:

- an initial payment of 40 million CHF (€41.9 million) due and paid at the date of closing,
- a net cash adjustment payment of 2.8 million CHF (€2.9 million) at the end of the year in accordance with the terms of the acquisition agreement
- additional milestone payments of up to 65 million CHF contingent on the following outcomes:
    - positive Phase 2 results related to VS-01-ACLF,
    - regulatory approval of VS-01-ACLF, and
    - positive Phase 2 results related to VS-02.

Furthermore, the former shareholders of Versantis are eligible to receive 1/3 of the net proceeds resulting from the potential sale of the Priority Review Voucher of VS-01’s pediatric application by GENFIT to a third party, or 1/3 of the fair market value of this Voucher if GENFIT opts to apply it to one of its own programs.

Acquisition costs totaled €1.8 million.

The impact of this acquisition as reflected within the line item "Acquisitions of consolidated undertakings, net of cash acquired" in the consolidated statement of cash flows is a net cash outflow of €41.5 million.

Accounting treatment - IFRS 3

Paragraph B7B sets out an optional test (the concentration test) to permit a simplified assessment of whether an acquired set of activities and assets is not a business. An entity may elect to apply, or not apply, the test. The concentration test is met if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets.

GENFIT chose to use the available option stated as per IFRS 3 and perform a concentration test to determine if the transaction qualifies as a business combination or asset acquisition. In accordance with the concentration test methodology as defined in paragraph B7B of IFRS 3, the acquisition of Versantis by GENFIT was determined to be an asset acquisition based on the VS-01-ACLF program because its fair value represents more than 90% of the value of all assets acquired. Therefore, the acquisition costs of €1.8 million were included and capitalized in the total cost of the operation to determine the net book value of the VS-01-ACLF program on the date of the acquisition. Conditional milestone payments were not included in this analysis.

Accounting treatment - IAS 21

Consistent with paragraph 8 of IAS 21, Versantis AG is considered as a foreign operation as its activities are conducted primarily in Swiss Francs. The Swiss Franc is thus also considered to be Versantis AG's functional currency. Versantis AG's subsidiary, Versantis Inc., is considered as a foreign operation as its activities are conducted primarily in US Dollars. The US Dollar is thus considered to be Versantis Inc.'s functional currency. For further information on converting and presenting Versantis' activity in euros, refer to note 4.3.2 - Translation of foreign subsidiary financial statements.

Note that on the Consolidated Statements of Other Comprehensive Income and Loss, for the period ending December 31, 2022, on line item "Other comprehensive income (loss) that are or may be reclassified to profit or loss," substantially all of the loss amount of €1.4 million is due to the application of IAS 21 for Versantis.

Supplementary information

The consolidated value of net assets acquired of Versantis AG and Versantis, Inc. on September 29, 2022 is as follows :

Total acquired assets and liabilities, in thousands of euros	**29/9/2022**
Cash and cash equivalents	5,076
Current trade and others receivables	209
Other current assets	78
Intangible assets	45,323
Property, plant and equipment	326
Other non-current financial assets	14
Total acquired assets	51,026
Current trade and other payables	3,202
Current provisions	858
Other current tax liabilities	63
Lease liabilities	302
Total acquired liabilities	4,425
Total purchase price	**46,601**

The exchange rate used above to convert the assets and liabilities of Versantis AG into euros was 1.04843 (1 CHF = 1.04843) on September 29, 2022. The exchange rate used above to convert the assets and liabilities of Versantis, Inc. into euros was 0.9706 (1 USD = 0.9706) on September 29, 2022.

The net book value of assets and liabilities as of December 31, 2022 is as follows, per the application of IAS 21:

Net assets, in thousands of euros	31/12/2022
Cash and cash equivalents	2,168
Current trade and others receivables	17
Other current assets	197
Intangible assets	43,850
Property, plant and equipment	295
Other non-current financial assets	13
Total assets	46,540
Current trade and other payables	1,614
Current provisions	672
Other current tax liabilities	33
Lease liabilities	282
Total liabilities	2,601
Net assets	**43,939**

The exchange rate used above to convert the assets and liabilities of Versantis AG into euros was 1.01554 (1 CHF = 1.01554) on December 31, 2022. The exchange rate used above to convert the assets and liabilities of Versantis, Inc. into euros was 0.93756 (1 USD = 0.93756) on December 31, 2022.

Research and development expenses for the period between September 29, 2022 and December 31, 2022 attributable to Versantis total €1,187 thousand. If the acquisition had taken place on January 1, 2022, research and development expenses would have been €5,833 thousand.

General and administrative expenses for the period between September 29, 2022 and December 31, 2022 attributable to Versantis total €228 thousand.

For further information, refer to Note 14 - "Goodwill and Intangible Assets"

2.2. Agreements and partnership with Ipsen

2021 Collaboration and License Agreement

In December 2021, GENFIT and Ipsen Pharma SAS ("Ipsen") entered into an exclusive licensing agreement for elafibranor, a Phase 3 asset evaluated in Primary Biliary Cholangitis (PBC), as part of a long-term global partnership ("Collaboration and License Agreement"). The agreement gives Ipsen exclusive worldwide license (with the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals, Inc. ("Terns Pharmaceuticals") holds the exclusive license to develop and commercialize elafibranor) to develop and commercialize elafibranor, GENFIT's first-in-class drug candidate, a PPAR alpha and PPAR delta agonist, for people living with PBC, a rare chronic inflammatory liver disease.

The Collaboration and License Agreement qualifies as a contract under IFRS 15, and meets the criteria under IFRS 15.9.

Under this agreement:

- GENFIT remains responsible for the Phase 3 ELATIVE trial until the completion of the double-blind period. Ipsen will assume responsibility for all additional clinical development, including completion of the long-term extension period of the ELATIVE trial, and commercialization.
- GENFIT received from Ipsen an upfront cash payment of €120 million in December 2021 (with an additional €24 million in collected VAT), of which €80 million was recognized as revenue in 2021. The remainder of this upfront payment (€40 million) has been recognized in 2021 as deferred revenue and will be recognized as revenue throughout the execution of the double-blind period of the ELATIVE study, in accordance with IFRS 15. In 2022, of the initial €40 million of deferred revenue, €15.9 million was recognized as revenue for services provided in accordance with IFRS 15.
- GENFIT is also eligible for milestone payments up to €360 million. These milestone payments constitute future variable income, dependent on the completion of key steps related to the development and sales of the licensed products. As such, in accordance with IFRS 15, this income will be recognized as revenue depending on the completion of these milestones. No such milestone payments were made in 2021 or 2022.

- GENFIT is eligible for tiered double-digit royalties of up to 20%, applied to the annual sales of licensed products realized by Ipsen. As such, in accordance with IFRS 15, this income will be recognized as revenue depending on the realization of these sales. No such royalties were earned in 2021 or 2022.

Beyond the collaboration between GENFIT and Ipsen in PBC, this agreement also constitutes a strategic partnership, allowing Ipsen to access the research skills of GENFIT and other clinical programs, including some rights to first negotiation (while not being constitutive of a service obligation under IFRS 15).

Ipsen Ownership Stake in GENFIT

Additionally, in 2021, Ipsen also became a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28 million investment. The new shares were issued pursuant to the twentieth resolution of GENFIT's June 30, 2021 shareholders' meeting. As of December 31, 2022, they are still subject to a lock-up period, ending in the event of positive ELATIVE results, on the earlier of i) the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorization of elafibranor in PBC or ii) the date on which the U.S. FDA grants approval of elafibranor in PBC. In addition, during the shareholder's meeting on May 25, 2022, GENFIT proposed and approved Ipsen as a board member. Ipsen is represented by Dr. Steven Hildemann, MD., PhD. He serves as Executive Vice President, Chief Medical Officer, Head of Global Medical Affairs and Pharmacovigilance at Ipsen.

2022 Follow-on Agreements: Transition Services Agreement and Inventory Purchase Agreement

In 2022, GENFIT and Ipsen entered into a Transition Services Agreement, which outlines the scope of services to facilitate the transition of some activities related to the Phase 3 clinical trial evaluating elafibranor in Primary Biliary Cholangitis. This agreement is a supplementary follow-on to the Collaboration and License Agreement mentioned above. We evaluated the agreement under IFRS 15 and we concluded that the services constitute a single performance obligation for which revenue is recognized as services are performed. In 2022, €1.0 million in revenue was generated from the services rendered by GENFIT to Ipsen in accordance said agreement and consistent IFRS 15.

In 2022, GENFIT and Ipsen entered into an Inventory Purchase Agreement, pursuant to which Ipsen purchased inventory from GENFIT, namely the elafibranor active pharmaceutical ingredient and related drug product, during the second half of 2022 with the prospect of transferring the conduct of the ELATIVE study to Ipsen. We evaluated the agreement under IFRS 15 and we concluded that the services constitute a single performance obligation for which revenue is recognized when inventory is provided to Ipsen. In 2022, €3.3 million was recognized as revenue from the sale of said inventory in accordance with said agreement and consistent IFRS 15.

Regarding the application of IFRS15, see Note 7 "Revenues and other income.".

2.3 Termination of RESOLVE-IT and the development program of elafibranor in NASH

Following the decision by the Company in July 2020 to terminate its Phase 3 RESOLVE-IT trial (see 2020 Form 20-F), the impacts of the RESOLVE-IT termination process, and more broadly the discontinuation of the elafibranor development program in NASH continued to have a significant impact in 2021.

Impact on subcontracting costs

In 2022, the residual impact of the RESOLVE-IT study are based on two main topics:

- Firstly, the Company did not received any charge in 2022 from the main subcontractor (CRO) for this study, because of the investigation sites closure and invoicing of final residual costs in 2021 .

- Secondly, the Company reversed 2021 accruals, amounting of €1.1 million, based on communication with the CRO (in particular as it relates to investigator costs).

Finally, the Company benefited in 2022 from an "end of study" credit note, ending the study in July, and bringing the provision recognized in the balance sheet for RESOLVE-IT to zero.

Impact on scientific equipment leased and owned

The Group has analyzed the impact of the closing of RESOLVE-IT and its decision to reorganize its activities on its scientific equipment. An inventory of the equipment that could be sold, kept as a spare, or disposed of, was completed in the second half of 2020.

Leased equipment

Following the sale and/or disposal of part of this equipment in 2021 and 2022, the loss in value of the remaining equipment (determined in order to take into account the potential loss compared to the net book value of the right of use to assets) amounted to €28 at December 31, 2022 (compared to €62 at the end of 2021 and €503 at the end of 2020).

Owned equipment

Following the disposal of part of this equipment in 2021 and an updated impairment analysis in 2022 related to certain unused equipment, the loss in value of the remaining equipment amounts to €27 at December 31, 2022 (compared to €25 at the end of 2021 and €363 thousand euros at the end of 2020).

Premises

The loss in value of the right to use the premises leased by the Company in Lille and Paris amounts to €479 (including the layout of the premises) as of December 31, 2022 (compared to €596 at the end of 2021 and €1,275 at the end of 2020), taking into account in particular the relocation of the Company's Paris offices in 2021 and the indexation of rent at the Loos site.

See Note 8 - "Property, Plant and Equipment".

Reorganization and reduction in force

Following the reorganization and reduction in force plan (*plan de sauvegarde de l'emploi* or "PSE") implemented by the company during the second half of 2020, the residual provision relating to the support measures granted under this PSE (premiums for quick return to employment, training, business creation aid) amounted to €21 at December 31, 2022 (compared to €171 at the end of 2021 and €523 at the end of 2020), taking into account reversals of €77 recorded in 2022.

3. BASIS OF PRESENTATION

The Consolidated Financial Statements of GENFIT have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"), and in accordance with IFRS as adopted by the European Union at December 31, 2022. The Comparative information is presented as of and for the years ended December 31, 2021 and December 31, 2020.

The consolidated financial statements have been prepared using the historical cost measurement basis except for certain assets and liabilities that are measured at fair value in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality and aggregation

These consolidated financial statements for the year ended December 31, 2022 were prepared under the responsibility of the Board of Directors that approved such statements on April 13, 2023.

The term IFRS includes International Financial Reporting Standards ("IFRS"), International Accounting Standards (the "IAS"), as well as the Interpretations issued by the Standards Interpretation Committee (the "SIC"), and the International Financial Reporting Interpretations Committee ("IFRIC").

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

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

3.1. Changes in accounting policies and new standards or amendments

The accounting policies applicable for these consolidated annual financial statements are the same as those applied to the previous consolidated annual financial statements.

The following new standards are applicable from January 1, 2022, but do not have any material effect on the Group's financial statements as of and for the year ended December 31, 2022.

- Amendment to IAS 37 - Onerous Contracts — Cost of Fulfilling a Contract,
- Amendment to IFRS 3 - Reference to the Conceptual Framework,
- Amendment to IAS 16 - Proceeds before intended use, and
- Annual IFRS improvements - 2018-2020 Cycle.

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

The GENFIT Group has not identified any standards or amendments issued and in force and anticipated as of January 1, 2021 or applicable to the periods starting as of January 1, 2022 that may have a significant impact on the Group's consolidated financial statements, notably:

– IFRS 17 Insurance Contracts, effective in 2023,

- Amendments to IFRS 17 - First application of IFRS 17 and IFRS 9 - Comparative Information, effective in 2023,
- Amendments to IAS 1 and Practice Statement 2 - Disclosure of Accounting Policies, effective in 2023,
- Amendments to IAS 8 Definition of Accounting Estimates, effective in 2023,
- Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction, effective in 2023, and
- Amendments to IAS 1 Classification of Liabilities as Current or Non-current, effective in 2024.

4. SUMMARY OF MATERIAL ACCOUNTING INFORMATION

4.1. Use of estimates and judgments

In preparing these consolidated financial statements, management makes judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, incomes and expenses. Actual amounts may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

The estimates and underlying assumptions mainly relate to research tax credits (see Note 7.2 "Other income", employee benefits (see Note 25 "Employee benefits"), leases (see Note 15 “Property, plant and equipment including Leases”), share-based payments (see Note 9 "Share-based compensation"), accruals related to clinical trials (see Note 8 "Operating expenses"), convertible loans (see Note 20.1 "Breakdown of convertible loan"), accounting judgments related to the Versantis acquisition (see Note 2.1 "Acquisition of the Clinical-stage Biopharmaceutical Company Versantis"), the valuation of our investment in Genoscience (See Note 18 "Other financial assets"), and the allocation of income to the performance obligations provided for in the agreement entered into with Ipsen (see Note 7 "Revenues and Other Income").

When assessing going concern, the Group’s Board of Directors considers mainly the following factors:

The liquidity available at the statement of financial position date, the cash spend projections for next 12-month period as from the date of the financial statements are issued and the availability of other funding.

4.2. Consolidation

Going concern

The consolidated financial statements were prepared on a going concern basis. The Group believes it has sufficient resources to continue operating for at least twelve months following the consolidated financial statements’ publication.

Consolidated entities

The Group controls an entity when it is exposed to variable returns from its involvement with the entity, and it has the ability to affect those returns through its power over the entity.

The Group controls all the entities included in the scope of consolidation.

GENFIT Pharmaceuticals SAS was dissolved on December 23, 2022 in accordance with article 1844-5 of the Civil Code in France. All assets and liabilities of the company was transferred to GENFIT SA.

4.3. Foreign currency

4.3.1. Foreign currency transactions

Transactions in foreign currencies are translated into the respective functional currencies of the entities of the Group at the exchange rates applicable at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the reporting date.

The resulting exchange gains or losses are recognized in the statements of operations.

4.3.2. Translation of foreign subsidiary financial statements

The assets and liabilities of foreign operations having a functional currency different from the euro are translated into euros at the closing exchange rate. The income and expenses of foreign operations are translated into euros at the exchange rates effective at the transaction dates or using the average exchange rate for the reporting period unless this method cannot be applied due to significant exchange rate fluctuations.

Gains and losses arising from foreign operations are recognized in the statement of other comprehensive loss. When a foreign operation is partly or fully divested, the associated share of gains and losses recognized in the currency translation reserve is transferred to the statements of operations.

The Group's presentation currency is the euro, which is also the functional currency of GENFIT S.A.

The functional currency of GENFIT CORP and Versantis, Inc. is the U.S. dollar. The applicable exchange rates used to translate the financial statements of this entity for each of the periods are as follows:

	Year ended		
Ratio : 1 US dollars (USD) = x euros (EUR)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Exchange rate at period end	0.81493	0.88292	0.93756
Average exchange rate for the period	0.87755	0.84542	0.95105

The functional currency of Versantis AG is the Swiss Franc. The applicable exchange rates used to translate the financial statements of this entity for each of the periods are as follows:

Ratio : 1 CH franc (CHF) = x euros (EUR)	Year ended		
	2020/12/31	**2021/12/31**	**2022/12/31**
Exchange rate at period end	N/A	N/A	1.01554
Average exchange rate for the period	N/A	N/A	1.01710

Note that the average rate immediately above is based on the period between September 29, 2022 and December 31, 2022.

5. SEGMENT INFORMATION

The Board of Directors and Chief Executive Officer are the chief operating decision makers.

The Board of Directors and the Chief Executive Officer oversee the operations and manage the business as one segment with a single activity; namely, the research and development of innovative medicines and diagnostic solutions, the marketing of which depends on the success of the clinical development phase.

The assets, liabilities and operating income (loss) are mainly located in France and in Switzerland (the latter as a result of the acquisition of Versantis in September 2022).

Revenue breakdown by geographical area

Revenue by destination	Year ended		
(in € thousands)	**12/31/2020**	**12/31/2021**	**12/31/2022**
Revenue from France	100 %	100 %	100 %
Revenue from other countries	— %	— %	— %
TOTAL	**100 %**	**100 %**	**100 %**

In 2022, revenue was generated entirely in France. Substantially all revenue was generated from Ipsen in 2022.

In 2021, revenue was generated entirely in France. Substantially all revenue was generated from Ipsen in 2021.

In 2020, revenue was generated entirely in France. Revenue originated from license agreements with Labcorp and one-off revenue resulting from the sale of goods and services notably within the scope of the license and collaboration agreement with Terns Pharmaceuticals.

Non-current assets by geographical area

Non-current assets break down by geographical area as follows:

NON-CURRENT ASSETS	**As of December 31, 2021**			**As of December 31, 2022**		
(thousands of euros)	France	Switzerland	**Total**	France	Switzerland	**Total**
TOTAL	13,623	0	**13,623**	12,923	44,158	**57,081**

6. FINANCIAL RISKS MANAGEMENT

The Group may be exposed to the following risks arising from financial instruments: foreign exchange risk, interest rate risk, liquidity risk and credit risk.

6.1. Foreign exchange risk

The Group's overall exposure to the foreign exchange risk depends, in particular, on:

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

Given the significant portion of its operations denominated in US dollars, the Group decided to limit the conversions into euros of its US dollar denominated cash, issued notably from its March 2019 Nasdaq IPO in US dollars, and not to use any specific hedging arrangements, in order to cover expenses denominated in US dollars over the coming years.

The following table shows the sensitivity of the Group's cash and cash equivalent and expenses in U.S. dollars to a variation of 10% of the U.S. dollar against the euro in 2020, 2021 and 2022.

Sensitivity of the Group's cash and cash equivalents to a variation of +/- 10% of the US dollar against the euro (in € thousands or in US dollar thousands, as applicable)	**As of**	
	2021/12/31	**2022/12/31**
Cash and cash equivalents denominated in US dollars	81,713	34,192
Equivalent in euros, on the basis of the exchange rate described below	72,146	32,057
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	80,163	35,619
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	65,588	29,143

Sensitivity of the Group's expenses to a variation of +/- 10% of the US dollar against the euro (in € thousands or in US dollar thousands, as applicable)	**Year ended**		
	2020/12/31	**2021/12/31**	**2022/12/31**
Expenses denominated in US dollars	47,277	12,566	14,884
Equivalent in euros, on the basis of the exchange rate described below	38,528	11,095	13,955
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	42,808	12,328	15,506
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	35,025	10,086	12,686

2022/12/31: Equivalent in euros, on the basis of 1 euro = 1.0666 dollars US.

2021/12/31: Equivalent in euros, on the basis of 1 euro = 1.1326 dollars US.

2020/12/31: Equivalent in euros, on the basis of 1 euro = 1.2271 dollars US.

The following table shows the sensitivity of the Group's cash and cash equivalent and expenses in Swiss Francs to a variation of 10% of the Swiss Franc against the euro in 2022.

Sensitivity of the Group's cash and cash equivalents to a variation of +/- 10% of the CH franc against the euro (in € thousands or in CH franc thousands, as applicable)	As of		
	2020/12/31	2021/12/31	2022/12/31
Cash and cash equivalents denominated in CH franc	N/A	N/A	2,321
Equivalent in euros, on the basis of the exchange rate described below	N/A	N/A	2,357
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	N/A	N/A	2,618
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	N/A	N/A	2,142
Sensitivity of the Group's expenses to a variation of +/- 10% of the CH franc against the euro (in € thousands or in CH franc thousands, as applicable)	**Year ended**		
	2020/12/31	2021/12/31	2022/12/31
Expenses denominated in CH franc	N/A	N/A	2,016
Equivalent in euros, on the basis of the exchange rate described below	N/A	N/A	2,048
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	N/A	N/A	2,275
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	N/A	N/A	1,862

2022/12/31: Equivalent in euros, on the basis of a 1 euro = 0.9847 CHF.

Cash, cash equivalents and financial assets (in € thousands)	As of		
	2020/12/31	2021/12/31	2022/12/31
At origin, denominated in EUR			
Cash and cash equivalents	80,391	186,609	101,536
Current and non current financial assets	1,391	4,355	9,456
Total	**81,782**	**190,964**	**110,993**
At origin, denominated in USD			
Cash and cash equivalents	90,637	72,147	32,057
Current and non current financial assets	67	76	7
Total	**90,704**	**72,223**	**32,064**
At origin, denominated in CHF			
Cash and cash equivalents	—	—	2,358
Current and non current financial assets	—	—	—
Total	**—**	**—**	**2,358**
Total, in EUR			
Cash and cash equivalents	171,029	258,756	136,001
Current and non current financial assets	1,458	4,431	9,464
Total	**172,486**	**263,187**	**145,464**

6.2. Interest rate risk

As of December 31, 2022, the Group was only liable for governmental advances or conditional advances and bank loans with no interest or interest at a fixed rate, generally below market rate.

As of December 31, 2021 and 2022, the Group's financial liabilities totaled €74.2 million and €75.3 million respectively (net of the equity component of the convertible loan and debt issue costs). Current borrowings are at a fixed rate. The Group's exposure to interest rate risk through its financial assets is also insignificant 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.

6.3. Liquidity risk

The Group's loans and borrowings mainly consist of bonds convertible or exchangeable into new or existing shares (OCEANE), repayable for an nominal amount of €57 million on October 16, 2025 (see Note 20.1 "Breakdown of convertible loan"), government advances for research projects and bank loans. For conditional advances, reimbursement of the principal is subject to the commercial success of the related research project (see Note 20.2.1 "Refundable and conditional advances").

The Company has conducted a specific review of its liquidity risk and considers that it is able to meet its future maturities. On December 31, 2021 and 2022, the Group had €263,187 and €145,464 respectively in cash and cash equivalents and other financial assets. The Company does not believe it is exposed to short-term liquidity risk. The Company believes that the Group's cash and cash equivalents and current financial instruments are sufficient to ensure its financing for the next 12 months, in light of its current projects and obligations.

If the Group's funds are insufficient to cover any additional financing needs, the Group would require additional financing. The conditions and arrangements for any such new financing would depend, among other factors, on economic and market conditions that are beyond the Group's control.

6.4. 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.

7. REVENUES AND OTHER INCOME

7.1. Revenues from contracts with customers

Accounting policy overview

Under IFRS 15, revenue is recognized when the Company fulfills a performance obligation by providing separate goods or services to a customer, i.e., when the customer obtains control of those goods or services. An asset is transferred when the customer obtains control of that asset or service.

Under this standard, each contract must be analyzed, on a case-by-case basis, in order to verify whether it contains performance obligations towards third parties, and, if applicable, to identify their nature in order to determine the appropriate accounting of amounts that the Company has received or is entitled to receive from third parties, for example:

- The transfer of control over the intellectual property, via a license granted by the Company, as it exists at the time of the sale, the date of which will determine that of the revenue recognition;
- If the license is considered as a right of access to the intellectual property of the Company over the life of the license, the revenue would be recognized over this lifetime;
- The supply of products whose revenues would be recognized at the time of transfer of control of the delivered products; and
- Potential revenue from milestones, or from royalties or royalties based on sales, would not be recognized until the achievement of the milestone or completion of the sale.

Financial statement line item detail

In 2022, the total revenues and other income amounted to €26,566 (€85,579 in 2021, and €7,758 in 2020).

Revenue amounted to €20,195 in 2022 (€80,069 in 2021, and €765 in 2020).

Revenue is primarily composed of:

1. Licensing Agreement (Ipsen). In December 2021, GENFIT and Ipsen entered into an exclusive licensing agreement for elafibranor, a Phase 3 asset evaluated in Primary Biliary Cholangitis (PBC), as part of a long-term global partnership ("Collaboration and License Agreement").
    - In 2022, €15.9 million was attributable to the partial recognition of deferred revenue of €40 million from 2021 as noted immediately below, in line with the progress in the ELATIVE clinical study and expenses incurred during the period.
    - In 2021, €80 million was attributable to the recognition of the initial payment received from Ipsen pursuant to the license agreement entered into in December 2021 (of the total amount of €120 million). The remaining balance of the initial payment, i.e. 40 million euros, was recorded as deferred income.
2. Transition Services Agreement (Ipsen). In 2022, GENFIT and Ipsen entered into a Service Transition Agreement, which describes the scope of the services provided by GENFIT to Ipsen in order to facilitate the transition of certain activities related to the Phase 3 clinical trial, evaluating elafibranor in PBC.
    - In 2022, the services provided under this contract generated €1.0 million in revenue.
3. Inventory Purchase Agreement (Ipsen). GENFIT and Ipsen also entered into an Inventory Purchase Agreement in 2022, which provided for the purchase by Ipsen of batches of active ingredients and elafibranor products during the second half of 2022.
    - In 2022, inventory sold to Ipsen under this contract generated €3.3 million in revenue.

4. Other revenue

- In 2022, other revenue was not significant.
- In 2021, other revenue recognized relates to license agreements with Labcorp for the deployment of NIS4 diagnostic technology in the field of NASH, amounting to €69.
- In 2020, revenue of €765 mainly originated from the income generated by the license agreements with Labcorp and one-off revenue resulting from the sale of goods and services notably within the scope of the license and collaboration agreement with Terns Pharmaceuticals.

Application of IFRS 15 to the Ipsen License Agreement signed in 2021

Pursuant to IFRS 15, 27, 28 and 29, we have identified that the agreement provides for four distinct performance obligations:

- The license for elafibranor,
- The completion of the ELATIVE Phase 3 trial until the end of the double-blind period,
- The knowledge transfer related to elafibranor, as well as support for Ipsen in future undertakings and processes, and
- The provision of drug tablets that may be needed by Ipsen to conduct their clinical trials.

The compensation under this agreement consists of an upfront payment, milestone payments, and royalties on future sales of elafibranor by Ipsen. Besides, it must be noted that, with respect to (i) support services other than the knowledge transfer and (ii) the provision of drug tablets, the agreement provides for separate prices covering all costs borne by the Company to provide those goods and services, therefore constituting in each case an individual and distinct sale price for the relevant goods or service, which is not included in the aforementioned price elements.

We estimate the individual sale price of the clinical trial phase to be €40 million, including forecasted external costs, personnel expenses for the relevant staff, indirect costs pertaining to the work environment of such staff, augmented of a customary margin rate for CRO (Clinical Research Organization) contracting. This calculation of the individual sale price for the clinical trial phase reflects observable price conditions as recommended under IFRS 15.79.c. We used the same method to calculate the individual sale price of the knowledge transfer.

Regarding the calculation of the individual sale price of the license, we have analyzed recommended methods under IFRS 15.79 and determined that method (c) is the most relevant, considering in particular that the amount of this individual sale price is variable and partly uncertain. Thus, we applied the "residual" method, which stipulates that the individual sale price of the license corresponds to the difference between the total amount of the price and the individual sale prices of the knowledge transfer and the clinical trial phase. Moreover, referring to IFRS 15.B61, we determined that the date of transfer of control over the license corresponds to the date of the knowledge transfer, i.e. December 16, 2021, when key elements of the know-how were made available to Ipsen.

Regarding the recognition of revenue related to the license, we have chosen the following methods:

- The upfront payment, minus the portion of prices allocated to knowledge transfer services and clinical phase execution, has been recognized at the date of transfer of control, i.e. December 16, 2021 according to the above, as it is a static license (without implication or associated service provision);
- Milestone payments constitute variable and uncertain income, which would be, if applicable, recognized in revenue at the time they become highly probable, which means, in this case, due by Ipsen;
- Royalties would be progressively recognized in revenue as sales are completed by Ipsen, in accordance with the IFRS 15 exception for royalties constituting variable income.

Regarding the recognition of revenue related to the Phase 3 ELATIVE trial until the end of the double-blind period, we have chosen the following method:

- The part of the upfront payment allocated to this service will be recognized progressively as completion progresses.

Regarding the recognition of revenue related to the knowledge transfer, we have chosen the following method:

- The part of the upfront payment allocated to this service has been recognized on December 16, 2021 in accordance with the above.

It must be noted that the 8% equity purchase by Ipsen in the Company mentioned in Note 2.2 under the terms of which Ipsen is represented in the Company's Board of Directors, has been completed on the basis of a subscription price agreed upon by the parties as representative of the value of GENFIT at the time, as we had secured future financing and created favorable conditions for the completion of the development and commercial launch of our main program. Therefore, the amount paid by Ipsen for its equity purchase does not interfere in the determination of the price of the licensing and collaboration agreement signed in December 2021 (including the Upfront Payment and other payments due for milestones identified above) and has been entirely recognized in the Group's equity.

Application of IFRS 15 to the Ipsen Transition Services Agreement and Inventory Purchase Agreement signed in 2022

In 2022, GENFIT and Ipsen entered into a Transition Services Agreement, which outlines the scope of services to facilitate the transition of some activities related to the Phase 3 clinical trial evaluating elafibranor in Primary Biliary Cholangitis. This agreement is a supplementary follow-on to the Collaboration and License Agreement mentioned above. We evaluated the agreement under IFRS 15 and we concluded that the services constitute a single performance obligation for which revenue is recognized as services are performed.

In 2022, GENFIT and Ipsen entered into an Inventory Purchase Agreement, pursuant to which Ipsen purchased inventory from GENFIT, namely the elafibranor active pharmaceutical ingredient and related drug product, during the second half of 2022 with the prospect of transferring the conduct of the ELATIVE study to Ipsen. We evaluated the agreement under IFRS 15 and we concluded that the services constitute a single performance obligation for which revenue is recognized when inventory is provided to Ipsen.

7.2. Other income

7.2.1. Research tax credit

The Research Tax Credit ("Crédit d'Impôt Recherche," or "CIR") is granted to entities by the French tax authorities in order to encourage them to conduct technical and scientific research. Entities that demonstrate that their research expenditures meet the required CIR criteria receive a tax credit that may be used for the payment of their income tax due for the fiscal year in which the expenditures were incurred, as well as in the next three years. If taxes due are not sufficient to cover the full amount of tax credit at the end of the three-year period, the difference is paid in cash to the entity by the tax authorities. If a company meets certain criteria in terms of sales, headcount or assets to be considered a small/mid-size company, immediate payment of the Research Tax Credit can be requested. The Group meets such criteria.

The Group applies for CIR for research expenditures incurred in each fiscal year and recognizes the amount claimed in the line item "Other income" in the statements of operations in the same fiscal year. In the notes to the financial statements, the amount claimed is recognized under the heading "Research tax credit" (see Note 16, "Trade and other receivables" and the table below).

7.2.2. Government grants

Government grants

The Group received until 2016 various forms of government grants. This government aid is provided for and managed by French state-owned entities, and specifically "BPI France" ("Banque Publique d'Investissement"), formerly named "OSEO Innovation".

Subsidies received are non-refundable.

The breakdown of Other income is as follows:

Other income	Year ended		
(in € thousands)	2020/12/31	2021/12/31	2022/12/31
CIR tax credit	6,020	5,282	6,017
Other operating income	968	223	320
Government grants and subsidies	5	5	34
TOTAL	**6,993**	**5,510**	**6,371**

The research tax credit (CIR) amounted to €6,017 in 2022 (€5,282 in 2021), due to the reduction in research and development expenses.

In comparison, the 2020 Research Tax Credit amounted to €7,911, partially balanced with the expense amounting to €1,892 corresponding to the resolution of the dispute on the 2010, 2011, 2012 and 2014 Research Tax Credit.

During 2022, the Group recognized €320 in “Other operating income” (€968 in 2020 and €223 in 2021), mainly comprised of exchange gains on trade receivables.

8. OPERATING EXPENSES

Accounting policies

Research and development expenses

Research expenses are recorded in the financial statements as expenses.

In accordance with IAS 38, Intangible Assets, development expenses are recognized as intangible assets only if all the following criteria are met:

- Technical feasibility necessary for the completion of the development project;
- Intention on the Group's part to complete the project and to utilize it;
- Capacity to utilize the intangible asset;
- Proof of the probability of future economic benefits associated with the asset;
- Availability of the technical, financial, and other resources for completing the project; and
- Reliable evaluation of the expenses attributed to the intangible asset during its development.

As of the date of these financial statements these criteria have not all been met.

Classification of operating expenses

Research and development expenses include:

- employee-related costs;
- costs related to external employees seconded to the Company (such as clinical development, biometrics and IT…);
- lab supplies and facility costs;
- fees paid to scientific advisers and contracted research and development activities conducted by third parties;
- intellectual property fees corresponding to the filing of the Group's patents, and
- provision and reversals of provisions in relation to the Research Tax Credit dispute.

Contracted research and development activities conducted by third parties include services subcontracted to research partners for technical and/or regulatory reasons. In particular, this includes the production of active ingredients and therapeutic units, all or a part of clinical trials and preclinical trials that are necessary to the development of GENFIT's drug candidates and biomarker candidates.

General and administrative expenses include:

- employee-related costs for executive, business development, intellectual property, finance, legal and human resources and communications functions;
- facility-related costs;
- marketing, legal, audit and accounting fees;
- press relations and communications firm fees;
- the cost of external employees seconded to the Company (such as security, reception, and accounting...);
- other service costs (recruitment, etc.); and
- intellectual property fees corresponding to the maintenance of the Group's patents.

Marketing and market access expenses include:

- employee-related costs for marketing and business development functions; and
- marketing, and market access firm fees.

Reorganization and restructuring expenses include:

- the accruals and provisions recognized within the scope of the reduction in force plan;
- the extraordinary amortization, loss of value and impairment of fixed assets recognized within the scope of the reorganization of GENFIT;
- the impairment of the right of use of the leased equipment and premises;
- the portion of the OCEANEs renegotiation expenses;

- the provision recognized for some of the costs of the closing process for the RESOLVE-IT study, which, after detailed analysis, do not have any future economic advantage for the PBC program.

Financial statement line item detail

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

Operating expenses and other operating income (expenses) (in € thousands)	Year ended 2021/12/31	Of which : Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(35,166)	(1,305)	(18,808)	(8,192)	(4,593)	(2,247)	(19)
General and administrative income (expenses)	(16,153)	(161)	(85)	(7,379)	(8,003)	(541)	15
Marketing and market access expenses	(1,539)	(1)	(1)	(783)	(741)	(13)	—
Reorganization and restructuring income (expenses)	(142)	(5)	—	—	(2,343)	2,206	—
Other operating income (expenses)	(763)	—	—	—	(338)	4	(429)
TOTAL	**(53,763)**	**(1,472)**	**(18,895)**	**(16,354)**	**(16,019)**	**(591)**	**(433)**

Operating expenses and other operating income (expenses) *(in € thousands)*	Year ended 2022/12/31	Of which : Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(35,818)	(1,876)	(17,407)	(10,029)	(5,177)	(1,328)	—
General and administrative expenses	(16,405)	(248)	(71)	(6,772)	(9,168)	(146)	—
Marketing and market access expenses	(992)	(3)	(1)	(565)	(416)	(6)	—
Reorganization and restructuring income (expenses)	11	—	—	—	—	11	—
Other operating income (expenses)	(652)	—	—	—	(667)	—	16
TOTAL	**(53,855)**	**(2,128)**	**(17,479)**	**(17,366)**	**(15,429)**	**(1,469)**	**16**

Research and development expenses at each reporting date take into account estimates for ongoing activities subcontracted as part of the clinical trials and not yet invoiced, on the basis of detailed information provided by subcontractors and reviewed by the Group's internal departments. The accuracy of these estimates for some types of expenses improves with the progression of the trials and the review of their determination methods. For regulatory reasons, research services for clinical trials and the production of active ingredients and therapeutic units are contracted out to third parties.

The "Other expenses (maintenance, fees, travel, taxes...)" mainly includes:

- Legal fees, audit and accounting fees;
- Advisor fees (banking, press relations, communication, IT, market access, marketing, scientific advising);
- Intellectual property expenses, including in particular the charges and fees incurred by the Company for patent applications and maintenance;
- Expenses related to insurance, notably those triggered by the Company listing on the Nasdaq since 2019;
- Expenses related to the rental, use, and maintenance of the Group's premises;
- Expenses related to external personnel contracted out to the company (safety and security, front desk, clinical and IT services); and
- Expenses related to travel and conferences, including mainly employee travel costs as well as scientific, medical, financial and business development conference registration fees.

2022 Activity

Research and Development Expenses

The increase in research and development costs is generally explained by the increase in costs related to new programs and product candidates, in particular NTZ, VS-01 and GNS 561, offset by the sharp reduction in study costs related to RESOLVE-IT.

General and Administrative Expenses

The increase in general and administrative expenses is broadly explained by the increase in costs related to liability insurance, the increase in costs related to consulting fees, and other charges in the normal course of business.

Marketing and Market Access Expenses

This decrease is mainly explained by the decrease in marketing activity in the United States and France.

Reorganization and Restructuration Expenses

For the year ended December 31, 2022, reorganization and restructuration expenses were not significant.

Employee expenses

Employee expenses and number of employees were as follows:

Employee expenses	**Year ended**		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Wages and salaries	(13,570)	(10,328)	(12,188)
Social security costs	(5,047)	(4,775)	(4,765)
Changes in pension provision	74	(154)	(169)
Employee profit-sharing	—	(628)	—
Share-based compensation	(1,236)	(470)	(245)
TOTAL	**(19,779)**	**(16,354)**	**(17,366)**

Number of employees at year-end	Year ended		
	2020/12/31	2021/12/31	2022/12/31
Average number of employees	193	122	133
Number of employees			
Research and development	66	55	73
Services related to research and development	16	18	18
Administration and management	43	47	55
Marketing and commercial	5	2	2
TOTAL	**130**	**122**	**148**

The increase in employee expenses resulted mainly from an increase in workforce of the average headcount from 122 in 2021 to 133 in 2022.

As the Company recorded a net profit in 2021, it granted a profit-sharing plan to its employees in accordance with the French Law, totaling €(628). As the Company recorded a net loss in 2022, there was no profit sharing in said year.

9. Share-based compensation

Accounting policies

The fair value of equity-settled share-based compensation granted to employees, officers, board members and consultants as determined on the grant date is recognized as a compensation expense with a corresponding increase in equity, over the vesting period. The amount recognized as an expense is adjusted to reflect the actual number of awards for which the related service and non-market performance conditions are expected to be met.

Evaluation models

The fair value of equity-settled share-based compensation granted to employees are measured using i) the Black-Scholes model for share warrants ("Bons de Souscriptions d'Actions" or "BSA") and stock options ("SO") and ii) the Monte Carlo model for free shares ("actions gratuites" or "AGA").

Data and key assumptions used in evaluations

For evaluating BSAs, the following data and key assumptions are utilized in accordance with IFRS 2 - Share based payment: issue price, exercise price, expected volatility, exercise period, expected dividends, risk free interest rate (based on government bonds), and conversion ratio.

For evaluating AGAs, the following data and key assumptions are utilized in accordance with IFRS 2 - Share based payment: grant date, share price at grant date, expected volatility, vesting period, expected dividends, risk free interest rate (based on government bonds), conversion ratio, and expected employee turnover.

For evaluating SOs, the following data and key assumptions are utilized in accordance with IFRS 2 - Share based payment: grant date, share price at grant date, exercise price, expected volatility, vesting period, exercise period, expected dividends, risk free interest rate (based on government bonds), conversion ratio, and expected employee turnover.

Regarding SOs and AGAs, market conditions are taken into account in the determination of the fair value of the plans award. For share-based compensation awards with non-vesting conditions, the grant date fair value of the share-based compensation is measured to reflect such conditions and there is no adjustment for differences between expected and actual outcomes.

Volatility assumptions in the above tables are determined by reference to the Company's historical share price observed on the grant date over a two- and three-year period prior to the grant date, adjusted for extreme variations, if any.

Consultants

GENFIT may also grant equity-settled share-based compensation in exchange for services to consultants who are not considered employees. In such cases, the value of the services is measured when they are rendered by the consultants and the share-based compensation exchanged for the services is measured at an equal amount. If the value of the services cannot be measured reliably, then such value is measured with reference to the fair value of the equity instruments granted.

Financial detail

Share-based compensation granted to employees and executive officers corresponds to stock options and free shares.

Share-based compensation granted to board members and consultants corresponds to share warrants. For the measurement of this share-based compensation, the Group 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.

In 2022, only SO and AGA plans were granted as share-based compensation.

The expense recognized during 2022 pursuant to IFRS 2 was €245 (compared to €470 at December 31, 2021 and €1,236 at December 31, 2020).

The table below shows the share-based compensation by plan:

Share-based compensation - expense	Year ended		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
AGA S 2016-1	—	—	—
AGA S 2016-2	—	—	—
AGA D 2016-1	21	—	—
AGA D 2016-2	6	—	—
SO 2016-1	49	—	—
SO 2016-2	13	—	—
SO US 2016-1	—	—	—
SO US 2016-2	—	—	—
AGA S 2017-1	—	—	—
AGA S 2017-2	13	—	—
AGA D 2017-1	—	—	—
AGA D 2017-2	4	—	—
SO 2017-1	335	—	—
SO 2017-2	110	—	—
SO US 2017-1	—	—	—
SO US 2017-2	—	—	—
BSA-2017-A	—	—	—
BSA-2017-B	—	—	—
AGA S 2018	62	—	—
AGA D 2018	65	—	—
SO 2018	225	186	—
SO US 2018	24	24	—
AGA S 2019	55	39	50
AGA D 2019	63	16	6
SO 2019	123	105	(21)
SO 2019 - US	35	(11)	(16)
BSA 2019	20	—	—
SO US 2019	14	(7)	—
SO D 2020	—	14	14
SO C 2020	—	40	40
SO US 2020	—	19	19
AGA S 2021	—	29	32
AGA D 2021	—	5	7
SO D 2021	—	2	13
SO C2021	—	9	55
SO US 2021	—	2	9
AGA S 2022	—	—	11
AGA D 2022	—	—	2
SO D 2022	—	—	4
SO C 2022	—	—	17
SO US 2022	—	—	4
SO SU 2022	—	—	—
TOTAL	**1,236**	**470**	**245**

9.1. Share warrants

The following table summarizes the data relating to share warrants and the assumptions used for the measurement thereof, in accordance with IFRS 2—Share-based Payment:

Share warrants (BSA)	2019	2017	
	BSA 2019	BSA 2017-A	BSA 2017-B
Option pricing model		Black Scholes	
Fair value per IFRS 2	€0.75	€3.78	€3.81
Issue price	€1.23	€2.00	€2.00
Exercise price	€12.32	€19.97	€19.97
Expected volatility	40.0 %	36.4 %	35.7 %
End of exercise period	5/31/2024	6/30/2022	7/15/2022
Expected dividends	0 %	0 %	0 %
Risk free interest rate	0 %	0 %	0 %
Conversion ratio	1:1	1:1	1:1

The services performed by the consultants are mainly:

- to evaluate product development plans and propose, if necessary, changes to strategic or technical approaches;
- to advise the Company's management and the Scientific Board in identifying strategies and selecting drug candidates, based in particular on the scientific results obtained by the Group (new therapeutic targets, new compounds); and
- to assist and advise the Group in its alliance strategies, such as external growth-supporting synergies (acquisition of new competencies and the purchase of operating rights, drug candidates and innovative technologies, etc.)

Information on share warrants activity is as follows for 2022:

Grant Date	Type	BSAs issued	BSAs outstanding as of January 1, 2022	BSAs awarded	BSAs exercised	BSAs cancelled/forfeited	BSAs outstanding as of December 31, 2022	BSAs exercisable as of December 31, 2022
31/10/2019	BSA 2019	35,070	35,070	0	0	0	35,070	35,070
06/12/2017	BSA 2017-A	18,345	18,345	0	0	18,345	0	0
06/12/2017	BSA 2017-B	18,345	18,345	0	0	18,345	0	0
TOTAL			**71,760**	**0**	**0**	**36,690**	**35,070**	**35,070**

Information on share warrants activity is as follows for 2021:

Grant Date	Type	BSAs issued	BSAs outstanding as of January 1, 2021	BSAs awarded	BSAs exercised	BSAs cancelled/forfeited	BSAs outstanding as of December 31, 2021	BSAs exercisable as of December 31, 2021
31/10/2019	BSA 2019	35,070	35,070	0	0	0	35,070	35,070
06/12/2017	BSA 2017-A	18,345	18,345	0	0	0	18,345	18,345
06/12/2017	BSA 2017-B	18,345	18,345	0	0	0	18,345	18,345
TOTAL			**71,760**	**0**	**0**	**0**	**71,760**	**71,760**

9.2. Free shares (actions gratuites attribuées or AGA)

The following table summarizes the data relating to free shares and the assumptions used for the measurement thereof, in accordance with IFRS 2—Share-based Payment:

Free Shares (AGA)	2022	2021		2019	2018	2017	2016
	AGA D & S 2022	AGA S 2021	AGA D 2021	AGA D & S 2019	AGA D & S 2018	AGA D & S, 2017-1 & 2017-2	AGA D & S, 2016-1 & 2016-2
Option pricing model				Monte Carlo			
Fair value per IFRS 2	€4.08	€4.00	€4.15	€17.06	€20.02	€21.95	€20.78
Grant date	10/14/2022	03/30/2021	03/17/2021	07/18/2019	11/22/2018	12/06/2017	12/15/2016
Share price at grant date	€4.08	€4.00	€4.15	€17.06	€20.02	€21.95	€20.78
Expected volatility	50 %	51 %	51 %	40.2 %	38 %	53.7 %	63 %
Vesting period	From 14/10/2022 to 16/10/2025	From 30/03/2021 to 31/03/2024	From 17/03/2021 to 31/03/2024	From 18/07/2019 to 16/09/2022	From 18/07/2019 to 16/09/2022	From 06/12/2017 to 31/12/2020	From 15/12/2016 to 15/12/2019
Expected dividends	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Risk free interest rate	2.24 %	-0.59 %	-0.59 %	0 %	0 %	0 %	0 %
Conversion ratio	1:1	1:1	1:1	1:1	1:1	1:1	1:1
Expected employee turnover	0 %	0 %	0 %	0 %	15 %	15 %	15 %

The final allocation of free shares is subject to continued employment with the Group and performance conditions.

Information on free shares activity is as follows for 2022:

Grant Date	Type	AGAs issued	AGAs outstanding as of January 1, 2022	AGAs awarded	AGAs vested	AGAs cancelled/ forfeited	AGAs outstanding as of December 31, 2022
14/10/2022	AGA S 2022	39,200		39,200		300	38,900
14/10/2022	AGA D 2022	20,000		20,000			20,000
30/03/2021	AGA S 2021	32,400	29,000			2,700	26,300
17/03/2021	AGA D 2021	15,000	15,000				15,000
18/07/2019	AGA S 2019	17,556	10,782		10,782		0
18/07/2019	AGA D 2019	19,070	13,068		8,712	4,356	0
TOTAL			**67,850**	**59,200**	**19,494**	**7,356**	**100,200**

Information on free shares activity is as follows for 2021:

Grant Date	Type	AGAs issued	AGAs outstanding as of January 1, 2021	AGAs awarded	AGAs vested	AGAs cancelled/ forfeited	AGAs outstanding as of December 31, 2021
30/03/2021	AGA S 2021	32,400		32,400		3,400	29,000
17/03/2021	AGA D 2021	15,000		15,000			15,000
18/07/2019	AGA S 2019	17,556	12,330			1,548	10,782
18/07/2019	AGA D 2019	19,070	15,710			2,642	13,068
TOTAL			**28,040**	**47,400**	**-**	**7,590**	**67,850**

9.3. Stock options (options de souscription d'actions or SO)

The following table summarizes the data relating to stock options and the assumptions used for the measurement thereof, in accordance with IFRS 2—Share-based Payment:

Stock options (SO)	2022				2021		
	SO SU 2022	SO D 2022	SO C 2022	SO US 2022	SO D 2021	SO C 2021	SO US 2021
Option pricing model				Black Scholes			
Fair value per IFRS 2	€1.40	€1.57	€1.90	€1.56	€1.06	€1.30	€1.07
Grant date	12/2/2022	10/17/2022	10/17/2022	10/17/2022	10/20/2021	10/20/2021	10/20/2021
Share price at grant date	€3.46	€4.16	€4.16	€4.16	€3.24	€3.24	€3.24
Exercise price	€2.95	€3.91	€3.12	€3.94	€3.26	€2.61	€3.22
Expected volatility	49.0 %	50.0 %	50.0 %	50.0 %	50.0 %	50.0 %	50.0 %
Vesting period	From 3/12/2022 to 3/12/2025		Du 17/10/2022 au 17/10/2025			Du 20/10/2021 au 20/10/2024	
Exercise period	From 3/12/2022 to 3/12/2032		Du 18/10/2025 au 17/10/2032			Du 21/10/2024 au 21/10/2031	
Expected dividends	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Risk free interest rate	2.1 %	2.24 %	2.24 %	2.24 %	-0.6 %	-0.6 %	-0.6 %
Conversion ratio	1:1	1:1	1:1	1:1	1:1	1:1	1:1
Expected employee turnover	0 %	0 %	0 %	0 %	0 %	0 %	0 %

Stock options (SO)	2020			2019		
	SO D 2020	SO C 2020	SO US 2020	SO 2019	SO US 1 2019	SO US 2 2019
Option pricing model				Black Scholes		
Fair value per IFRS 2	€1.16	€1.46	€1.12	€4.59	€3.67	€3.23
Grant date	12/31/2020	12/31/2020	12/31/2020	7/18/2019	7/18/2019	11/27/2019
Share price at grant date	€3.99	€3.99	€3.99	€17.06	€17.06	€14.50
Exercise price	€4.38	€3.50	€4.52	€13.99	€16.90	€14.31
Expected volatility	49.0 %	49.0 %	49.0 %	40.0 %	40.0 %	40.0 %
Vesting period		Du 31/12/2020 au 31/12/2023			Du 18/07/2019 au 16/09/2022	Du 27/11/2019 au 16/01/2023
Exercise period		Du 01/01/2024 au 31/12/2027			Du 17/09/2022 au 17/09/2029	Du 17/01/2023 au 17/01/2030
Expected dividends	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Risk free interest rate	-0.7 %	-0.7 %	-0.7 %	0.0 %	0.0 %	0.0 %
Conversion ratio	1:1	1:1	1:1	1:1	1:1	1:1
Expected employee turnover	0 %	0 %	0 %	0 %	0 %	0 %

Stock options (SO)	2018		2017	2016
	SO 2018	SO US 2018	SO 2017	SO 2016
Option pricing model			**Black Scholes**	
Fair value per IFRS 2	€9.32	€6.90	€9.32	€10.30
Grant date	11/7/2018	11/7/2018	12/6/2017	12/15/2016
Share price at grant date	€22.10	€22.10	€21.95	€20.79
Exercise price	€16.00	€21.65	€17.91	€15.79
Expected volatility	44.1 %	44.1 %	53.7 %	63.0 %
Vesting period		Du 07/11/2018 au 31/12/2021	Du 06/12/2017 au 31/12/2020	Du 15/12/2016 au 15/12/2019
Exercise period		Du 01/01/2022 au 31/12/2028	Du 01/01/2021 au 31/12/2027	Du 16/12/2019 au 16/12/2026
Expected dividends	0 %	0 %	0 %	0 %
Risk free interest rate	0.0 %	0.0 %	0.0 %	0.0 %
Conversion ratio	1:1	1:1	1:1	1:1
Expected employee turnover	15 %	15 %	15 %	15 %

Definitive vesting is subject to continued employment with the Group and performance conditions.

Information on stock options activity is as follows for 2022:

Grant Date	Type	SO issued	SO outstanding as of January 1, 2022	SO awarded	SO cancelled/ forfeited	SO exercised	SO outstanding as of December 31, 2022	SO exercisable as of December 31, 2022
02/12/2022	SO SU 2022	8,750		8,750			8,750	0
17/10/2022	SO D 2022	35,000		35,000			35,000	0
17/10/2022	SO C 2022	131,000		131,000			131,000	0
17/10/2022	SO US 2022	34,625		34,625			34,625	0
20/10/2021	SO D 2021	35,000	35,000				35,000	0
20/10/2021	SO C 2021	134,375	134,375		10,000		124,375	0
20/10/2021	SO US 2021	32,500	25,000				25,000	0
31/12/2020	SO D 2020	35,000	35,000				35,000	0
31/12/2020	SO C 2020	103,750	81,250				81,250	0
31/12/2020	SO US 2020	56,250	50,000				50,000	0
18/07/2019	SO 2019	107,880	77,015		25,672		51,343	51,343
18/07/2019	SO US 1 2019	30,620	7,670		2,557		5,113	5,113
07/11/2018	SO 2018	122,000	68,329				68,329	68,329
07/11/2018	SO US 2018	17,500	9,713				9,713	9,713
06/12/2017	SO 2017-1	64,164	43,212				43,212	43,212
06/12/2017	SO 2017-2	32,086	17,765				17,765	17,765
15/12/2016	SO 2016-1	41,917	34,398				34,398	34,398
15/12/2016	SO 2016-2	20,958	15,308				15,308	15,308
TOTAL			**634,035**	**209,375**	**38,229**	**0**	**805,181**	**245,181**

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Information on stock options activity is as follows for 2021:

Grant Date	Type	SO issued	SO outstanding as of January 1, 2021	SO awarded	SO cancelled/ forfeited	SO exercised	SO outstanding as of December 31, 2021	SO exercisable as of December 31, 2021
20/10/2021	SO D 2021	35 000		35 000			35 000	-
20/10/2021	SO C 2021	134 375		134 375			134 375	-
20/10/2021	SO US 2021	32 500		32 500	7 500		25 000	-
31/12/2020	SO D 2020	35 000	35 000				35 000	-
31/12/2020	SO C 2020	103 750	103 750		22 500		81 250	-
31/12/2020	SO US 2020	56 250	56 250		6 250		50 000	-
18/07/2019	SO 2019	107 880	94 530		17 515		77 015	-
18/07/2019	SO US 1 2019	30 620	23 620		15 950		7 670	-
27/11/2019	SO US 2 2019	13 350	8 900		8 900		-	-
07/11/2018	SO 2018	122 000	71 678		3 349		68 329	68 329
07/11/2018	SO US 2018	17 500	9 713				9 713	9 713
06/12/2017	SO 2017-1	64 164	43 212				43 212	43 212
06/12/2017	SO 2017-2	32 086	17 765				17 765	17 765
15/12/2016	SO 2016-1	41 917	34 398				34 398	34 398
15/12/2016	SO 2016-2	20 958	15 308				15 308	15 308
TOTAL			**514 124**	**201 875**	**81 964**	**0**	**634 035**	**188 725**

9.5. Performance conditions

The SO and SO US stock option plans as well as certain free share plans (AGA "D") implemented in 2016, 2017, 2018 and 2019 are subject to internal performance conditions related to the progress of the Group's research and development programs, and to external performance conditions related to the evolution of the Company's stock price.

The other free share plans (AGA "S") and SO plans implemented starting in 2020 are subject only to internal performance conditions.

Performance conditions of 2022 plans

Plans	Nature of performance conditions
SO D 2022 ***SO C 2022*** ***SO US 2022*** ***SO SU 2022*** ***AGA S 2022*** ***AGA D 2022*** *Evaluation date for performance conditions:* *- 10/17/2025 for SO D 2022/SO C 2022/SO US 2022/AGA S 2022/AGA D 2022* *- 12/3/2025 for SO SU 2022*	**Internal conditions -** a) 50% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 10,000 of the Free Shares for the AGA D 2022 will vest, if during the 2022 financial year and then at any time during the Vesting Period, 3 new R&D programs (at the rate of one third of these 2022 instruments per new program) complete the Company's R&D program portfolio (as it was at 12/31/2021); that these programs are at the so-called clinical development stage when this addition is made or that they reach this stage afterwards and that this addition originates: (i) a business-development operation (licensing-in, M&A, etc.), or (ii) the identification of new opportunities resulting from internal research (repositioning). b) 25% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 5,000 of the Free Shares for the AGA D 2022 will vest, if at least one of the following three conditions relating to the development of the elafibranor development program is fulfilled: (i) obtaining the main results of the first part of the ELATIVE trial in the second quarter of 2023; (ii) filing of a Marketing Authorization Application for elafibranor in the second half of 2023; (iii) marketing authorization for elafibranor in 2024. c) 15% of the instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 3,000 of the Free Shares for the AGA D 2022 will vest, if at least one of the following two conditions relating to the development of the NTZ program in the ACLF is fulfilled: (i) First clinical results in 2022; (ii) Start of a Phase 2 clinical trial in the first half of 2023. d) 10% of instruments SO D 2022/SO C 2022/SO US 2022/ SO SU 2022/AGA S 2022 will be exercisable or definitively vest, and 2,000 of the Free Shares for the AGA D 2022 will vest, if as part of the development of the GNS561 program, a Phase 2b trial starts in the first half of 2023. **External conditions -** Each applicable portion of all 20,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, is then subject to the External Condition according to the methods described below. The degree of fulfillment of the External Condition relating to the Company's stock market price will be determined according to the relative performance of GENFIT shares. Each applicable portion of all 20,000 Free Shares under the AGA D 2022 plan, as each Internal Conditions above is met, will be definitively acquired per the following conditions: (a) No AGA D 2022 shall vest if the Final Price is strictly lower than the Initial Price; (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value lower than the Ceiling Price, the number of AGA D 2022 definitively allocated will be equal to:[(Final Price / Initial Price) -1] x 1/2 of the number of AGA D 2022 instruments (c) All AGA D 2022 if the Final Price is equal to or higher than the Ceiling Price. The notions of “Final Price”, “Initial Price” and “Ceiling Price” are defined in the plan regulations.

Performance conditions of 2021 plans

Plans	Nature of performance conditions
SO D 2021 ***SO C 2021*** ***SO US 2021*** *Evaluation date for performance conditions: 10/20/2024*	a) 50% of the Stock Options will be exercisable if at least one of the following three conditions relating to the development of elafibranor in PBC and to the ELATIVE clinical trial is fulfilled: (i) ELATIVE topline results are released to the market before or during the second quarter of 2023; (ii) a new drug application is filed for elafibranor in PBC with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in the second half of 2023 or before; (iii) elafibranor is approved by a regulatory authority in 2024. b) 15% of the Stock Options will be exercisable if at least one of the following two conditions relating to the development of NTZ and the ACLF franchise is fulfilled: (i) a Phase 2 clinical study or a more advanced clinical study evaluating NTZ is in ongoing or was carried out; (ii) the Company develops or acquires the rights to a new molecule (including through repositioning) for development in ACLF. c) 15% of the Stock Options will be exercisable if at least one of the following two conditions relating to the NIS4 diagnostic technology is fulfilled: (i) if a research and development partnership agreement relating to the implementation of the NIS4 diagnostic technology into an IVD test with at least one major NASH player ("big pharma", biotech company, institution, etc.) is entered into by the Company; (ii) Labcorp's NASHnext LDT is reimbursed by at least three payers in the United States (insurance, integrated system, etc). d) 20% of the Stock Options will be exercisable if at least one of the following two conditions relating to the development of the product pipeline of the Company is fulfilled: (i) At least one new molecule (excluding elafibranor and NTZ) is developed by the Company or the Company has acquired development rights to a new molecule outside of the ACLF franchise (performance already covered by b(ii) above); (ii) At least two Phase 2 clinical studies or more advanced clinical studies are ongoing or have been completed ; not including a Phase 2 clinical study or more advanced clinical study in NTZ (performance already covered by b(i) above).

Plans	Nature of performance conditions
AGA S 2021 ***AGA D 2021*** *Evaluation date for performance conditions: 3/31/2024*	**Internal conditions -** a) 50% of the Free Shares AGA S 2021 will be exercisable, and 7,500 of the Free Shares AGA D 2021 will be exercisable, if at least one of the following three conditions relating to PBC and ELATIVE is fulfilled: (i) "Last Patient Visit" in ELATIVE in the fourth quarter of 2022 or earlier; (ii) If the results of ELATIVE are released to the market before or during the first half of 2023; (iii) if a registration request is filed for elafibranor in PBS with the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) in 2023. b) 25% of the Free Shares AGA S 2021 will be exercisable, and of the Free Shares AGA D 2021 will be exercisable, if at least one of the following two conditions relating to the NIS4 diagnostic is fulfilled: (i) if a research and development partnership agreement with at least one major NASH player ("big pharma", biotech company, institution, etc.) is entered into by the Company; (ii) the NIS4 diagnostic is used in at least 20 clinical studies. c) 25% of the Free Shares AGA S 2021 will be exercisable, and 3,750 of the Free Shares AGA D 2021 will be exercisable, if at least one of the following two conditions relating to the product pipeline of the Company is fulfilled: (i) initiation of a clinical study for a new indication with elafibranor or NTZ; (ii) if the Company develops or acquires the rights to a new molecule. **External conditions -** Each applicable portion of all 15,000 Free Shares under the AGA D 2021 plan, as each Internal Conditions above is met, is then subject to the External Condition according to the methods described below. The degree of fulfillment of the External Condition relating to the Company's stock market price will be determined according to the relative performance of GENFIT shares. Each applicable portion of all Free Shares under the AGA D 2021 plan, as each Internal Conditions above is met, will be definitively acquired per the following conditions: (a) No AGA D 2021 shall vest if the Final Price is strictly lower than the Initial Price; (b) If the Final Price is between (i) a value equal to or greater than the Initial Price and (ii) a value lower than the Ceiling Price, the number of AGA D 2021 definitively allocated will be equal to:[(Final Price / Initial Price) -1] x 1/2 of the number of AGA D 2021 instruments (c) All AGA D 2021 if the Final Price is equal to or higher than the Ceiling Price. The notions of "Final Price", "Initial Price" and "Ceiling Price" are defined in the plan regulations.

10. FINANCIAL INCOME AND EXPENSES

Financial income and expenses	Year ended		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Interest income	1,442	274	137
Foreign exchange gain	4,983	8,876	7,470
Financial income from renegotiating the convertible bond debt OCEANE	0	35,578	0
Other financial income	119	52	605
TOTAL - Financial income	**6,544**	**44,780**	**8,212**
Financial expenses			
Interest expenses	(11,643)	(4,846)	(4,341)
Interest expenses for leases	(134)	(109)	(69)
Foreign exchange losses	(13,508)	(2,163)	(340)
Other financial expenses	(11)	(5)	(8)
TOTAL - Financial expenses	**(25,296)**	**(7,122)**	**(4,758)**
FINANCIAL GAIN (LOSS)	**(18,752)**	**37,658**	**3,453**

Interest income recognized is almost exclusively related to current financial assets. Other financial income similarly is almost exclusively related to accrued interest income for ongoing current financial assets at the end of the year.

The financial expenses are related to the interest of the OCEANEs and they mainly relate to the payment of coupons at the rate of 3.5% and the amortization of the discount of the bond debt at the effective interest rate of 8.8% to accrete the bond debt up to the amount that will be repaid (or converted) at maturity, recognizing a theoretical annual interest accrual as a result of the accretion on the period of an amount equivalent to the equity component at an effective interest rate.

The portion of financial gain related to currency exchange is a net gain of €7,130 in 2022 notably due to the difference in currency exchange recognized on the cash equivalents and other current financial assets in US dollars, as GENFIT has decided to keep some of its cash in US dollars. See Note 13 "Cash and cash equivalents". These cash investments in US dollars are to be used to pay directly expenses in US dollars (natural currency hedge).

As a reminder, financial income in 2021 included notably the one-time buyback bonus of €35.6 million issued from the renegotiation of the OCEANEs completed in said year.

11. INCOME TAX

Accounting policies

Income tax expense (or benefit) comprises current tax expense (or benefit) and deferred tax expense (or benefit), as applicable.

Deferred taxes are recognized for all the temporary differences arising from the difference between the tax basis and the accounting basis of assets and liabilities.

Deferred tax assets are recognized for unused tax losses, unused tax credits and temporary deductible differences to the extent that:

- it is probable that future taxable profit will be available against which they can be used; or
- if there are deferred tax liabilities for the same entity in the same tax jurisdiction on which they can be applied.

Financial detail

For 2022, the corporate income tax payable of the Parent company GENFIT SA amounted to €4,906, which is recognized as "Other current tax liabilities" in the consolidated financial statements.

It is of note that we benefited from a reduced tax rate on part of the income from the licensing agreement signed with Ipsen pursuant to Article 238 of the French Tax Code.

The determination of the income tax expense recognized in the consolidated financial statements, which amounted to (a gain) of €(116) for 2021, is summarized in the table "Effective tax rate" hereunder.

Breakdown of deferred taxes by nature

(in € thousands)	As of 12/31/2020	Impact on equity	Impact on the profit/loss	As of 12/31/2021
Deferred tax liabilities	(2,050)	(2,721)	2,455	(2,315)
Deferred tax assets	1,282	—	430	1,712
TOTAL	**(767)**	**(2,721)**	2,885	(602)

(in € thousands)	As of 12/31/2021	Impact on equity	Impact on the profit/loss	As of 12/31/2022
Deferred tax liabilities	(2,315)	—	545	(1,770)
Deferred tax assets	1,712	—	(453)	1,260
TOTAL	**(602)**	**—**	**93**	**(510)**

Effective tax rate

(in € thousands)	Year ended 2020/12/31	2021/12/31	2022/12/31
Profit (loss) for the period	(101,221)	67,259	(23,719)
Tax gain (expense)	428	(2,215)	116
Profit (loss) for the period before taxes	**(101,649)**	**69,474**	**(23,836)**
Tax rate in France	28.92 %	27.37 %	25.00 %
Theoretical tax expense calculated at the French tax rate	**29,401**	**(19,018)**	**5,959**
Increase / decrease in tax benefit arising from :			
Tax credits	1,739	1,512	1,504
Permanent differences	(404)	833	(31)
Differences between rates	172	7,323	(67)
Tax losses for the period, unrecognised as deferred tax assets	(28,603)	0	(7,037)
Utilisation of previously unrecognised tax losses	0	5,590	0
IFRS adjustments without tax incidence	(358)	(129)	(61)
Non recognition of deffered tax assets related to temporary differences	(775)	(24)	331
Recognition of deferred tax assets against deferred tax liabilities	(706)	430	(453)
Tax effects related to the renegociation of the convertible debt	0	1,370	0
Others	(39)	(102)	(29)
Income tax expense recognised in profit or loss	**428**	**(2,215)**	**116**
Effective income rate	(0.42)%	(3.19)%	(0.49)%

Tax Inspection

We are subject to a tax audit by the French revenue service on our tax returns or operations subject to review on the 2019 and 2020 periods (including the Research Tax Credit claimed for these periods), which started on December 10, 2021 and is still ongoing at the date of this document.

The research tax credit receivable from amounted to €11,299 as of December 31, 2022, €6,017 of which relates to 2022. The balance for 2021 has not yet been reimbursed in 2022 given the ongoing tax audit. The amount of the balance for 2021 is €5,282.

11.1. Losses available for offsetting against future taxable income

At December 31, 2020, 2021 and 2022, the tax loss carry forwards for the Company amounted to €483,356, €449,679 and €477,149, respectively.

Such carry forwards can be offset against future taxable profit within a limit of €1.0 million per year plus 50% of the profit exceeding this limit. Remaining unused losses will continue to be carried forward indefinitely.

In 2021, the amount of tax loss carry forwards used to offset taxable profit were €33.7 million.

11.2.Deferred tax assets and liabilities

The Group's main sources of deferred tax assets and liabilities as of December 31, 2021 and 2022 related to:

- Tax loss carry forwards: €449,679 and €477,149 respectively;
- Temporary differences related to:
  - the OCEANEs: a deferred tax liability for €2,315 and €1,770 as of December 31, 2021 and 2022, respectively, and a deferred tax asset for €1,712 and €1,260 as of December 31, 2021 and 2022,
  - Post-employment benefits: a deferred tax liability for €287 and €216, as of December 31, 2021 and 2022, respectively, each offset by a deferred tax asset of the same amount.

The Company offsets its deferred tax assets and liabilities (€1,260 and €1,770, respectively), as permitted by IAS 12, resulting in a net deferred tax liability of €510 as of December 31, 2022.

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

12. Earnings (loss) per share

Basic earnings (loss) per share are calculated by dividing profit or loss attributable to the Company's ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per share are calculated by adjusting profit attributable to ordinary shareholders and the average number of ordinary shares outstanding weighted for the effects of all potentially dilutive instruments (share warrants, redeemable share warrants, free shares, stock options and bonds convertible into new and/or existing shares).

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

Earnings per share	Year ended		
	2020/12/31	2021/12/31	2022/12/31
Profit (loss) for the period (in € thousands)	**(101,221)**	**67,259**	**(23,719)**
Weighted average number of ordinary shares used to calculate basic earnings (loss) per share	38,858,617	44,739,756	49,673,936
Basic earnings (loss) per share (€/share)	**(2.60)**	**1.51**	**(0.48)**
Weighted average number of ordinary shares used to calculate diluted earnings (loss) per share	**38,858,617**	**55,613,634**	**49,673,936**
Diluted earnings (loss) per share (€/share)	**(2.60)**	**1.23**	**(0.48)**

The weighted average numbers of ordinary shares as noted above exclude shares held by Genfit.

The following table summarizes the potential common shares not included in the computation of diluted earnings per share because their impact would have been antidilutive:

Potential common shares not included in the computation of diluted earnings per share	Year ended
	2022/12/31
BSA	35,070
STOCK OPTIONS	637,726
AGA	53,887
OCEANES	10,580,141

13. CASH AND CASH EQUIVALENTS

Cash and cash equivalents comprise cash on hand, bank accounts and term deposits, together with short-term deposits and highly liquid investments. They are readily convertible to a known amount of cash and thus present a negligible risk of a change in value. They also include Undertakings for Collective Investments in Transferable Securities (UCITs) whose characteristics allow them to be classified as cash and cash equivalents.

Initially recognized at their purchase cost at the transaction date, investments are subsequently measured at fair value. Changes in fair value are recognized in net financial income (expenses).

The main components of cash equivalents were:

- UCITS and interest-bearing current accounts, available immediately;
- Term accounts, available within the contractual maturities or by the way of early exit with no penalty; and
- Negotiable medium-term notes, available with a quarterly maturity or by the way of early exit with no penalty.

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

Cash and cash equivalents	As of	
(in € thousands)	**2021/12/31**	**2022/12/31**
Short-term deposits	69,045	119,090
Cash on hand and bank accounts	189,711	16,910
TOTAL	**258,756**	**136,001**

Short-term deposits	As of	
(in € thousands)	2021/12/31	2022/12/31
TERM ACCOUNTS	69,045	119,090
TOTAL	**69,045**	**119,090**

14. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The company does not have any goodwill.

Intangible assets

Intangible assets mainly consist of software and operating licenses acquired by the Group. They are recognized at cost less accumulated amortization and impairment. Amortization expense is recorded on a straight-line basis over the estimated useful lives of the intangible assets. The estimated useful lives of both software and license agreements are between 1 and 8 years.

In the event of an acquisition not qualifying as a business combination under IFRS 3, GENFIT initially records the acquired asset at cost of the consideration transferred, excluding variable payments that are dependent on future events. No liability is recognized initially for these contingent payments. A liability will be recorded when the condition that triggers the obligation occurs.

The variable payments that would be due if the asset acquired complies with agreed-upon specifications at specific dates in the future are recognized as an adjustment to the cost of the related asset.

Acquisition of Versantis

As previously noted in note 2.1 Acquisition of the Clinical-stage Biopharmaceutical Company Versantis, on September 29, 2022, GENFIT acquired Versantis AG, a private Swiss-based clinical stage biotechnology company focused on addressing the growing unmet medical needs in liver diseases.

The Phase 2 ready program, VS-01-ACLF, a program in scavenging liposomes technology, was deemed to be the asset with substantially all attributable value in accordance with the optional concentration test of fair value under paragraph B7A of IFRS 3. Of the total acquisition price paid of €46.6 million, €43.9 million was allocated to Intangible assets in accordance with IAS 38 - Intangible Assets. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction. Further, given the nature of the intangible asset, it was determined to have a definite useful life of 20 years, consistent with patents lifetimes in the United States and the European Union. Amortization will start upon EMA/FDA regulatory approval and until then will be subject to an annual impairment test in accordance with IAS 38 - Intangible Assets.

The following tables show the variations in intangible assets for the years ended December 31, 2021 and 2022:

(in € thousands)	As of 12/31/2020	Increase	Decrease	Translation adjustments	Reclassification	As of 12/31/2021
Gross						
Software	1,440	126	(255)	—	(17)	1,294
Patents	91	—	(21)	—	—	70
Other intangibles	—	—	(17)	—	17	—
TOTAL—Gross	1,531	127	(294)	—	—	1,364
Accumulated depreciation and impairment						
Software	(1,213)	(152)	176	—	—	(1,190)
Patents	(21)	—	21	—	—	—
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	(1,234)	(152)	197	—	—	(1,190)
TOTAL - Net	**297**	**(26)**	**(97)**	**—**	**—**	**174**

(in € thousands)	As of 12/31/2021	Increase	Decrease	Translation adjustments	Reclassification	As of 2022/12/31
Gross						
Software	1,294	81	(398)	—	—	977
Patents	70	281	—	—	—	351
Other intangibles	—	43,569	—	—	—	43,569
TOTAL—Gross	1,364	43,931	(398)	—	—	44,897
Accumulated depreciation and impairment						
Software	(1,190)	(79)	329	—	—	(940)
Patents	—	—	—	—	—	—
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	(1,190)	(79)	329	—	—	(940)
TOTAL - Net	**174**	**43,852**	**(69)**	**—**	**—**	**43,957**

15. PROPERTY, PLANT AND EQUIPMENT

Property, Plant and Equipment

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

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

Estimated useful lives are as follows:

Building on non-freehold land	10 years
Fittings and fixtures	Between 9 and 25 years
Scientific equipment	Between 2 and 12 years
Computer equipment	Between 2 and 5 years
Furniture	Between 4 and 10 years
Vehicles	Between 4 and 6 years

Any gain or loss on disposal of an item of property, plant and equipment is determined by comparing the proceeds from disposal with the carrying amount of the item. The net amount is recognized in the consolidated statements of operations under the line item "Other operating income (expenses)."

Leases

IFRS 16 introduces for the lessee a single model of accounting on the balance sheet for leases. The lessee recognizes a "right of use" asset which represents its right to use the underlying asset, and a lease liability for its obligation to pay the rent.

The Group recognizes a "right of use" asset and a lease liability at the start of the lease term. The "right of use" asset is initially measured at cost and then at cost less any amortization and accumulated impairment losses. The amount can be adjusted based on certain revaluations of the lease liability.

The lease liability is initially measured at the discounted value of the rents owed and not yet paid at the start date of the contract. The discount rate used is the implicit interest rate of the contract or, if it cannot be easily determined, the Company’s incremental borrowing rate of the lessee. The Group generally uses the latter as the discount rate.

The lease liability is then adjusted by the interest expense minus the amounts of rent paid. It is revalued in the event of a change in future rents following a change in the index or rate, a new estimate of the amount to be paid under a residual value guarantee or, where applicable, a revaluation of the exercise of an option to purchase or to extend, or the non-exercise of an option to terminate (which then becomes reasonably certain).

The Group has exercised its judgment in determining the term of the lease agreements that provide for extension options. The fact that the Group has determined that it is reasonably certain to exercise such options has an impact on the lease term used and has a significant impact on the amount of lease debt and the "right of use" asset in the accounts. The amount of short term or low value leases which are not included in the IFRS 16 model is not material.

The following tables show the variations in tangible assets for the years ended December 31, 2021 and 2022:

Property, plant and equipment - Variations (in € thousands)	As of As of As of 2020/12/31	Increase	Decrease	Translation adjustments	Reclassification	As of As of As of 2021/12/31
Gross						
Buildings on non-freehold land	12,167	—	(1,912)	—	56	10,311
Scientific equipment	9,080	71	(2,831)	—	—	6,320
Fittings	1,703	(4)	(234)	—	9	1,474
Vehicles	99	60	(67)	—	—	91
Computer equipment	1,534	30	(18)	—	(4)	1,542
Furniture	329	—	(50)	—	—	279
In progress	—	330	(342)	—	12	—
TOTAL - Gross	**24,911**	**487**	**(5,454)**	**—**	**74**	**20,017**
Accumulated depreciation						
Buildings on non-freehold land	(2,603)	(1,417)	1,120	—	—	(2,900)
Scientific equipment	(5,952)	(1,061)	2,145	—	—	(4,868)
Fittings	(982)	(91)	190	(5)	—	(888)
Vehicles	(85)	(13)	67	—	—	(31)
Computer equipment	(1,217)	(195)	14	(6)	—	(1,403)
Furniture	(251)	(12)	50	—	—	(213)
In progress	—	—	—	—	—	—
TOTAL - Accumulated depreciation	**(11,090)**	**(2,789)**	**3,587**	**(11)**	**—**	**(10,304)**
Accumulated impairment						
Buildings on non-freehold land	(1,182)	—	679	—	—	(503)
Scientific equipment	(866)	—	779	—	—	(87)
Fittings	(93)	—	—	—	—	(93)
Vehicles	—	—	—	—	—	—
Computer equipment	(27)	—	15	—	—	(12)
Furniture	(3)	—	—	—	—	(3)
In progress	—	—	—	—	—	—
TOTAL - Accumulated impairment	**(2,172)**	**—**	**1,473**	**—**	**—**	**(699)**
TOTAL - Net	**11,648**	**(2,302)**	**(394)**	**(11)**	**74**	**9,015**

Property, plant and equipment - Variations (in € thousands)	As of 2021/12/31	Increase	Decrease	Translation adjustments	Reclassification	As of 2022/12/31
Gross						
Buildings on non-freehold land	10,311	610	—	—	—	10,921
Scientific equipment	6,320	228	(82)	—	—	6,467
Fittings	1,474	61	—	—	2	1,537
Vehicles	91	—	—	—	—	91
Computer equipment	1,542	98	(149)	—	8	1,500
Furniture	279	—	—	—	—	279
In progress	—	16	—	—	(16)	—
TOTAL - Gross	**20,017**	**1,014**	**(230)**	**—**	**(7)**	**20,794**
Accumulated depreciation						
Buildings on non-freehold land	(2,900)	(1,033)	—	—	—	(3,934)
Scientific equipment	(4,868)	(697)	79	4	—	(5,481)
Fittings	(888)	(95)	—	(2)	—	(985)
Vehicles	(31)	(12)	—	—	—	(43)
Computer equipment	(1,403)	(105)	148	(5)	—	(1,365)
Furniture	(213)	(10)	—	—	—	(223)
In progress	—	—	—	—	—	—
TOTAL - Accumulated depreciation	**(10,304)**	**(1,953)**	**227**	**(3)**	**—**	**(12,032)**
Accumulated impairment						
Buildings on non-freehold land	(503)	—	48	—	—	(455)
Scientific equipment	(87)	—	28	—	—	(59)
Fittings	(93)	—	69	—	—	(24)
Vehicles	—	—	—	—	—	—
Computer equipment	(12)	—	2	—	—	(10)
Furniture	(3)	—	—	—	—	(3)
In progress	—	—	—	—	—	—
TOTAL - Accumulated impairment	**(699)**	**—**	**147**	**—**	**—**	**(552)**
TOTAL - Net	**9,015**	**(939)**	**144**	**(3)**	**(7)**	**8,210**

Assets related to contracts that were originally classified as legacy finance leases are scientific equipment and are accounted for under IFRS 16. Their net carrying value as of December 31, 2021 and 2022 amounted to €114 and €27 respectively.

Amortization

Amortization of an asset starts when it becomes available for use. The asset should be in the location and condition that is required for it to be operating in the manner intended by management, which – in the case of in process research and development (IPR&D) acquired from Versantis, will happen once it receives regulatory and marketing approval. Until that point, it is tested for impairment annually in accordance with the requirements of IAS 36. The asset is tested for impairment by comparing its recoverable amount with its carrying amount once a year, at a minimum. An additional impairment test is required whenever there is an indication that an intangible asset may be impaired.

Impairment

If indicators of impairment are identified, amortizable intangible assets and depreciable tangible assets are subject to an impairment test under the provisions of IAS 36, Impairment of Assets.

The Group has considered that the discontinued use of some equipment following the termination of RESOLVE-IT as well as the decision to no longer use part of the leased premises were indicative of an impairment loss requiring the completion of an impairment test of property, plant and equipment or of the rights of use recognized in the statement of financial position for this equipment and lease agreements.

The recovery value of an asset is the higher value between the value in use and the fair value less costs of divestment. The value in use is evaluated in relation to the future forecasted cash flows, discounted at current interest rates, before tax, which reflects the current market appreciation of the time value of money and the risks specific to the asset. In the present case, the recovery value of the tested assets corresponds to their fair value less costs of divestment.

The impacts related to the impairment of tangible assets and rights of use related to equipment and premises that are no longer in use due to the discontinuation of the RESOLVE-IT study are recognized in the consolidated statement of operations under “Reorganization and restructuring costs”.

Impairment test of assets under IAS 36

Some equipment belonging to the Group and others under a leasing agreement were no longer in use following the reorganization of the group's activities and the termination of the RESOLVE-IT trial decided in mid-2020.

This indication of loss of value led the Group to conduct an impairment test over owned and leased equipment, based on the value at which this equipment may be divested (on the basis of agreements with the lessors on the early purchase of the equipment and near-term purchase offers) in order to determine the recovery value.

In 2021, part of these elements, mainly scientific equipment, were sold. As a result the accumulated impairment for these equipments was reduced to €196, including:

- €87 for scientific equipment (of which €25 related to owned equipment and €62 of leased equipment),
- €93 for fittings, and
- €15 for computer equipment and furniture,

including associated liabilities.

In 2022, part of these elements, mainly scientific equipment, were sold. As a result the accumulated impairment for these equipments was reduced to €97, including:

- €59 for scientific equipment (of which €31 related to owned equipment and €28 of leased equipment),
- €24 for fittings, and
- €13 for computer equipment and furniture,

including associated liabilities.

Similarly, parts of the leased premises (a portion of the office space in Paris and of the former laboratories at headquarters) were no longer in use. The vacant space is segmented and separate from the premises that will continue to be occupied. An impairment test of the rights of use of this space has also been performed. The test of the rights of use pertaining to these premises in 2021 had resulted in the recognition of an accumulated impairment of €503.

In 2022, the corresponding accumulated impairment was reduced to €455 as of December 31, 2022.

Supplemental IFRS 16 Disclosures

Right of use assets and accumulated amortization

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

Therefore, the right of use assets and related accumulated amortization as of December 31, 2021 included in the table above affect:

- The line item "Building on non-freehold land" amounting to €10,056 and €2,831, respectively;
- The line item "Scientific equipment", amounting to €1,369 and €1,255 respectively.

Therefore, the right of use assets and related accumulated amortization as of December 31, 2022 included in the table above affect:

- The line item "Building on non-freehold land" amounting to €10,665 and €3,839, respectively;
- The line item "Scientific equipment", amounting to €1,502 and €1,475 respectively.

Right of use additions

Right of use asset additions during 2022 amounted to: €743

Lease terminations - 2021

In 2021, GENFIT SA and GENFIT CORP terminated the respective lease agreements for their offices, respectively located in Paris, France and Cambridge, MA, which they both relocated to a coworking space. The rental of these office spaces, as a service contract, no longer falls under IFRS 16. The impact of this change in 2021 is limited as both relocations happened during the second half of the year.

16. TRADE AND OTHER RECEIVABLES

Accounting policies

Trade and other receivables are recognized at fair value, which is the nominal value of invoices unless payment terms require a material adjustment for the time value discounting effect at market interest rates. Trade receivables are subsequently measured at amortized cost. Impairment losses on trade accounts receivable are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables .

Receivables are classified as current assets, except for those with a maturity exceeding 12 months after the reporting date, according to IFRS 9 standards ("expected credit loss").

Trade and other receivables consisted of the following:

Trade and other receivables - Total	As of	
(in € thousands)	2021/12/31	2022/12/31
Trade receivables, net	57	3,188
Research tax credit	5,282	11,299
Social security costs receivables	4	1
VAT receivables	1,038	1,288
Grants receivables	5	4
Other receivables	852	126
TOTAL	**7,239**	**15,906**
Of which : Current	7,236	15,906
Of which : Non-current	3	—

Trade receivables, net

Trade receivables amounted to €3,188 as of December 31, 2022. The balance mainly corresponds to revenue related to the inventory purchase agreement with Ipsen.

Research tax credit

The research tax credit receivable for the year 2021 amounted to €5,282.

The research tax credit receivable for the year 2022 amounts to €11,299. This balance includes the 2021 balance as there is currently a tax inspection taking place by the French tax authorities.

VAT receivables

The VAT receivable amounted to €1,288 at December 31, 2022.

The VAT receivable amounted to €1,038 at December 31, 2021.

Other receivables

The line item “other receivables” primarily consists of credit notes from suppliers for €126 and €752, respectively, as of December 31, 2022 and December 31, 2021.

17. INVENTORIES

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

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

18. OTHER FINANCIAL ASSETS

Accounting policies

A financial asset is initially recognized as measured at amortized cost, at fair value through other comprehensive income - debt instrument, at fair value through other comprehensive income - equity instrument, or at fair value through profit or loss.

Financial assets will not be reclassified after initial recognition, unless we change our economic model of financial asset management. If so, all affected financial assets would be reclassified as of the first day of the first reporting period following the change in economic model.

A financial asset is measured at amortized cost if both of the following conditions are met, and if it is not measure at fair value through profit or loss:

- Its ownership is part of an economic model of which the objective is to hold assets in order to receive its contractual cash flows;
- Its contractual conditions provide for cash flows at defined dates, which correspond only to principal payments and interest on the remaining principal amount.

A debt instrument is measured at fair value through other comprehensive income if both of the following conditions are met, and if it is not measure at fair value through profit or loss:

- Its ownership is part of an economic model of which the goal is met through both the receipt of contractual cash flows and the sale of financial assets;
- Its contractual conditions provide for cash flows at defined dates, which correspond only to principal payments and interest on the remaining principal amount.

At the time of initial recognition of an equity instrument that is not held for trading, we may irrevocably choose to present future changes in fair value in other comprehensive income. This choice is made for each investment.

All financial assets that are not categorized as measured at amortized cost or at fair value through other comprehensive income as previously described are measured at fair value through profit or loss.

Financial detail

Other financial assets consisted of the following:

Financial assets - Total	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Non consolidated equity investments	3,133	3,133
Other investments	—	483
Financial investments	—	4,550
Loans	388	428
Deposits and guarantees	397	335
Liquidity contract	513	534
TOTAL	**4,431**	**9,464**
Of which : Current	—	4,550
Of which : Non-current	4,431	4,914

Financial assets - Variations	**As of**	**Increase**	**Decrease**	**As of**
(in € thousands)	**31/12/2021**			**31/12/2022**
Non consolidated equity investments	3,133	—	—	3,133
Other investments	—	483	—	483
Financial investments	—	4,550	—	4,550
Loans	388	40	—	428
Deposits and guarantees	397	33	(95)	335
Liquidity contract	513	0	21	534
TOTAL	**4,431**	**5,107**	**(74)**	**9,464**

The total amount of financial assets of the Company was €4,431 at December 31, 2021, as is €9,464 at December 31, 2022. This change is mainly due to the short term financial asset with a term of 180 days.

Non-consolidated equity investments

As of December 31, 2022, the value of "Non-consolidated equity investments" totaled €3,133. The balance solely relates to our equity purchase in Genoscience Pharma which took place in 2021. The initial transaction amount in 2021 totaled €3,133.

We did not complete the equity purchase in Genoscience Pharma for trading purposes. Therefore, pursuant to IFRS 9, we elected to classify the equity in Genoscience Pharma we acquired in December 2021 as equity instruments recognized at fair value through other comprehensive income (OCI). At the time of initial recognition in 2021, this investment in equity instruments has been measured at fair value, inclusive of acquisition costs related to the purchase. The amount recognized on the balance sheet at December 31, 2021 corresponds to the subscription price agreed upon between the parties as representative of the value of Genoscience Pharma a few days before closing of the period. For future closings, changes in fair value on these equity instruments are recognized as OCI. This OCI may not be reused as profit or loss, including in the case of a sale. If applicable, only dividends related to the investment in equity instruments will be recognized as profit provided that all conditions are met.

For 2022, and in accordance with IFRS 13, we updated our estimated of the fair value of our equity stake in Genoscience Pharma, which was based on a valuation methodology including a royalty based income approach using discounted cash flow techniques for the company's main scientific research programs. The aforementioned income method utilizes management’s estimates of future operating results, cash flows discounted using a weighted-average cost of capital that reflects market participant assumptions, and the expected success rate of each program. Based on our analysis performed as of December 31, 2022, the initial valuation of €3,133 is still appropriate and no loss or gain has been recognized in OCI.

Other investments

As of December 31, 2022, the value of "Other investments" totaled €483. The balance relates solely relates to our investment in CAPTECH SANTE.

On May 24, 2022, GENFIT undertook to subscribe for 50 units of the CAPTECH SANTE Professional Equity Fund (Fonds Professionnel de Capital Investissement – FPCI) in the amount of €500. On June 25, 2022, the management company made an initial call for funds from GENFIT in an amount equal to 35% of the subscription amount, i.e. €175, which GENFIT paid. The remaining subscription amount of €325 must be paid upon successive calls from the fund management company.

GENFIT’s investment in CAPTECH SANTE constitutes a debt instrument that does not meet the SPPI (solely payments of principal and interest) criterion test. It is therefore classified as a financial asset recognized at fair value through profit or loss. This investment is also consistent with a regular way purchase of a financial asset. GENFIT has opted to use the trade date as date of initial recognition. An amount of €500 was therefore recognized in the Group’s balance sheet on May 24, 2022.

As of December 31, 2022, a loss of €17 was recognized based on the net asset value of the units as of said date.

Financial investments

As of December 31, 2022, the value of "Financial investments" totaled €4,550. This relates solely to a short term investment whose term is 180 days.

Liquidity contract

The liquidity contract consists of a share buyback program contracted to investment service provider CM-CIC Market Solutions in order to facilitate the listing of the Group's shares.

As of December 31, 2022, the liquidity account had a cash balance of €534, and as of December 31, 2021 a cash balance of €513.

CM-CIC Market Solutions holds the following number of GENFIT shares on behalf of the Company, recorded as a deduction in equity:

Financial assets - Current	**As of**	
	2021/12/31	**2022/12/31**
Number of shares (recorded as a deduction from equity)	**137,012**	**138,691**

19. OTHER ASSETS

Other assets of €1,998 at December 31, 2022 and €2,101 at December 31, 2021, and respectively consisted of prepaid expenses related to current operating expenses.

20. LOANS AND BORROWINGS

Accounting policies

Financial liabilities are initially recognized at fair value, net of directly attributable transaction costs, and are subsequently measured at amortized cost using the effective interest rate method.

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

The bonds convertible or exchangeable into new or existing shares (OCEANEs—see Note 20.1 "Breakdown of convertible loan") are recognized as follows: in accordance with IAS 32, Financial Instruments—Presentation, if a financial instrument has different components and the characteristics indicate that some should be classified as liabilities and others as equity, the issuer must recognize the different components separately.

The liability component is measured, at the date of issuance, at its fair value on the basis of future contractual cash flows discounted at market rates (taking into consideration the issuer's credit risk) of a debt having similar characteristics but without the conversion option.

The value of the conversion option is measured by the difference between the bond's issue price and the fair value of the liability component. After deduction of the pro rata portion of expenses related to the transaction, this amount is recognized in the line item "Share premium" under shareholders' equity and is subject to a calculation of deferred tax according to IAS 12.28.

The liability component (after deduction of the pro rata portion of the transaction expenses attributed to the liability and the conversion option) is measured at amortized cost. A non-monetary interest expense, recorded in net loss is calculated using an effective interest rate to progressively bring the debt component up to the amount which will be repaid (or converted) at maturity. A deferred tax liability is calculated on the basis of this amount. The shareholders' equity component is not remeasured.

20.1. Breakdown of convertible loan

Introduction

On October 16, 2017, the Company issued 6,081,081 OCEANEs at par with a nominal unit value of €29.60 per bond for an aggregate nominal amount of €180 million. The original terms and conditions are summarized below:

At origin (10/16/2017) :	
Number of bonds	6,081,081
Nominal amount of the loan	179,999,997.60€
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	10/16/2017 At par
Redemption	10/16/2022 Redemption prior to maturity at the option of the Company from 11/6/2020 if the arithmetic volume-weighted average 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.

2021 activity, buyback and amendment of terms

On November 23, 2020, GENFIT proposed to all OCEANEs bondholders a renegotiation offer involving two interdependent components:

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

The completion of these commitments for partial repurchase, made in late 2020, remained entirely subject to approval of the new terms of the OCEANEs, by both the Shareholders' and Bondholders' Meetings, which on January 25, 2021, approved this renegotiation offer. Following the shareholders' and bondholders' decisions, GENFIT completed the partial buyback of 2,895,260 OCEANEs at a price of €16.40 (including accrued interest of €0.30) for a total buyback cost of €47.48 million. The settlement operations occurred on January 29, 2021. The repurchased OCEANEs were then cancelled by GENFIT.

For the non-cancelled, renegotiated OCEANEs ("OCEANEs 2022") (i.e. 3,185,821 remaining OCEANEs), the maturity is extended to October 16, 2025 and the conversion ratio changed from 1 OCEANE for 1 share to 1 OCEANE for 5.5 shares. The nominal amount and the payout value of the remaining OCEANEs remains unchanged at €29.60 per bond.

This renegotiation operation of the OCEANEs has been recognized in the consolidated accounts for the half-year ended June 30, 2021, as:

- the derecognition of the full initial OCEANEs as of January 25, 2021 against a payment of €47.48 million, and
- the issuance of 3,185,821 new amended OCEANEs.

As the conversion option for the new OCEANEs (2025 maturity) fits the definition of an equity instrument under IAS 32 (Financial Instruments: Presentation), the components of this new OCEANEs (debt vs. equity) has been recognized separately on January 25, 2021, in accordance with the accounting rules and methods presented in this note.

The obligation and option components have been valued separately. The option component has been valued using a traditional binomial model.

The hypotheses considered to calculate the fair value of these new OCEANEs are the following:

- credit spread in the 874/976 bps interval;
- volatility: first level: 30% second level: 35%; and

- no-risk rate: 5-year Euros swap equals -0.45%.

On this basis, at January 25, 2021, the fair value of a new amended OCEANEs has been estimated at €27.80, of which a debt component of €24.12 and a €3.68 component that has been recognized in equity.

2021 accounting impacts of the debt renegotiation

On January 25, 2021 an amount of €94.8 million was derecognized and an amount of €76.8 million was recognized for the amended obligations, in exchange of:

- An increase in equity of €11.7 million before deferred taxes (corresponding to the recognition of the value of the conversion option of the amended OCEANEs);
- The payment of €47.5 million for the OCEANEs partial buyback; and
- The recognition of a financial gain (buyback bonus) of €35.6 million before tax.

2021 accounting impacts of the conversions completed following the debt renegotiation

Following the implementation of the partial buyback operation and the approval of the amendment of the terms of the OCEANEs:

- 552,238 of the new OCEANEs were subject to a request for share conversion in January 2021. On February 4, 2021, as a result of these conversion requests, a capital increase of €759,327.25 has been recognized, corresponding to the creation of 3,037,309 new shares. This conversion of 552,238 new OCEANEs resulted in a reduction in financial debt for the Group of €13.32 million.
- 483,330 of the new OCEANEs were subject to a request for share conversion in February 2021. On March 2, 2021, as a result of these conversion requests, a capital increase of €664,578.75 has been recognized, corresponding to the creation of 2,658,312 new shares. This conversion of 483,330 new OCEANEs resulted in a reduction in financial debt for the Group of €11.66 million.
- 216,591 of the new OCEANEs were subject to a request for share conversion in March 2021. On April 6, 2021, as a result of these conversion requests, a capital increase of €297,812.50 has been recognized, corresponding to the creation of 1,191,250 new shares. This conversion of 216,591 new OCEANEs resulted in a reduction in financial debt for the Group of €5.2 million.
- 10,000 of the new OCEANEs were subject to a request for share conversion in August 2021. On September 1, 2021, as a result of these conversion requests, a capital increase of €13,750 has been recognized, corresponding to the creation of 55,000 new shares. This conversion of 10,000 new OCEANEs resulted in a reduction in financial debt for the Group of €0.2 million.

The potential issuance of new shares upon conversion requests of the outstanding OCEANEs would represent 21.24% of the share capital of the Company at December 31, 2021 (representing a 17.52% dilution if all OCEANEs were converted).

All fees and commission paid in relation to this operation have been directly recognized as operating expenses. The fees disbursed have been recognized in the financial statements for a total of €745 in 2020 and €2,303 in 2021.

Updated balances after renegotiation

Following the renegotiation, and as of December 31, 2021 and 2022, number of bonds, nominal amount, nominal unit value and effective interest rate are as follows:

After OCEANEs buyback :	
Number of bonds	3,185,821
Nominal amount of the loan	94,300,301.60€
Nominal unit value of the bonds	29.60€
Effective interest rate	8.8%
As of 31/12/2021 :	
Number of bonds	1,923,662
Nominal amount of the loan	56,940,395.20€
Nominal unit value of the bonds	29.60€
Effective interest rate	8.8%
As of 31/12/2022 :	
Number of bonds	1,923,662
Nominal amount of the loan	56,940,395.20€
Nominal unit value of the bonds	29.60€
Effective interest rate	8.8%

Final reimbursement is scheduled for October 16, 2025.

The potential issuance of new shares upon conversion requests of the outstanding OCEANEs would represent 21.29% of the share capital of the Company at December 31, 2022 (representing a 17.5% dilution if all OCEANEs were converted).

Conversion terms

There are no specific terms that need to be met for a holder of OCEANEs to convert their debt into GENFIT shares.

Deferred taxes

Deferred tax assets and deferred tax liabilities recognized on the balance sheet as of December 31, 2021 and 2022 related to the OCEANEs are disclosed in Note 11.2 "Deferred tax assets and liabilities".

Current and non current balances

Convertible loans - Total	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Convertible loans	48,097	50,276
TOTAL	**48,097**	**50,276**

Convertible loans - Current	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Convertible loans	415	415
TOTAL	**415**	**415**

Convertible loans - Non current	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Convertible loans	47,682	49,861
TOTAL	**47,682**	**49,861**

20.2. Breakdown of other loans and borrowings

Other loans and borrowings consisted of the following:

Other loans and borrowings - Total	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Refundable and conditional advances	3,229	3,229
Bank loans	15,824	15,196
Obligations under leases	7,069	6,559
Accrued interests	16	14
Other financial loans and borrowings	—	—
TOTAL	**26,138**	**24,999**

Other loans and borrowings - Current	As of	
(in € thousands)	2021/12/31	2022/12/31
Refundable and conditional advances	—	—
Bank loans	667	3,619
Obligations under leases	1,089	1,032
Accrued interests	16	14
Other financial loans and borrowings	—	—
TOTAL	**1,773**	**4,665**

Other loans and borrowings - Non current	As of	
(in € thousands)	2021/12/31	2022/12/31
Refundable and conditional advances	3,229	3,229
Bank loans	15,156	11,578
Obligations under leases	5,980	5,527
Accrued interests	—	—
Other financial loans and borrowings	—	—
TOTAL	**24,365**	**20,334**

20.2.1. Refundable and conditional advances

The following table summarizes advances outstanding at December 31, 2022 and 2021.

Refundable and conditional advances—general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2022/12/31
BPI FRANCE - IT-DIAB	12/23/2008	3,229	3,229	—	—	3,229
Development of a global strategy for the prevention and management of type 2 diabetes						
TOTAL		**3,229**	**3,229**	**—**	**—**	**3,229**

Refundable and conditional advances—general overview (in € thousands)	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2021/12/31
BPI FRANCE - IT-DIAB	12/23/2008	3,229	3,229	—	—	3,229
Development of a global strategy for the prevention and management of type 2 diabetes						
TOTAL		**3,229**	**3,229**	**—**	**—**	**3,229**

BPI FRANCE IT-DIAB

On December 23, 2008, the Group received an advance from Bpifrance (the BPI France IT-DIAB) as part of a framework innovation aid agreement involving several scientific partners and for which the Group was the lead partner. The contribution expected at each stage by each of the partners in respect of work carried out and results achieved is defined in the framework agreement. With respect to the Group, the aid consisted of a €3,229 conditional advance and a €3,947 non-repayable government grant.

The conditional advance is not refundable except in the event of success. The program ended on December 31, 2014. In the event of success, defined as the commercial spin-offs of the IT-Diab program which involves products for the treatment or diagnosis of type 2 diabetes, in that case, the financial returns generated will be used initially to repay the €3,229 conditional advance and the agreement stipulates that the conditional advance will be regarded as repaid in full when the total payments made in this regards by the recipient, discounted at the rate of 5.19%, equal the total amount, discounted at the same rate, of the aid paid. Any further amounts will be classified as additional payments, up to a maximum amount of €14,800.

As provided in the project assistance contract, we sent a letter to Bpifrance in December 2019 in order to notify it of our Labcorp and Terns Pharmaceuticals contracts while indicating that elafibranor was now aimed at treating hepatic diseases and no longer type 2 diabetes as provided for in the aid agreement. We proposed to Bpifrance 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 our arguments, and in June 2020 following the publication of the results of the RESOLVE-IT study, and a new letter was sent in November 2020. In this context, we are awaiting a proposal from Bpifrance on new financial terms related to this situation and a draft amendment to the repayable advance agreement. Until we receive a response from Bpifrance, we consider that the fair value of this liability corresponds to the amount paid by Bpifrance.

20.2.2. Bank loans

Introduction

In the context of the COVID-19 pandemic, the Company secured:

- A State-Guaranteed Loan (or *"Prêt Garanti par l'Etat (PGE) Bancaire"*) for an amount of €11,000 (€10,919 net of fees), granted on June 24, 2021 by a syndicate of four French banks and paid out on June 29, 2021, 90% guaranteed by the French government with an initial term of one year with repayment options up to six years;
    - In the loan table below, this includes instruments "CDN PGE," "CIC PGE," "BNP PGE," and "NATIXIS PGE."
- A State-Guaranteed Loan (or *"Prêt Garanti par l'Etat (PGE) Bpifrance"*) for an amount of €2,000 (€1,985 net of fees) granted on July 20, 2021 by BPI France and paid out on July 23, 2021, 90% guaranteed by the French government with an initial term of one year with repayment options up to six years;
    - In the loan table below this is represented by line "BPI PGE."
- A Subsidized Loan (or "*BPI Prêt Taux Bonifié*") for an amount of €2,250 (€2,250 net of fees) granted on November 23, 2021 by BPI France and paid out on November 26, 2021, with an initial term of six years.
    - In the loan table below this is represented by line "BPI PRÊT TAUX BONIFIE."

Accounting Treatment

The company has determined after analysis under IFRS that the subsidized loan should be treated in the same manner as the PGEs and that the review pursuant to IAS20 should not apply, in light of the facts, notably, that this subsidized loan:

- Constitutes Government Assistance under the "Umbrella" Scheme Notified by the French Government to the European Commission under the following references: State Aid SA.56985 (2020/N) - France - COVID-19: Temporary Framework to support companies;
- Has therefore not been granted to the Company in connection with research expenses on a particular project or investment;
- Supports the Company's cash position, similarly to the aforementioned PGEs, negotiated with and granted by Bpifrance in addition to these PGEs.

Conditions and interest rates

In 2022, as we were already planning to do in late 2021, GENFIT requested an extension of both the Bank PGE and the BPI France PGE. Both extensions were granted by the respective counterparties. Regarding the Bank PGE, the loan’s post-extension terms did not result in a revision of the maturity date of 29 June 2025 used at the time of the closing on 31 December 2021 (8 linear quarterly payments between September 29, 2023 and June 29, 2025), nor the amount of the “guarantee premiums” (which increases progressively from 0.25% in the first year to 1% in the third year and beyond). Only the interest rate for the second to fourth years was determined at the time of the extension and is therefore changed in relation to the assumptions used as of 31 December 2021. This annual interest rate is as follows (fixed):

- BNP PGE (loan of €4,900): 0.45%
- Natixis PGE (loan of €3,000): 0.40%
- CIC PGE (loan of €2,200): 0.75%
- CDN PGE (loan of €900): 1.36%

Regarding the BPI France PGE, the extension resulted in a one-year extension of the loan's maturity compared with the assumption made as of 31 December 2021, i.e. 23 July 2027 (20 linear quarterly payments between October 23, 2022 and July 23, 2027) instead of 23 July 2026, as well as a change in the rate of the "guarantee premium" and a change in the interest rate of the loan. The revised terms from 1 August 2022 are as follows: the interest rate is 2.25% (including 1.00% under the French State guarantee).

Regarding the Subsidized Loan, the terms have remained unchanged since the time of closing in November 2021, providing for a 4-quarter deferment of capital amortization, followed by 20 equal quarterly payments (amortization and interest) between February 28, 2023 and November 30, 2027, at a fixed interest rate of 2.25% per annum

In accordance with the ANC recommendation (Recommendations and observations relating to the recognition of the consequences of COVID-19 in the accounts and positions prepared as from 1 January 2020), the accounting treatment relating to the extension of the two PGEs applied in the Group's consolidated financial statements as of 30 June 2022 is as follows:

- Bank PGE: in the absence of a revision of the probable maturity, the revision of the interest rate of the non-guaranteed loan was accounted for prospectively as soon as the revised interest rate was known after agreement with the bank. The EIR after taking the extension into account is now as follows:
  - BNP PGE (loan of €4,900): 1.16% per annum
  - Natixis PGE (loan of €3,000): 1.11% per annum
  - CIC PGE (loan of €2,200): 1.46% per annum
  - CDN PGE (loan of €900): 2.08% per annum

For reference, the EIR was 0.75% per annum at December 31, 2021 for all Bank PGE.

• BPI France PGE: in view of the revision of the maturity of the PGE and the revision of the cost of the guarantee, the revision of the flows to be paid results, for the portion corresponding to the revision of the cost of the guarantee, in an increase in the debt in the amount of €44 against earnings, discounting new cash flows at the effective interest rate used for the closing as of 31 December 2021. Only the change in the revised interest rate has been accounted for prospectively. The EIR after taking the extension into account is now 1.65% per annum (1.95% at December 31, 2021).

Balances by loan

Bank loans consisted of the following as of December 31, 2022:

Bank loans *(in € thousands)*	**Loan date**	**Facility size**	**Interest rate**	**Available As of 2022/12/31**	**Installments**	**Outstanding As of 2021/12/31**	**Outstanding As of 2022/12/31**
CDN 3	April 2016	500	0.72 %	—	60 monthly	—	—
CDN 4	June 2017	600	0.36 %	—	48 monthly	—	—
CDN 5	November 2018	500	0.46 %	—	48 monthly	115	—
CIC 4	December 2016	265	0.69 %	—	60 monthly	4	—
CIC 5	July 2017	1,000	0.69 %	—	60 monthly	152	—
BNP 2	June 2016	500	0.80 %	—	20 quarterly	—	—
BNP 3	October 2016	1,050	0.80 %	—	20 quarterly	105	—
BNP 4	April 2017	800	0.87 %	—	60 monthly	217	54
AUTRES	-	—	— %	—	0	20	17
CDN PGE	June 2021	900	1.36 %	—	8 quarterly	900	900
CIC PGE	June 2021	2,200	0.75 %	—	8 quarterly	2,200	2,200
BNP PGE	June 2021	4,900	0.45 %	—	8 quarterly	4,900	4,900
NATIXIS PGE	June 2021	3,000	0.40 %	—	8 quarterly	3,000	3,000
BPI PGE	July 2021	2,000	2.25 %	—	16 quarterly	2,000	1,900
BPI PRÊT TAUX BONIFIE	November 2021	2,250	2.25 %	—	20 quarterly	2,250	2,250
TOTAL		20,465		**—**		**15,864**	**15,221**

20.2.3. Maturities of financial liabilities

Maturity of financial liabilities *(in € thousands)*	As of 2022-12-31	Less than 1 year	Less than 2 years	Less than 3 years	Less than 4 years	Less than 5 years	More than 5 years
BPI FRANCE - IT-DIAB	3,229	—	—	—	—	—	3,229
TOTAL - Refundable and conditional advances	**3,229**	**—**	**—**	**—**	**—**	**—**	**3,229**
Convertible loans	50,276	415	—	49,861	—	—	—
Bank loans	15,196	3,619	6,339	3,601	867	771	—
Leases	6,559	1,032	1,011	1,022	1,034	1,046	1,414
Accrued interests	14	14	—	—	—	—	—
TOTAL - Other loans and borrowings	**72,046**	**5,080**	**7,350**	**54,485**	**1,901**	**1,817**	**1,414**
TOTAL	**75,275**	**5,080**	**7,350**	**54,485**	**1,901**	**1,817**	**4,643**

Based on the nominal amount of €50,276 at December 31, 2022, the convertible bond results in the payment of yearly interest of €1,993 (payable in two biannual installments). Its repayment is due on October 16, 2025.

21. FAIR VALUE OF FINANCIAL INSTRUMENTS

Accounting policies

IFRS 9 “Financial Instruments” takes into account the following three aspects of booking financial instruments :

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

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

Pursuant to IFRS 7 – Financial Instruments: Disclosures, the financial instruments are presented into three categories according to a hierarchical method used to establish their fair value.

If financial instruments are measured at fair value, they are measured according to a hierarchy comprising three levels of valuation inputs:

- Level 1: Fair value measured on the basis of quoted prices in active markets for identical assets or liabilities;
- Level 2: Fair value measured on the basis of valuation methods relying on quoted prices for similar assets, liabilities or observable inputs in active markets;
- Level 3: Fair value measured on the basis of valuation methods relying entirely or in part on unobservable inputs such as quoted prices in inactive markets or the valuation based on multiples for non-listed securities.

Financial detail

The following tables provide the financial assets and liabilities carrying values by category and fair values as of December 31, 2022 and December 31, 2021:

	As of 31/12/2021							
	Carrying value					Fair value		
(in € thousands)	As per statement of financial position	Assets at fair value through profit & loss	Assets at fair value through OCI	Assets at amortized cost	Debt at amortized cost	Level 1	Level 2	Level 3
Assets								
Equity investments	3,133		3,133					3,133
Financial investments	—							
Loans	388			388			388	
Deposits and guarantees	397			397			397	
Trade receivables	57			57			57	
Cash and cash equivalents	258,756	258,756				258,756		
TOTAL - Assets	**262,731**	**258,756**	**3,133**	**842**	**—**	**258,756**	**842**	**3,133**
Liabilities								
Conditional advances	3,229				3,229			3,229
Convertible loans	48,097				48,097		48,097	
Bank loans	15,824				15,824		15,824	
Obligations under finance leases	7,069				7,069		7,069	
Accrued interests	16				16		16	
Trade payables	12,304				12,304		12,304	
Other payables	579				579		579	
TOTAL - Liabilities	**87,118**	**—**	**—**	**—**	**87,118**	**—**	**83,889**	**3,229**

	As of 31/12/2022							
	Carrying value					Fair value		
(in € thousands)	As per statement of financial position	Assets at fair value through profit & loss	Assets at fair value through OCI	Assets at amortized cost	Debt at amortized cost	Level 1	Level 2	Level 3
Assets								
Equity investments	3,133		3,133					3,133
Other investments	483	483						483
Financial investments	4,550	4,550				4,550		
Loans	428			428			428	
Deposits and guarantees	335			335			335	
Trade receivables	3,188			3,188			3,188	
Cash and cash equivalents	136,001	136,001				136,001		
TOTAL - Assets	**148,119**	**141,034**	**3,133**	**3,951**	**—**	**140,551**	**3,951**	**3,617**
Liabilities								
Conditional advances	3,229				3,229			3,229
Convertible loans	50,276				50,276		52,708	
Bank loans	15,196				15,196		15,196	
Obligations under finance leases	6,559				6,559		6,559	
Accrued interests	14				14		14	
Trade payables	8,613				8,613		8,613	
Other payables	1,325				1,325		1,325	
TOTAL - Liabilities	**85,214**	**—**	**—**	**—**	**85,214**	**—**	**84,416**	**3,229**

22. TRADE AND OTHER PAYABLES

Accounting policies

Trade and other payables are initially recognized at the fair value of the amount due. This value is usually the nominal value, due to the relatively short period of time between the recognition of the instrument and its repayment.

Financial detail

Trade and other payables consisted of the following:

Trade and other payables - Total	As of	
(in € thousands)	**2021/12/31**	**2022/12/31**
Trade payables (*)	12,304	8,613
Social security costs payables	4,087	4,838
VAT payables	23,725	200
Taxes payables	744	316
Other payables	579	1,325
TOTAL	**41,438**	**15,293**

Trade and other payables - Current	As of	
(in € thousands)	**2021/12/31**	**2022/12/31**
Trade payables	12,304	8,613
Social security costs payables	4,087	4,838
VAT payables	23,725	200
Taxes payables	744	316
Other payables	128	877
TOTAL	**40,988**	**14,845**

Trade and other payables - Non current	As of	
(in € thousands)	**2021/12/31**	**2022/12/31**
Trade payables	—	—
Social security costs payables	—	—
VAT payables	—	—
Taxes payables	—	—
Other payables	450	448
TOTAL	**450**	**448**
(*) Of which : Accrued expenses	*6,201*	*3,924*

At December 31, 2022, trade payables amounted to €8,613 (€12,304 at December 31, 2021). This change is due to a reduction in accrued expenses relating to yet unbilled amounts from the clinical trial sites via the Clinical Research Organizations (CROs) in charge of the Company's clinical trials. (€3,924 and €6,201 at December 31, 2022 and 2021 respectively). The timeframe in which those invoices will be received by the Company is unknown and may be spread out over a long period after the services have been performed.

The VAT debt amounted to €200 at December 31, 2022 (€23,725 at December 31, 2021). This decrease is related to the VAT amount collected on the upfront payment received from Ipsen in December 2021, paid in January 2022.

23. DEFERRED INCOME AND REVENUE

Out of the €120 million upfront payment received from Ipsen in application of the licensing agreement signed in December 2021, an amount of €40 million was recognized as Deferred income in 2021. The Deferred income is recognized as revenue as GENFIT carries out its part of the double-blind ELATIVE study, based on the progress made relative to the originally developed budget. As of December 31, 2022, the Company considers that this initial budget is still appropriate based on progress performed.

In 2022, €15.9 million of said balance was recognized as revenue. As of December 31, 2022, €24.1 million of Deferred income remains, of which €14.4 million relates to Current deferred income and of which €9.7 million relates to Non-current deferred income, which was determined based on the original budget.

See "Note 7 "Revenues and Other income."

24. Provisions

Accounting policies

In accordance with IAS 37, Provisions Contingent Liabilities and Contingent Assets, provisions are recognized when the Group has a present obligation (legal, regulatory, contractual or constructive) as a result of a past event, for which it is probable that an outflow of resources will be required to settle the obligation, and of which the amount can be estimated reliably.

The amount recognized as a provision is the best estimate at the reporting date of the expenditure required to settle the present obligation.

Provisions are discounted when the time value effect is material.

A provision for reorganization is recognized when the Group has approved a formal and detailed plan for its reorganization and has either started to implement it or publicly disclosed it. A provision for onerous contract is estimated at the actual value of the lowest expected cost of either the cancellation or the execution of the contract, the latter being established on the basis of the additional costs required to fulfill the obligations stipulated by the contract. Before a provision is established, the Group recognizes any impairment loss that occurred on the assets dedicated to this contract.

Future milestone and revenue based royalty payments may be recorded pursuant to Contingent liability under IAS 37 or intangible asset under IAS 38. Under IAS 38, we record a provision when we have a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. Under IAS 38, we record intangible asset when it is probable that the expected future economic benefits that are attributes to the assets will flow to us and the cost of asset can be measured reliably.

Financial detail

RESOLVE-IT

See Note 2.3 “Termination of RESOLVE-IT and the development program of elafibranor in NASH”.

Genoscience Pharma

On December 16, 2021, GENFIT completed the acquisition of exclusive rights from Genoscience Pharma to develop and commercialize the investigational treatment GNS561 in cholangiocarcinoma (CCA) in the United States, Canada and Europe, including the United Kingdom and Switzerland. GNS561 is a novel clinical-stage autophagy/PPT1 inhibitor developed by Genoscience Pharma and cholangiocarcinoma is an orphan disease.

Under the agreement, Genoscience Pharma is eligible for clinical and regulatory milestone payments for up to €50 million and tiered royalties. The first payable milestones are contingent on positive Phase 2 clinical trial results in CCA, and may total up to €20 million, if applicable.

The following payable milestones are contingent on positive Phase 3 results. These payments, when due, will be subject to a review to determine if they are eligible for activation pursuant to IAS 38. If so, they will be recorded as capital upon disbursement. Otherwise, they also constitute contingent liabilities which will be recognized when due.

In addition, we also have a right of first negotiation with respect to any license or assignment, or option for a license or an assignment, with any third party to develop or commercialize other Genoscience assets in the field of CCA, to the extent Genoscience is looking to partner the asset with a third party or receives a spontaneous offer for collaboration.

For the period commencing on the date of the agreement until the first regulatory approval of GNS561 for commercialization, Genoscience Pharma has the right to repurchase the license to GNS561 in CCA at a pre-determined price in the event that Genoscience Pharma receives an offer from a third party to acquire or obtain a license to GNS561 in all indications, provided that GENFIT shall first have the opportunity to negotiate the acquisition or license to GNS561 in all indications or match the offer from the third party.

Pursuant to IAS 37, our obligations under the terms of the agreement we entered into with Genoscience Pharma constitute contingent liabilities not recognized in the Company's consolidated financial statements at December 31, 2021 or December 31, 2022.

Versantis

See Note 2.1 "Acquisition of the Clinical-stage Biopharmaceutical Company Versantis"

At December 31, 2022 and at December 31, 2021, this line item amounted to €61 and €313, respectively.

Change in provisions	As of	Increase	Decrease	Decrease	As of
(in € thousands)	2021/12/31		(used)	(unused)	2022/12/31
Provision for litigation	87	0	(14)	(73)	0
Provision for charges	225	4	(92)	(77)	61
TOTAL	**313**	**4**	**(106)**	**(150)**	**61**

This change mainly reflects provision reversals recorded in 2022 related to:

- The estimated support costs related to the reduction in force plan (PSE) implemented starting in late 2020 (return-to-work bonuses, trainings, business start-up assistance and various other benefits): reversal of €169 (of which €92 was used), with the corresponding provision amounting to €61 at December 31, 2022.

25. EMPLOYEE BENEFITS

Accounting policies

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

25.1. Defined benefit plans

Defined benefit plans relate to French retirement benefit plans under which the Group is committed to guaranteeing a specific amount or level of contractually defined benefits. The obligation arising from these plans is measured on an actuarial basis using the projected unit credit method. The method consists of measuring the obligation based on a projected end-of-career salary and vested rights at the measurement date, according to the provisions of the collective bargaining agreement, corporate agreements and applicable law.

Actuarial assumptions are used to determine the benefit obligations. The amount of future payments is determined on the basis of demographic and financial assumptions such as mortality, staff turnover, pay increases and age at retirement, and then discounted to their present value. The discount rate used is the yield at the reporting date on AA credit-rated bonds with maturity dates that approximate the expected payments for the Group's obligations.

Re-measurements of the net defined benefit liability which comprise actuarial gains and losses are recognized in the statements of other comprehensive loss.

The Group determines the net interest expense on the net defined benefit liability for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period to the then-net defined benefit liability, taking into account any changes in the net defined benefit liability during the period as a result of contributions and benefit payments.

25.2. Defined contribution plans

Under defined contribution plans, the management of plans is performed by an external organization, to which the Group pays regular contributions. Payments made by the Group in respect of these plans are recognized as an expense for the period in the statements of operations.

25.3. Short-term employee benefits

A liability is recognized for the amount expected to be paid under short-term cash bonus or profit-sharing plans if the Group has a present legal or constructive obligation to pay the amount as a result of past service provided by the employee, and the obligation can be estimated reliably.

Detailed breakdown

In France, pension funds are generally financed by employer and employee contributions and are accounted for as a defined contribution plan with the employer contributions recognized as expense as incurred. The Group has no actuarial liabilities in connection with these plans. Related expenses recorded for the years ended December 31, 2022, December 31, 2021, and December 31, 2020 amounted to €876, €774, and €923, respectively.

French law also requires payment of a lump sum retirement indemnity to employees based on years of service and annual compensation at retirement, which are accounted for as a defined benefit plan. Benefits do not vest prior to retirement. The liability is calculated as the present value of estimated future benefits to be paid, applying the projected unit credit method whereby each period of service is seen as giving rise to an additional unit of benefit entitlement, each unit being measured separately to build up the final liability. At December 31, 2022 and December 31, 2021 pension provisions recorded were €782 and €864, respectively.

As part of the measurement of the retirement indemnity to employees, the following assumptions were used for all categories of employees in 2021 and 2022:

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

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

Rate	**As of**	
(in € thousands)	**2021/12/31**	**2022/12/31**
Salary growth rate - in 2022	3.00 %	3.00 %
Salary growth rate - beyond	3.00 %	3.00 %
Discount rate (iboxx)	0.87 %	3.25 %

The discount rates are based on the market yield at December 31, 2021 and 2022 on high-quality corporate bonds.

The following table presents the changes in the present value of the defined benefit obligation:

Changes in the present value of the defined benefit obligation *(in € thousands)*	
Defined benefit obligation as of January 01, 2021	**922**
Current service cost	154
Interest cost on benefit obligation	5
Actuarial losses / (gains) on obligation	—
Past service costs	(216)
Service paid to employees	—
Defined benefit obligation as of December 31, 2021	**864**
Current service cost	169
Interest cost on benefit obligation	8
Actuarial losses / (gains) on obligation	—
Past service costs	(258)
Service paid to employees	—
Defined benefit obligation as of December 31, 2022	**782**

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

	Retirement and post-employment benefits	
Sensitivity of the Group's retirement and post-employment benefits to a variation of the discount rate *(in € thousands)*	**Changes in assumptions / discount rate**	**Impact / present value of the undertaking**
+	0.25 %	(23)
-	0.25 %	24

The following assumed benefit payments under the Company's French retirement indemnity are expected to be paid as follows:

2023	0
2024	0
2025	37
2026	21
2027	78
Years 2028 and thereafter	646

26. EQUITY

Accounting policies

Share capital comprises ordinary shares and ordinary shares with double voting rights classified in equity. Costs directly attributable to the issue of ordinary shares or share options are recognized as a reduction in the share premium.

The liquidity agreement consists of a share buyback program contracted to an investment service provider. Purchases and sales of the Company's shares carried out under the contract are recognized directly in shareholders' equity under treasury shares. See Note 18 "Other financial assets"

Detailed breakdown

Share capital

Number of shares	As of	
	2021/12/31	2022/12/31
Ordinary shares issued (€0.25 par value per share)	49,815,489	49,834,983
Convertible preferred shares registered	0	0
Total shares issued	**49,815,489**	**49,834,983**
Less treasury shares	0	0
Outstanding shares	**49,815,489**	**49,834,983**

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).

Changes in share capital in 2022

The Chief Executive Officer, acting on the decision and delegation of the Board of Directors on July 18, 2019, noted on September 16, 2022 that some of the performance and attendance conditions linked to the AGA D 2019 and AGA S 2019 free shares were met at the end of the year. 19,494 free shares were thus definitively acquired and as many new shares were created. The share capital was increased accordingly.

At December 31, 2022, the remaining unused authorizations to issue additional share-based compensation or other share-based instruments (stock options, free shares and share warrants) represent a total of 306,435 shares.

Changes in share capital in 2021

On February 4, 2021, as a result of share conversion requests in January 2021, a capital increase of €759,327.25 has been recognized, corresponding to the creation of 3,037,309 new shares.

On March 2, 2021, as a result of share conversion requests in February 2021, a capital increase of €664,578.75 has been recognized, corresponding to the creation of 2,658,312 new shares.

On April 6, 2021, as a result of share conversion requests in March 2021, a capital increase of €297,812.50 has been recognized, corresponding to the creation of 1,191,250 new shares.

On September 1, 2021, as a result of share conversion requests in August 2021, a capital increase of €13,750 has been recognized, corresponding to the creation of 55,000 new shares.

The Chief Executive Officer, acting on a decision and delegation from the Board of Directors on December 16, 2021, recognized on December 22, 2021 the execution of a capital increase for the benefit of Ipsen Pharma SAS. 3,985,239 new shares were created (and €28 million was collected from Ipsen Pharma SAS) on this occasion. The share capital was increased accordingly.

At December 31, 2021, the total number of shares comprising the share capital, taking into account the above, was 49,815,489 shares.

At December 31, 2021, the remaining unused authorizations to issue additional share-based compensation or other share-based instruments (stock options, free shares and share warrants) represent a total of 323,125 shares.

27. LITIGATION AND CONTINGENT LIABILITIES

Class Action

In May 2020, following the Group announcement on the interim results of our RESOLVE-IT Phase 3 clinical trial in which elafibranor had not achieved the primary or key secondary endpoints, a purported shareholder class action complaint was filed in state court in the Commonwealth of Massachusetts, naming the Group, the board of directors and certain members of the senior management as defendants, alleging that defendants made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws.

In October 2020, the plaintiff voluntarily dismissed the Commonwealth of Massachusetts action, but in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering.

In March 2021, the Company and the other defendants filed a motion to dismiss. In August 2021, the Supreme Court of the State of New York, New York County, granted the motion and dismissed the complaint with prejudice. The plaintiff appealed and in December 2022, the Supreme Court, Appellate Division, First Department affirmed the dismissal of the complaint, except that it deleted the phrase “with prejudice” from the Supreme Court’s judgment. The time to appeal the decision of the Appellate Division has expired.

28. RELATED PARTIES

Compensation of key management personnel

The aggregate compensation of the members of the Company’s Board of Directors (including the Chairman of the Board) and to the Chief Executive Officer includes the following:

	Year ended		
(in € thousands)	**2020/12/31**	**2021/12/31**	**2022/12/31**
Fixed compensation owed	518	518	585
Variable compensation owed	71	163	169
Attendance fees - board of Directors	456	488	421
Contributions in-kind	26	23	21
Share-based payments	41	58	74
Employer contributions	405	443	410
Consulting fees	0	0	0
TOTAL	**1,517**	**1,693**	**1,680**

Biotech Avenir

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

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

At December 31, 2022, Biotech Avenir SAS held 3.79% of the share capital of the Company.

The Company did not carry out any transactions with Biotech Avenir in 2022, 2021, or 2020, with the exception of the domiciliation without charge.

Ipsen Pharma SAS

The licensing agreement signed with Ipsen Pharma SAS in December 2021 provides for a certain number of service agreements that were signed with the Company in 2022, notably the Inventory Purchase Agreement and the Transition Services Agreement.

These agreements cover support for Ipsen in future proceedings and processes (other than knowledge transfer) and the provision of drug tablets which Ipsen may require to execute its clinical trial. As per the agreement signed with Ipsen in December 2021, the prices under these agreements cover all costs borne by the Company to provide the relevant goods and services, without economic benefit for Ipsen.

See note 7.1 "Revenues and other income".

29. COMMITMENTS

Obligations under the terms of subcontracting agreements

The Group enters into contracts for its business needs with clinical research organizations (CROs) for clinical trials, as well as with Contract Manufacturing Organizations (CMOs) for clinical and commercial supply manufacturing, commercial and pre-commercial activities, research and development activities and other services and products for operating purposes. The Group's agreements generally provide for termination with specified periods of advance notice.

Such agreements are generally cancellable contracts and not included in the description of the Group's contractual obligations and commitments.

Obligations under the terms of license and collaboration agreements

The Company has entered into a licensing agreement with Genoscience Pharma whereby we are obligated to pay royalties and milestone payments based on future events that are uncertain and therefore they constitute contingent liabilities not recognized in the Company's consolidated financial statements for the period ending December 31, 2022. Refer to Note 24 "Provisions".

Obligations related to the Versantis acquisition

The company entered into an agreement with the former shareholders of Versantis whereby we are obligated to pay milestone payments based on future events that are uncertain and there therefore they constitute contingent liabilities not recognized in the Company's consolidated financial statements for the period ending December 31, 2022. Refer to Note 2.1.

Obligations under the terms of lease agreements

The Company has guaranteed its rental payment obligation under the lease agreement for the headquarters in Loos, France in the amount of €600 at December 31, 2022, €600 at December 31, 2021.

Contingent assets

The Company has entered into a licensing agreement with Terns Pharma whereby we could receive milestone payments based on future events that are uncertain and therefore they constitute contingent assets not recognized in the Company's consolidated financial statements for the period ending December 31, 2022.

Milestones include Development Milestone Payments upon the achievement of the development milestones for the licensed product and Commercial Milestone Payments upon the achievement of commercial milestones depending on reaching certain aggregate thresholds. There are also potential mid-teen royalties based on sales by Terns Pharmaceuticals in Greater China. The potential Development and Commercial Milestone payments may represent up to $193 million .

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30. SUPPLEMENTAL CASH FLOW INFORMATION

Supplemental cash flow information

Disclosure of non-cash financing and investing activities

Accrued property, plant and equipment, 2022: €142

Accrued property, plant and equipment, 2021: €76

Accrued property, plant and equipment, 2020: €83

Other non-cash items

On the Consolidated Statements of Cash Flows, "Other non-cash items" includes the bonus generated by the partial buyback following the renegotiation completed in January 2021 for the amount of €35,578, for 2021. Similarly, on the Consolidated Statements of Operations, this amount was included in "Financial Income" in 2021.

GENFIT SA
Corporation with a Board of Directors and a share capital of € 12,458,745.75
Registered office: Parc Eurasanté, 885 Avenue Eugène Avinée, 59120 LOOS
424 341 907 R.C.S. LILLE Métropole

ARTICLES OF ASSOCIATION

Updated as of September 16, 2022

PART I
FORM - NAME - REGISTERED OFFICE - PURPOSE - TERM

ARTICLE 1 - Form

The owners of the shares created below and of those that may be created at a future date have formed a limited liability company (hereafter, the "**Company**") governed by the laws and regulations in force (hereafter, the "**Law**") and by these Articles of Association.

ARTICLE 2 - Name

The Company's name is: "GENFIT".

On all deeds and documents issued by the Company, its corporate name must be preceded or immediately followed by the words "Limited Company with Board of Directors" and a declaration of the company's capital, as well as the place of registration and the Company's registration number in the Trade and Companies Register.

ARTICLE 3 - Registered office

The Company's registered office is at PARC EURASANTÉ, 885 Avenue Eugène Avinée, 59120 LOOS.

It may be transferred to any other place, in accordance with the provisions of the laws and regulations in force.

ARTICLE 4 - Purpose- *Raison d'être*

4.1 *Purpose*

The Company's direct or indirect purpose, both in France and abroad is:

- Research concerning the production and sale, at different stages of development, of biological molecules and all other activities regardless of what they may be, linked to the pharmaceutical industry.

- And more generally, to carry out all commercial, industrial, financial, securities or real estate transactions and operations linked directly or indirectly to its activity or capable of its facilitation.

4.2 *Raison d'être*

The Company has defined its *raison d'être* as:

The Company is a late-stage biopharmaceutical company committed to improving the lives of patients with severe liver diseases who have a significant unmet medical need.

The Company's *raison d'être* is based on the affirmation of its long-term commitment with regard to the position it wishes to occupy in society, not only as an economic contributor whose purpose is to be part of the long term and to create value for its counterparts and its ecosystem, but also as an innovative biotechnology company aiming to improve the quality of life of patients, and finally as a corporate citizen seeking to facilitate the professional and personal development of its employees.

ARTICLE 5 - Term

The Company, except in the event of its extension or early dissolution, has a term of 99 years starting as from the date of its registration in the trade and companies register.

PART II
CONTRIBUTIONS - COMPANY CAPITAL - FORM OF SHARES - RIGHTS AND OBLIGATIONS ATTACHED TO THE SHARES

ARTICLE 6 - Capital

The Company's capital is fixed at the sum of twelve million four hundred fifty eight thousand seven hundred forty five euros and seventy five cents (€ 12,458,745.75). It is divided into forty nine million eight hundred thirty four thousand nine hundred eighty three (49,834,983) ordinary shares of twenty-five cents of Euro (€ 0.25) each, fully subscribed and paid up in cash.

ARTICLE 7 - Changes to the capital

I. Capital may be increased, either by issuing new ordinary shares or preference shares, or by increasing the nominal value of the existing shares.

New shares may be paid-up either in cash, or by contributions in kind, or by offsetting them against cash receivables, or by the incorporation of profits, reserves or issue premiums into the capital, or as a consequence of a merger or split, or as a consequence of a right attached to securities giving access to the capital being exercised, and in such circumstances payment of the corresponding sums.

Securities representing new capital are issued, either at their nominal value, or at this amount plus an issue premium.

Only the Extraordinary General Meeting is competent to agree to an increase in capital based on a report from the Board of Directors containing the information required by Law.

Under the terms laid down by Law, the Extraordinary General Meeting may, however, delegate this competence to the Board of Directors. Within the limits of the powers thus granted by the Extraordinary General Meeting, the Board of Directors has the powers required for the purpose of increasing the capital one or more times, to set the terms of the increase, to monitor the increase and to amend the Articles of Association as a consequence.

When the Extraordinary General Meeting decides on an increase in capital, it may delegate the powers required to carry out the transaction to the Board of Directors.

When it is a matter of delegating powers or competence, the Board of Directors is required to prepare a supplementary report for the next Ordinary General Meeting.

If the capital is increased by incorporating profits, reserves or issue premiums, the Extraordinary General Meeting must rule under the terms of a quorum and majority specified for Ordinary General Meetings. In this case, it may decide that rights forming fractional shares are neither negotiable nor transferable and that the corresponding securities must be sold. Money arising from the sale will be allocated to the holders in proportion to their rights.

An increase in the capital achieved by increasing the nominal amount of shares can only be determined with the unanimous consent of the shareholders, except when it results from the incorporation of profits, reserves or issue premiums into the capital.

II. The Extraordinary General Meeting of shareholders, or the Board of Directors where such authority has been delegated, may also, subject, if applicable, to creditors' rights, authorise or agree on a reduction of capital for any reason and in any manner. Under no circumstances may a reduction in capital impinge upon shareholder equality.

A decision to reduce capital to an amount lower than the legal minimum can only be agreed upon under the condition precedent of an increase in capital designed to raise it to an amount at least equal to the legal minimum, unless the Company intends converting into another form of Company. Failing this, any interested party may apply to the courts for the dissolution of the Company; dissolution cannot be pronounced, if on the day the Court rules on the substance, the matter has been rectified.

ARTICLE 8 - Paying up of shares

Shares subscribed for in cash must be paid up by at least a quarter of their nominal value at the time of subscription and, if where relevant, by the whole of the issue premium.

The surplus must be paid up in one or more instalments, when called for by the Board of Directors and within a period of five years from the date the capital increase becomes final.

Calls for funds are brought to subscribers' attention by registered letter with a form for acknowledgement of receipt at least fifteen (15) days before the date fixed for each instalment.

Should a shareholder fail to pay up the sums due and payable for the amount of shares he has subscribed for, at the times fixed by the Board of Directors, these sums will automatically be subject to interest in the Company's favour, at the legal rate defined in article L.313-2 of the French Monetary and Financial Code, as from the expiry of the month following the date they become due and without any need for an application to the courts or formal notice. In addition, shares for which payment is due and has not been made on the expiry of a period of thirty (30) days as from formal notification sent to the defaulting shareholder is without effect, cease to give the right to admission to General Meetings and to vote in these General Meetings and will be deducted for the calculation of the quorum. The right to dividends and the preferential rights to subscribe to capital increases attached to the shares are suspended. These rights are recovered after payment of the sums due in terms of capital and interest. The shareholder can then request payment of dividends that have not lapsed and exercise the preferential subscription right if the time limit fixed for the exercise of this right has not expired.

Capital must be fully paid-up before any new shares can be issued that must be paid up in cash.

ARTICLE 9 - Form of shares – Management of securities accounts

Shares issued must be recorded in individual accounts opened in the name of each shareholder by the Company or, if legislation permits, depending on the shareholder's choice, by any authorised intermediary, and kept under the terms and according to the procedures specified by the Law.

The company is allowed to make use of the provisions specified by the Law, and in particular article L. 228-2 of the French Commercial Code, with regard to the identification of holders of bearer securities. To this end, it may at any time ask the central securities depository that keeps its securities account, against remuneration for which it is responsible, for the information referred to in article L. 228-2 of the French Commercial Code. Thus the Company in particular has the right at any time to ask for the name and date of birth or if it is a matter of a company, the name and year of incorporation, the nationality and address of holders of securities conferring an immediate or subsequent right to vote at its General Meetings, as well as the number of securities held by each of them and, if need be, any restrictions to which the securities may be subject.

The Company, after having followed the procedure laid down in the preceding paragraph and in the light of the list provided by the central securities depository, has the option of requesting, either through this central depository or directly to the people included on this list, and where the Company believes they may be registered on behalf of third-parties, the information concerning the ownership of securities specified in the preceding paragraph. These persons are required, when they are acting as intermediaries, to reveal the identity of the owners of the securities. The information is supplied directly to the authorised financial intermediary keeping the account, who is responsible for communicating it, depending on the circumstances, to the Company or to the above-mentioned central securities depository.

ARTICLE 10 - Transmission of shares

Securities registered in an account are passed on by transfer from one account to another.

Shares paid up in cash are freely negotiable from the time of the capital increase. Shares paid for by a contribution are freely negotiable from the time of the capital increase, i.e. on the date of the General Meeting or of the meeting of the Board of Directors, acting by delegation, that approves the contributions, in the event of a contribution in kind during the life of the company.

Transfer of ownership results from their registration in the buyer's account, on the date and under the terms defined by Law.

Subject to the provisions laid down by the Law, the shares are freely transferable.

ARTICLE 11 - Exceeding of thresholds

Any individual or company referred to in articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code acquiring directly or indirectly, alone or in concert, a number of shares representing a fraction of the Company's capital or voting rights greater than or equal to two percent (2%) or a multiple of this percentage, must inform the Company of the total number of shares and voting rights and securities giving access to capital or voting rights it owns immediately or subsequently, by registered letter with advice of delivery addressed to the registered office within a period of four (4) stock exchange days as from the date it exceeds the aforesaid investment threshold or thresholds.

The obligation to provide the information specified above also applies under the same terms when such holdings are reduced below each of the thresholds referred to above.

The individual or company required to provide the above information is, in addition obliged to inform the Company of the objectives it intends pursuing during the next twelve (12) months when the thresholds are crossed, either upwards or downwards, of a tenth, fifth or third of the capital or voting rights. This declaration specifies whether the purchaser is acting alone or in concert, if it intends stopping its purchases or sales or continuing them, or whether it intends acquiring or transferring control of the Company, requesting its nomination or that of one or more other persons, or its resignation, as a director of the Board of Directors.

If this declaration is not made under the terms expressed in the three paragraphs above, the shares or voting rights in excess of the fraction that should have been declared are deprived of voting rights in shareholders' General Meetings for all General Meetings that are held up to the expiry of a period of two years following the date such notification is regularised in accordance with article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

The above declarations apply without prejudice to declarations regarding the exceeding of thresholds specified by the Law.

ARTICLE 12 - Rights and obligations attached to the shares

Each share gives the right to a share in the profits and company assets proportional to the share of the capital it represents.

In addition, it gives the right to vote and the right of representation in General Meetings under the legal and statutory terms.

Shareholders are only liable up to the nominal amount of the shares they own; beyond this any call for funds is prohibited.

Ownership of a share automatically comprises acceptance of the Company's Articles of Association and decisions of the General Meeting.

Heirs, creditors, successors in title, or other representatives of a shareholder, may not require the Company's assets and securities to be sealed, nor ask for them to be shared or sold by auction, nor interfere in the actions of its administration. They must, in order to exercise their rights, refer to the company inventories and the decisions of the General Meeting.

Each time several shares are required in order to exercise a particular right, in the event of the exchange, amalgamation or allocation of securities, or as a consequence of an increase or reduction in capital, merger or other company transaction, owners of individual securities or of a number less than that required may only exercise these rights on condition that they make it their personal business to amalgamate and, possibly, purchase or sell the necessary securities.

However, the Company may, in circumstances where it has carried out either an exchange of securities subsequent to a merger, split, capital reduction, amalgamation or division transaction and the compulsory conversion of bearer shares into named securities, or distributions of securities charged to the reserves or linked to a capital reduction, or distributions or allocations of free shares, via a simple decision by the Board of Directors, sell securities that successors in title have not asked to be issued on condition that they carry out the advertising formalities specified by the regulations at least two years in advance.

From the date of this sale, old shares and old rights to distributions or allocations are cancelled as required and their holders may no longer lay claim to the distribution in cash of the net proceeds from the sale of securities not claimed.

ARTICLE 13 - Beneficial ownership / bare ownership

Shares are indivisible in respect of the Company.

Joint owners of shares are required to arrange to be represented in relation to the Company by one of them alone, considered as the sole owner or by a single representative; in the event of disagreement, the single representative may be appointed by the courts at the request of the joint owner making the application.

Unless an agreement to the contrary is notified to the Company, beneficial owners of shares validly represent bare owners in respect of the Company. Voting rights at Ordinary General Meetings belong to the beneficial owner and to the bare owner at Extraordinary General Meetings.

Unless otherwise agreed by the parties, when capital securities are subject to beneficial ownership, the preferential subscription rights attached to them belong to the bare owner.

PART III
ADMINISTRATION AND CONTROL OF THE COMPANY

ARTICLE 14 - Mode of administration

The company is directed by a Board of Directors.

ARTICLE 15 - Composition of the Board of Directors

The Company is governed by a Board of Directors composed of not less than three nor more than fifteen directors, without prejudice of the temporary exemption provided for in the event of merger, in which case the number may be increased to twenty-four.

The Ordinary General Meeting shall appoint the directors or renew their terms of office and may remove them from office at any time.

The directors may be individuals or legal entities. Upon their appointment, the legal entities are required to designate a permanent representative, who shall be subject to the same conditions and obligations and shall incur the same civil and criminal liability as if he were a director in his own name, without prejudice to the joint and several liability of the legal entity that he represents. The permanent representative shall be appointed for a term of office equivalent to the term of office of the legal entity that he represents. This term of office must be renewed upon each renewal of the legal entity's term of office.

When the legal entity removes its representative from office, it must immediately notify said removal from office to the Company, without delay by registered letter, and appoints a new permanent representative under the same terms and conditions; the same applies in the event of the death or resignation of the permanent representative.

The number of directors who are bound by an employment contract with the Company must not exceed one-third of the directors in office.

The number of directors over 75 years of age may not exceed one-third of the directors in office. If this limit is reached, the eldest director shall be deemed to have resigned.

In the event of a vacancy, due to death or resignation, of one or more directors' seats, the Board of Directors may, between two General Meetings, make provisional appointments.

However, if only one or two directors remain in office, the said director or directors, or failing that, the Auditors must immediately call the Ordinary General Meeting to complete the members of the Board of Directors.

Temporary appointments made by the Board of Directors shall be subject to approval by the next Ordinary General Meeting. Failing approval, deliberations made and actions previously carried out by the Board of Directors shall remain valid.

The director appointed to replace another director shall remain in office only for the unexpired period of his predecessor's term of office.

ARTICLE 16 - Term of office of the Directors

The term of office of the directors is five (5) years. This office ends at the end of the General Meeting called to approve the annual financial statements for the year ended and held during the year in which its term of office expires.

Directors are eligible for re-election.

They may be revoked at any time by the Ordinary General Meeting.

ARTICLE 17 - Chairman of the Board of Directors

The Board of Directors elects, from among its members who are individuals, a Chairman. It shall fix his/her term of office as Chairman, which shall not exceed the period of his/her term of office as director.

The age limit for holding the office of Chairman of the Board of Directors is set at 80 years of age. If he/she reaches this age, he/she shall be deemed to have automatically resigned.

The Chairman of the Board of Directors organises and manages the Board of Directors' work, for which he/she reports thereon to the General Meeting. He/she ensures that the Company's bodies operate properly and, in particular, that the directors are able to fulfil their assignments.

As it may be decided by the Board of Directors and as provided in the article 21-I of these Articles of Association, he/she may hold this office concurrently with that of Chief Executive Officer of the Company.

The Board of Directors may elect a Deputy Chairman which fulfils the functions of the Chairman in his/her absence.

ARTICLE 18 - Meetings and deliberations of the Board of Directors

I. Meetings

The Board of Directors meets as often as the Company's interest requires so, upon summons by the Chairman of the Board of Directors. When no meeting has been held for more than two (2) months, at least one-third of the members of the Board of Directors may request the Chairman to convene a meeting on a specific agenda.

The Chief Executive Officer may also request the Chairman of the Board of Directors to convene a Board of Directors' meeting on a specific agenda.

The Chairman is bound to comply with the requests made by virtue of the two previous paragraphs.

The Chairman of the Board of Directors chair the meetings. If the Chairman is unable to attend to his duties, the Board shall appoint one of the members present to chair the meeting.

The Board may appoint a secretary at each meeting, who is not required to be a Board of Directors' member.

An attendance record is also kept and signed by the directors attending the Board of Directors' meeting.

II. Deliberations

The Board of Directors meets as often as the Company's interest requires it, as convened by its Chairman, either at the head office, or in any other place indicated in the notification to attend. At least a third of the members of the Board of Directors may submit a motivated request to convene the Board of Directors to its Chairman by registered post. The Chairman must convene a Board of Directors' meeting at a date which may not be later than fifteen (15) days as from receipt of the request. Should the meeting not be convened within this period, the authors of the request may convene a Board of Directors' meeting themselves and set its agenda.

Notifications to attend can be issued by all means, even verbally.

Except when the Board of Directors is convened to carry out the operations referred to in the articles L.232-1 and L.233-16 of the French Commercial Code, the directors are deemed present, for the purpose of calculating the quorum and the majority, when they participate in the Board of Directors' meeting using videoconference or telecommunication means allowing them to be identified and ensuring an effective participation in accordance with applicable laws and regulations.

Any director may be represented in the deliberations of the Board of Directors by another director of the Board of Directors. Each member of the Board of Directors cannot have more than one representation's mandate.

The Board of Directors may validly deliberate only if at least half of its members are presents.

The Board of Directors' decisions are taken by a majority of members present and represented.

In the event of a split-vote, the chairman of the session's vote take precedence.

Evidence of the number of current members of the Board of Directors and their presence or representation shall result *vis-à-vis* third parties, the mere mention in the minutes of the Board of Directors of the names of the members present, represented or absent.

ARTICLE 19 - Minutes

The deliberations of the Board of Directors shall be recorded in minutes with the required details. The minutes are drawn up and signed in accordance with applicable laws and regulations.

These minutes are signed by the director acting as Chairman for the purpose of the meeting and at least one Director.

Copies or extracts of the minutes are validly certified by the Chairman of the Board of Directors or any person duly empowered for such purpose.

After the winding-up of the Company, copies or extract of the minutes are certified by any of the liquidators or by the sole liquidator.

ARTICLE 20 - Powers of the Board of Directors

The Board of Directors determines the orientations of the Company's activity and ensures their implementation. Subject to the powers expressly assigned to the general meetings, and within the limits of the corporate purpose of the Company, it shall deal with all issues pertaining to the proper functioning of the Company and settle by its decisions the Company's business.

In relation to third parties, the Company will be committed even by the actions of the Board of Directors which do not fall within the scope of the Company's purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that they could not be unaware thereof given the circumstances, it being understood that the sole publication of the Articles of Association is not sufficient to establish such proof.

The Board of Directors shall carry out audits and perform the controls and verifications that it deems appropriate. Each director receives all information needed to the fulfilment of its assignment and may obtain disclosure of all documents that he considers relevant.

The Board of Directors may decide on the creation of director's committees responsible for dealing with issues that the Board of Directors submits to them. It shall determine the membership, powers, privileges and operating rules of such committees, which shall carry on their business under its responsibility.

The Board of Directors shall distribute attendance fees among the directors, the total amount of which is voted by the General Meeting.

ARTICLE 21 - General Management

I. Choice between the two forms of General Management

The General Management of the Company is handled, under his responsibility, either by the Chairman of the Board of Directors or by another individual appointed by the Board of Directors and having the title of Chief Executive Officer.

The Board of Directors chooses between the two forms of General Management at the majority of members present or represented. It shall inform the shareholders in accordance with regulatory requirements.

When the Chairman of the Board of Directors assumes the General Management of the Company, the provisions hereinafter relating to the Chief Executive Officer shall apply to him.

II. Chief Executive Officer

The Chief Executive Officer may be chosen among the directors or elsewhere. The Board of Directors fixes his term of office and remuneration.

The age limit for being Chief Executive Officer is fixed to the age of 70. Once he has reached this age, he will be deemed to have automatically resigned.

The Board of Directors may dismiss the Chief Executive Officer at any time. If the dismissal is decided without sufficient justification, it may give rise to damages.

The Chief Executive Officer is invested with the broadest powers to act on behalf of the Company in all circumstances. He exercises these powers within the limits of the Company's purpose and subject to the powers expressly assigned by the French Law to the general meeting and the Board of Directors.

He represents the Company in relations with third parties. The Company will be committed even by the actions of the Chief Executive Officer which do not fall within the scope of the Company's purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that it could not be unaware thereof, given the circumstances, it being understood that the sole publication of the Articles of Association is not sufficient to establish such proof.

The provisions of the Articles of Association or the decisions of the Board of Directors that limit the powers of the Chief Executive Officer are not enforceable against third parties.

III. Deputy Chief Executive Officers

Based on proposal of the Chief Executive Officer, the Board of Directors may appoint one or more individuals to assist the Chief Executive Officer, having the title of Deputy Chief Executive Officer, whose remuneration shall be determined by the Board of Directors.

The number of Deputy Chief Executive Officers cannot exceed five.

The Board of Directors may dismiss the Deputy Chief Executive Officers at any time based on the proposal Chief Executive Officer. If the dismissal is decided without sufficient justification, it may give rise to damages.

When the Chief Executive Officer ceases to carry out or is prevented from carrying out his duties, the Deputy Chief Executive Officers shall, unless decided otherwise by the Board of Directors, retain their duties and attributions until the appointment of a new Chief Executive Officer.

With the consent of the Chief Executive Officer, the Board of Directors shall determine the limits and term of the powers granted to the Deputy Chief Executive Officers. They shall have, *vis-à-vis* third parties, the same powers as the Chief Executive Officer.

The age limit applicable to the Chief Executive Officer also applies to the Deputy Chief Executive Officers.

ARTICLE 22 – Plurality of terms of office

An individual may simultaneously hold a maximum of five offices of director or chairman of a board of directors of public companies (*société anonyme*) having their registered office in France.

However, an individual may not hold more than one office as Chief Executive Officer. As an exception, the Chief Executive Officer of a company may hold a second office of the same nature within another company controlled by the first company insofar as the securities of the controlled Company are not listed on a regulated market.

Directors who are not chairmen in other companies may hold an unlimited number of offices in controlled companies of the same kind.

The list of all mandates and functions held in all companies by each of the officers during the financial year is set forth in the management report of the Board of Directors.

ARTICLE 23 - Regulated agreements

I. All agreements entered into between the Company and one of the director of the Company, its Chief Executive Officer, one of its Deputy Chief Executive Officer, an observer as defined in article 24 below or a shareholder that holds over 10% of the voting rights, or further, if a legal person, a controlling Company within the meaning of article L. 233-3 of the French Commercial Code holding over 10% of the voting rights, must be subject to prior authorisation from the Board of Directors.

The same is true for agreements in which one of the persons referred to in the preceding paragraph is indirectly involved or for which they deal with the Company indirectly or through an intermediary.

Agreements between the Company and another company are also subject to prior authorisation if one of the directors of the Company, its Chief Executive Officer, one of its Deputy Chief Executive Officer or the Company's observer is the owner, a partner with unlimited liability, manager, director, Chief Executive Officer, director of the board of directors or the supervisory board, or, in a general manner is in a position of responsibility within this company.

The foregoing provisions are not applicable to agreements concerning day-to-day operations and entered into under normal conditions.

The directors of the Company, its Chief Executive Officer, its involved Deputy Chief Executive Officers are required to inform the Board of Directors as soon as he/she becomes aware of an agreement subject to authorisation. If he/she is a member of the Board of Directors, he/she shall not take part in the vote on the authorisation sought.

The President of the Board of the Directors gives notice to the Auditors of all authorised agreements and submits them to the General Meeting for approval.

II. The Auditors present a special report on these agreements to the General Meeting which rules on these agreements.

The party involved may not take part in the vote and the shares he owns are not taken into account when calculating either a quorum or a majority.

ARTICLE 24 - Observers

The Board of Directors may appoint, at its discretion, one or more observers, whether companies or individuals, shareholders or not.

The term of office of these observers is five years.
Observers may be re-elected indefinitely. Their appointment may be revoked at any time by the Board of Directors.

Observers are convened and participate to all meetings of the Board of Directors, with a consultative vote, according to procedures that are identical to those specified for directors of the Board of Directors, without having their absence affecting the value of the latter's deliberations.

Observers may not be assigned any management, supervisory or monitoring roles, the latter being under the exclusive jurisdiction of the statutory bodies prescribed for limited companies for which they must not be a substitute.

ARTICLE 25 - Obligation of confidentiality and responsibility

I. Directors of the Company, the Chief Executive Officer and, as the case may be, the Deputy Chief Executive Officers and the observers, as well as any person required to attend meetings of these bodies, are required to maintain total discretion in respect of information of a confidential nature that is supplied as such by the Chairman of the Board of Directors and/or the Chief Executive Officer.

II. Directors of the Company, the Chief Executive Officer and, as the case may be, the Deputy Chief Executive Officers, are, according to their respective responsibilities, responsible to the Company or to third-parties for infringements of the legal provisions governing public limited companies, for violations of

these Articles of Association, and for misconduct committed in the context of their responsibilities, under the terms and at the risk of the sanctions specified in the legislation in force.

PART IV
AUDITORS

ARTICLE 26 - The Auditors

Audits of the Company are carried out by one or more Auditors, in accordance with the legal requirements.

I. The Ordinary General Meeting appoints, pursuant to legal requirements, one or several Auditors which are entrusted with the mission determined by the Law. These appointments are for six financial years, and ends-up after the General Meeting called to rule on the annual financial statements for the sixth year after such appointments.

The Ordinary General Meeting also appoints, pursuant to legal requirements, one or several Alternate Auditors which may be required to replace the incumbents Auditors, in case of death, resignation, impediment or refusal.

II. The Auditors, are convened by registered post with confirmation of receipt:
- to every General Meeting, at the latest when the shareholders are convened; and
- at the same time than the members of the Board of Directors at the meetings reviewing and approving the yearly or semi-annual financial statements, whether individual or consolidated.

PART V
SHAREHOLDERS MEETINGS

A - Provisions common to the different types of Meetings

ARTICLE 27 - Meetings

The General Meeting, lawfully convened, represents all the shareholders.

Its deliberations undertaken in accordance with the Law and the Articles of Association are binding on all shareholders, even those that are absent, dissident or subject to incapacity.

Depending on the subject of the resolutions proposed, there are three forms of Meetings:

- Ordinary General Meetings,
- Extraordinary General Meetings,
- Special Meetings for holders of shares in a particular category.

ARTICLE 28 - Notifications to attend

Meetings are convened by the Board of Directors. They may also be convened by the Auditor or Auditors or by a court representative under the terms and procedures specified by the Law.

During a period of liquidation, Meetings are convened by the liquidator or liquidators.

Meetings are held at the registered offices or in any other place indicated in the notification to attend the meeting.

No later than thirty-five (35) days before the date of the Meeting, a notice of meeting is published in the French *Bulletin des Annonces Légales Obligatoires* (BALO). Notifications to attend are published at least fifteen (15) days before the date of the Meeting via a notice published in the BALO and inserted into a newspaper accepting legal announcements for the department in which the head office is located.

However, shareholders owning shares in their own name for at least one (1) month on the date the convocation’s notice is inserted into the newspaper shall be given notice individually, via an ordinary letter (or by registered letter if they request it and cover the related costs) sent to their last known address. This notification may also be sent via an electronic means of communication or remote data transmission, instead of by post, after obtaining the approval of the interested shareholders by post or by electronic means.

Notifications to attend must contain the following information:

- The identity of the Company,
- The date, place and time of the Meeting,
- The nature of the Meeting,
- The agenda for the Meeting.

When a Meeting is not able to deliberate due to a lack of the required quorum, a second Meeting must be convened at least ten (10) days in advance, in the same form as the first one. Notifications or letters inviting members to attend this second Meeting should reproduce the date and agenda of the first meeting.

ARTICLE 29 - Agenda

The agenda of the Meetings is determined by the author of the notification to attend.

One or more shareholders representing at least the share of the company's capital fixed by the Law and acting under and within the legal terms and deadlines, have the right to call for, by registered letter with a

form for acknowledgement of receipt or by electronic means or remote data transmission, points or draft resolutions to be included in the agenda for the Meeting.

The Meeting may not deliberate on a question that is not included in the agenda, which cannot be altered for a second convocation. It can, however, in all circumstances, revoke the appointment of one or more directors of the Board of Directors and proceed with their replacement.

ARTICLE 30 - Participation of Shareholders in General Meetings

The right to participate in Meetings is defined and justified in accordance with the provisions of article R.225-85 of the French Commercial Code.

For the calculation of the quorum and the majority, the Shareholders participating, as the case may be, to the Meeting by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in accordance with applicable laws and regulations and as set out below.

Each shareholder may vote by postal ballot or by proxy (including by electronic means) in accordance with the applicable legislation, and notably by means of a form filled in and sent to the Company in the conditions set by law and by regulations.

Any shareholder may also participate in and vote at meetings by videoconference or any other means of telecommunication or electronic transmission (including by the transmission of an electronic voting form or a proxy form) allowing him/her to be identified, under the conditions and in accordance with the procedures stipulated in the legal and regulatory provisions in force. The decision of the Board of Directors to use telecommunication facilities or videoconferencing will be published in the meeting notice and the notice of summons.

The submission and signature of the electronic form may be directly performed on a dedicated website with a login and a password. The proxy or vote, thus expressed prior to the Meeting by this electronic means, and the confirmation of receipt given thereof, shall be considered as irrevocable written instructions and binding on all parties, it being specified that, in the event of a transfer of ownership prior to the legal period for the purpose of recording the shares, the Company will consequently invalidate or modify, as applicable, the proxy or vote expressed prior to this date and this time.

ARTICLE 31 – Presidency – *Bureaux* - Attendance sheet

Meetings are chaired by the President of the Board of Directors, or in his/her absence, by a director specially appointed for this purpose by the Board of Directors. Failing this, the Meeting elects a President itself.

Two shareholders, present and willing, representing, both for themselves as well as representatives, the largest number of votes act as tellers.

The *Bureau* appoint a Secretary who may be chosen from outside the shareholders.

An attendance sheet should be completed for each Meeting containing the information prescribed by the Law.

ARTICLE 32 - Quorum - right to vote

In Ordinary and Extraordinary General Meetings, a quorum is calculated based on all the shares comprising the Company's capital and, in Special Meetings, based on all the shares in the relevant category, reduced by shares deprived of voting rights in accordance with the Law.

The right to vote attached to shares is proportional to the share of the capital they represent. Each capital or dividend share gives the right to one vote.

As an exception to the above provisions, any shareholder, regardless of nationality, whose shares are fully paid-up and have been registered in a nominative account in the name of the same holder for at least two years, enjoys a double voting right in accordance with the Law.

Forms that do not indicate a vote in any particular direction or that express an abstention are considered as votes against.

For the calculation of the quorum and the majority, the shareholders participating, as the case may be, to the meeting by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in compliance with applicable legal and statutory provisions and article 30 above.

ARTICLE 33 - Minutes

Meetings' deliberations are recorded in minutes prepared in a special register kept at the head office and signed by the members of the *bureau* of the General Meeting.

Copies or extracts of the minutes of the deliberations are certified either by the Chairman of the Board of Directors, or by a director of the Board of Directors, or by the Meeting's Secretary. In the event of dissolution, they can be certified by the liquidator(s).

ARTICLE 34 - Communication of documents

All shareholders have the right to obtain communication of, and the Board of Directors has an obligation to send them or provide them with, the documents they need to make an informed decision and judgement on the management and operation of the Company.

The nature of these documents and the terms of their dispatch or their availability to shareholders are determined in accordance with applicable legislation.

In order to exercise their right of communication, shareholders or their representatives may obtain the assistance of an expert registered in one of the lists drawn up by the Courts and Tribunals.

Exercising the right of communication carries with it the right of copying, except where this concerns inventories.

B - Provisions specific to Ordinary General Meetings

ARTICLE 35 - Ordinary General Meeting

Ordinary General Meetings can take all decisions, other than those with the effect of directly or indirectly modifying the Articles of Association.

They meet at least once a year, within six (6) months of the end of each financial year, to rule on the accounts for this financial year, unless this period of time is extended by order of the President of the Commercial Tribunal ruling at the Board of Directors' request.

They meet on an extraordinary basis each time the Company's interests require it.

The Ordinary General Meetings can only deliberate validly, when convened the first time, if the quorum, as calculated pursuant to article 32 above, is at least one fifth of the shares with voting rights.

The second time the Meeting is convened, no quorum is required as long as the original agenda has not been modified.

The Ordinary General Meetings shall act on the basis of a majority of votes of the shareholders participating to the Ordinary General Meetings in accordance with the conditions listed in article 30 above.

C - Provisions specific to Extraordinary General Meetings

ARTICLE 36 - Extraordinary General Meeting

Extraordinary General Meeting is the sole authorised to modify all the provisions of the Articles of Association and to decide in particular the conversion of the Company into a Company of another form. It may not however increase shareholders' commitments, subject to transactions resulting from a consolidation of shares carried out legally.

Extraordinary General Meeting can only deliberate validly, when convened the first time, if the quorum as calculated pursuant to article 32 above, is at least, a quarter of the shares with voting rights and, the second time as calculated pursuant to article 32 above, one fifth of the shares with voting rights. Where this latter quorum is not reached, the second Extraordinary General Meeting may be postponed to a later date being no more than two (2) months after it had been convened.

It shall act on the basis of a two thirds majority of votes of the shareholders participating to the Extraordinary General Meeting, in accordance with the conditions listed in article 30 above.

As a legal exception to the above provisions, a General Meeting that decides a capital increase by incorporation of reserves, profits or issue premiums, may rule under the terms of a quorum and a majority of an Ordinary General Meeting.

In addition, when an Extraordinary General Meeting is called on to deliberate concerning the approval of a contribution in kind or the granting of a special benefit, shares belonging to the contributor or the beneficiary are not taken into account when calculating the majority. The contributor or the beneficiary does not have voting rights, either for themselves or as representatives.

D - Provisions specific to Special Meetings of holders of shares of a particular category

ARTICLE 37 - Special Meeting

If several categories of shares exist, no modification may be made to the rights attributable to shares in one of these categories without a valid vote at an Extraordinary General Meeting open to all shareholders and, in addition, without a valid vote at a Special Meeting which is opened to owners of shares in the relevant category alone.

Special Meetings can only deliberate validly, when convened the first time, if the quorum, as calculated pursuant to article 32 above, is at least one-third of the shares with a voting right, whose right is due to be modified and, the second time as calculated pursuant to article 32 above, a fifth of the shares carrying a voting right, whose right is due to be modified. Where this latter is not reached, the second Special Meeting may be postponed to a later date being no more than two (2) months after it had been convened.

They shall act on the basis of a majority of two thirds of the votes of the shareholders participating to the Special Meeting, in accordance with the conditions listed in article 30 below.

PART VI
COMPANY YEAR - ANNUAL ACCOUNTS - ALLOCATION AND DISTRIBUTION OF PROFITS

ARTICLE 38 - Company year

The Company year starts on 1 January in each year and ends on 31 December.

ARTICLE 39 - Accounts

Official accounts of the Company's transactions should be kept in accordance with the laws and normal business practices.

At the end of each financial year, the Board of Directors should draw up an inventory of the various assets and liabilities existing on this date. It should also prepare a balance sheet describing the assets and liabilities, a profit and loss account summarising income and expenditure for the financial year, as well as an appendix supplementing and commenting on the information given in the balance sheet and profit and loss account.

All these documents should be made available to the Auditors in accordance with legal regulations.

ARTICLE 40 – Terms of dividends distribution

The profit and loss account which summarises income and expenditure for the financial year reveals by difference, after deduction of depreciation costs and provisions, the profit or loss for the financial year.

From profits, reduced if need be by previous losses, is first deducted five per cent to constitute the legal reserve fund; this deduction ceases to be mandatory when the aforesaid fund reaches a tenth of share capital; it is resumed when for any particular cause the reserve drops below this figure of a tenth.

Distributable profit is composed of the profit for the financial year, less previous losses and amounts allocated to reserves under the Law or the Articles of Association, increased by accumulated profits.

In addition the General Meeting may decide to distribute sums taken from the reserves that are available to it, specifically indicating the reserve accounts from which such distributions should be taken. However, as a priority, dividends are taken from the financial year's distributable profits.

Excluding circumstances of a reduction in capital, no distribution may be made to shareholders when shareholders equity is or following the distribution would become, less than the amount of capital increased by reserves at which level the Law or the Articles of Association do not permit a distribution.

After approval of the accounts and the existence of distributable sums has been ascertained, the General Meeting determines the share allocated to shareholders, in respect of a dividend, proportionally to the number of shares belonging to each of them.

However, after deduction of the sums allocated to the reserve, under the Law, the General Meeting may decide to allocate all or part of the distributable profit to the deferral account or to any general or special reserve accounts.

Losses, if such exist, are allocated to profits carried forward from previous financial years until they are absorbed or carried forward.

Interim dividends may be distributed, as decided by the Board of Directors before approval of the accounts for the financial year under the terms set out or authorised by the Law. The amount of these interim payments may not exceed the amount of profit as defined by the Law.

ARTICLE 41 - Dividends

I. Procedures for the payment of dividends or interim dividends are set out by the General Meeting or, failing that, by the Board of Directors. However payment must occur within a maximum period of nine (9) months after the close of the financial year, unless an extension is granted by court order.

No dividends may be claimed back from shareholders, unless the distribution was carried out in violation of the legal provisions

Unclaimed dividends within five years of their payment are lapsed.

II. The General Meeting ruling on the accounts for the financial year has the option of granting shareholders for all or part of the dividend distributed or interim payments made against the dividend, an option between payment of the dividend or interim payments in cash or in shares issued by the Company, under the terms set out or authorised by the Law.

PART VII
SHAREHOLDERS EQUITY BECOMING LESS THAN HALF THE CAPITAL

ARTICLE 42 - Early dissolution

If, due to losses recorded in the Company's accounts, shareholders' equity in the Company is reduced to less than half of the share capital, the Board of Directors must, within four (4) months following approval of the accounts in which this loss is recorded, convene an Extraordinary General Meeting in order to decide whether an early dissolution of the Company is necessary.

If dissolution is not decided on, the capital must be, within the deadline set out by the Law, reduced by an amount equal to that of the losses recorded if within this period, shareholders' equity has not returned to a value at least equal to half the Company's share capital.

In both circumstances, the Meeting's decision must be published under the regulatory requirements.

A decision to reduce capital to an amount lower than the legal minimum can only be agreed under the condition precedent of a capital increase designed to raise it to an amount at least equal to this minimum amount.

In the event of a breach of the requirements of one or more of the above paragraphs, any interested party may apply to the courts for the dissolution of the Company. The same applies if the shareholders have not been able to hold valid deliberations.

Nevertheless, the Court cannot pronounce dissolution if, on the day it is due to issue its ruling concerning the substance, the situation is rectified.

PART VIII
DISSOLUTION - LIQUIDATION

ARTICLE 43 - Dissolution

The Company is dissolved on expiry of the term set out by the Articles of Association, except where the term has been extended, or by a decision of the Extraordinary General Meeting.

The dissolution may also be ordered through a decision of the Courts at the request of any interested party, when the number of shareholders is reduced to less than seven for more than a year. In these circumstances, the Court may grant the Company a maximum period of six (6) months to rectify the situation; it may not order the Company's dissolution if, on the day when it rules on the substance, the situation has been rectified.

The Company is in liquidation, from the very moment of its dissolution, regardless of the cause, except in the event of dissolution carried out in accordance with article 1844-5 para. 3 of the French Civil Code.

Dissolution ends the duties of the directors of the Board of Directors, the Chief Executive Officer, and as the case may be, the Deputy Chief Executive Officers; however, the Auditors continue their mission.

The General Meeting retains the same powers as during the life of the Company.

The General Meeting that orders dissolution determines the method of liquidation and appoints one or more liquidators, whose powers it determines and who exercise their duties in accordance with the applicable law.

The Company's legal personality persists for the needs of its liquidation and until the liquidation process is complete, but its name must be followed by the reference "Company in liquidation" as well as the name or names of the liquidators on all deeds and documents issued by the Company and intended for third-parties.

Its shares remain negotiable up to the end of the liquidation process.

The net proceeds of liquidation, after liabilities have been settled, are used in full to reimburse paid-up and non-depreciated share capital.

The surplus, if there is one, shall be distributed among the shareholders in proportion to the number of shares held by each of them.

PART IX
DISPUTES

ARTICLE 44 - Disputes

All disputes that may arise during the life of or the liquidation of the Company, either between the shareholders and the Company, or between the shareholders themselves, concerning the Company's affairs, will be judged in accordance with the Law and subject to the jurisdiction of the competent Courts covering the district in which the headquarters is located.

To this end, in the event of a dispute, all shareholders are required to elect domicile in the jurisdiction of the Court covering the district in which the Company's head office is located and all summons or notifications will be legally served at this domicile.

In the absence of such election of domicile, summons or notifications will be validly served at the Office of the Public Prosecutor of the Republic to the District Court in the district in which the Company's head office is located.

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO

SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the ordinary shares, the American Depositary Shares and the articles of association, or bylaws, of GENFIT S.A. ("Genfit" or the "Company") is a summary and does not purport to be complete. This summary is subject to, and qualified in its entirety by reference to, the complete text of the Company's bylaws, which are incorporated by reference as Exhibit 1.1 of the Company's Annual Report on Form 20-F to which this description is also an exhibit. The Company encourages you to read the Company's bylaws carefully.

As of December 31, 2022, GENFIT S.A. had the following series of securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Ordinary Shares, nominal value €0.25 per share*	*	The Nasdaq Global Select Market*
American Depositary Shares, each representing one ordinary share, nominal value €0.25 per share	GNFT	The Nasdaq Global Select Market

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

I. ORDINARY SHARES

The Company is a *société anonyme* organized under the laws of France and registered at the Registry of Trade and Companies of Lille Métropole (*Registre du commerce et des sociétés*) under the number 424 341 907.

As of December 31, 2022, the Company's outstanding share capital consisted of a total of 49,834,983 issued ordinary shares, fully paid and with a nominal value of €0.25 per share.

Key Provisions of Our Bylaws and French Law Affecting Our Ordinary Shares

The description below reflects the terms of our bylaws and summarizes the material rights of holders of our ordinary shares under French law. Please note that this is only a summary and is not intended to be exhaustive. For further information, please refer to the full text of our bylaws, a copy of which has been filed as Exhibit 1.2 of the annual report on Form 20-F of which this description is also an exhibit.

Corporate Purpose - Raison d'être ***(Article 4 of the Bylaws)***

Our corporate purpose in France and abroad includes the research concerning the production and sale, at different stages of development, of biological molecules and all other activities regardless of what they may be, linked to the pharmaceutical industry, and more generally, to carry out all commercial, industrial, financial, securities or real estate transactions and operations linked directly or indirectly to its activity or capable of its facilitation.

The *raison d'être* of the Company is the following:

The Company is a late-stage biopharmaceutical company dedicated to the improvement of the lives of patients with severe liver diseases where there are considerable unmet medical needs.

The *raison d'être* of the Company relies on the affirmation of its longstanding commitment in the role it intends to have in society, not only as an economic agent aiming to have a long-term impact and create value for its partners and ecosystem, but also as an innovative biotech company aiming to improve the patients' quality of life, and finally, as a corporate citizen aiming to foster the personal and professional development of its employees.

Directors (Articles 14-25 of the Bylaws)

Duties of the Board. Our board of directors determines the orientations of the company's activity and ensures their implementation. Subject to the powers expressly assigned to the general meetings, and within the limits of the corporate purpose of our company, it shall deal with all issues pertaining to the proper functioning of the company and settle by its decisions our company's business. In relation to third parties, the company will be committed even by the actions of the board of directors which do not fall within the scope of our company's purpose, unless it proves that the third parties knew that the action fell outside the limits of said purpose or that they could not be unaware thereof given the circumstances.

Appointment and Term. Our board of directors must be composed of at least three members and up to 15 members, but may not exceed be temporary increased to 24 in the case of merger. In appointing and electing directors, we seek a balanced representation of women and men. The term of a director is 5 years, and directors may be re-elected at our annual ordinary shareholders meetings; however, a director over the age of 75 may not be appointed if such appointment would result in the number of directors over the age of 75 constituting more than one-third of the board. The number of directors who are also our employees cannot exceed one-third of the board. Directors may be natural persons or legal entities except for the chairman of the board who must be a natural person. Legal entities appointed to the board must designate a permanent representative. If a director dies or resigns between annual meetings, the board may appoint a temporary director to fill the vacancy, subject to ratification at the next ordinary general meeting, or, if such vacancy results in a number of directors below three, the board must call an ordinary general meeting to fill the vacancy.

Subject to the passing of the resolutions that will be presented at our 2023 annual meeting called to approve our financial statements for the year ended on December 31, 2022, the terms of our directors will be lowered to 3 years after the expiration of the current terms of our directors.

Organization. The board of directors must elect a chairman from among the board members. The chairman must be a natural person, age 80 or younger, and may be removed by the board at any time. The board may also elect a natural person as deputy chairman who will fulfill the functions of the Chairman in his absence and may designate one or more non-voting board observers, whether companies or individuals, shareholders or not.

Deliberations. At least half of the number of directors in office must be present to constitute a quorum. Decisions are made by a majority of the directors present or represented and, if there is a tie, the vote of the chairman will carry the decision. Meetings may be held as often as required; however, the chairman is required to call a meeting with a determined agenda upon the request of at least one-third of the directors if the board has not met for more than two months. French law and our charter and bylaws allow directors to attend meetings in person or, to the extent permitted by applicable law and with specified exceptions in our bylaws, by videoconference or other telecommunications means allowing them to be identified and ensuring an effective participation in accordance with applicable laws and regulations.

Directors' Voting Powers on Proposal, Arrangement or Contract in which any Director is Materially Interested. Under French law, any agreement entered into, directly or through an intermediary, between us and any director that is not entered into in the ordinary course of our business and upon standard market terms is subject to the prior authorization of the board of directors. The interested director cannot vote on such decision. All agreements entered into between our company and one of our director, our chief executive officer, one of its deputy chief executive officer, an observer or a shareholder that holds over 10% of the voting rights, or further, if a legal person, a controlling company within the meaning of article L.233-3 of the French Commercial Code holding over 10% of the voting rights, must be subject to prior authorization from the board of directors. The chairman will in turn gives notice to our statutory auditors of all authorized regulated agreements and submits them to the general meeting for approval.

Directors' Compensation. Director compensation for attendance at board meetings (*jetons de présence*) is determined at the annual ordinary general meeting. Independent directors have a right to a fixed amount of compensation for their duties as director and, if applicable, as member or chair of one or more board committees and to a variable amount of compensation depending on their actual participation at board meetings and, if applicable, committee meetings.

Board of Directors' Borrowing Powers. Subject to any limitation set up by the general meeting of shareholders, there are currently no limits imposed on the amounts of loans or borrowings that the board of directors may approve.

Directors' Share Ownership Requirements. Our directors are not required to own any of our shares.

Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)

Dividends. We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.

"Distributable Profits" consist of our statutory net profit in each fiscal year, calculated in accordance with accounting standards applicable in France, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to applicable French laws and regulations.

Legal Reserve. Pursuant to French law, we must allocate 5% of our statutory net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. However, it is resumed when for any particular cause the reserve drops below 10%.

Approval of Dividends. Pursuant to French law, our board of directors may propose a dividend for approval by the shareholders at the annual ordinary general meeting.

Upon recommendation of our board of directors, our shareholders may decide to allocate all or part of any distributable profits to special or general reserves, to carry them forward to the next fiscal year as retained earnings or to allocate them to the shareholders as dividends. However, dividends may not be distributed when our net assets are or would become as a result of such distribution lower than the amount of the share capital plus the amount of the legal reserves which, under French law, may not be distributed to shareholders. The amount of our share capital plus the amount of our legal reserves which may not be distributed was equal to €19,478,106.09 on December 31, 2022.

Our board of directors may distribute interim dividends after the end of the fiscal year but before the approval of the financial statements for the relevant fiscal year when the interim balance sheet, established during such year and certified by an auditor, reflects that we have earned distributable profits since the close of the last financial year, after recognizing the necessary depreciation and provisions and after deducting prior losses, if any, and the sums to be allocated to reserves, as required by law or the bylaws, and including any retained earnings. The amount of such interim dividends may not exceed the amount of the profit so defined.

Pursuant to French legislation, if a dividend is declared we may be required to pay a dividend tax in an amount equal to 3% of the aggregate dividend paid by us. However, the European Court of Justice, or ECJ, has ruled that the 3% dividend tax may not be applied to redistribution of dividends we receive from our subsidiaries established in another Member State of the EU, in that it creates double taxation of profits made within the EU as prohibited by Article 9 of the Parent-Subsidiary directive (ECJ, 1st ch. May 17, 2017, case C-365/16 AFEP).

Distribution of Dividends. Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our board of directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an

ordinary general shareholders' meeting or by our board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Shareholders may be granted an option to receive dividends in cash or in shares, in accordance with legal conditions. The conditions for payment of dividends in cash shall be set at the shareholders' meeting or, failing this, by the board of directors.

Timing of Payment. Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

Voting Rights. Each share shall entitle its holder to vote and be represented in the shareholders' meetings in accordance with the provisions of French law and of our bylaws. Ownership of one share implies, ipso jure, adherence to our bylaws and the decisions of the shareholders' meeting.

In general, each shareholder is entitled to one vote per share at any general shareholders' meeting. Pursuant to our bylaws, however, a double voting right is attached to each registered share which is held in the name of the same shareholder for at least two years.

Under French law, treasury shares or shares held by entities controlled by us are not entitled to voting rights and do not count for quorum purposes.

Rights to Share in Our Profit. Each share entitles its holder to a portion of the corporate profits and assets proportional to the amount of share capital represented thereby.

Rights to Share in the Surplus in the Event of Liquidation. If we are liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of our shares. Any surplus will be distributed pro rata among shareholders in proportion to the number of shares respectively held by them, taking into account, where applicable, of the rights attached to shares of different classes.

Repurchase and Redemption of Shares. Under French law, we may acquire our own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for one of the following purposes:

- to decrease our share capital, provided that such a decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at an extraordinary general meeting; in this case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;

- to meet obligations arising from debt securities that are exchangeable into equity instruments;

- to provide shares for distribution to employees or managers under a profit-sharing, free share or share option plan; in this case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or

- we benefit from a simple exemption when the acquisition is made under a liquidity contract complying with the general regulations of, and the market practice accepted by the French Financial Markets Authority (AMF).

All other purposes, and especially share buy-backs made for external growth operations in pursuance of Article 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulation and insider dealing rules.

Under MAR and in accordance with the General Regulations of the AMF (*Réglement Général de l'AMF*), a corporation shall report to the competent authority of the market on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of shares may result in us holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

Our share repurchase program is used exclusively in connection to our liquidity contract, by which the market for our ordinary shares is stimulated by an investment services provider. In compliance with the European regulatory framework, and in particular the provisions of European Regulation No. 2273/2003 of December 22, 2003, we entered into a liquidity contract on August 1, 2013 with CM-CIC Market Solutions in accordance with the Charter Code of Ethics of the French Financial Markets Association (AMAFI), recognized by the AMF. This contract is still in force on the date hereof.

During the financial year ended December 31, 2022, the Board of Directors implemented the program authorized by the General Meeting of June 30, 2021 and then by the General Meeting of May 25, 2022. We are required under AMF regulations to publish every six months, a report on the purchases and sales made under the liquidity contract, which is furnished to the SEC under cover of Form 6-K.

Sinking Fund Provisions. Our bylaws do not provide for any sinking fund provisions.

Liability to Further Capital Calls. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Requirements for Holdings Exceeding Certain Percentages. Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code coming to directly or indirectly own, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater than or equal to 2% or a multiple of this percentage, must inform us of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds. This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In addition, any shareholder required to deliver the above information shall inform us of its objectives it intends pursuing over the following 12 months, when the thresholds are crossed, either upwards or downwards, of a tenth, a fifth, or third of the capital or voting rights, including notably whether it acts alone or in concert, it intends to continue acquiring our shares, it intends to acquire or transfer control of the company, its intended management strategy for the company.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

These requirements apply without prejudice to requirements described below under the sections titled "Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)" and "Form, Holding and Transfer of Shares (Articles 9 and 10 of the Bylaws)—Ownership of Shares by Non-French Persons."

Actions Necessary to Modify Shareholders' Rights

Shareholders' rights may be modified as allowed by French law. However, the extraordinary shareholders' meeting is authorized to amend any and all provisions of our bylaws. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

Special Voting Rights of Warrant Holders

Under French law, the holders of warrants of the same class (i.e., warrants that were issued at the same time and with the same rights), including founder's warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

Rules for Admission to and Calling Annual Shareholders' Meetings and Extraordinary Shareholders' Meetings (Part V of the Bylaws)

Access to, Participation in and Voting Rights at Shareholders' Meetings. The right to participate in shareholders' general meetings is defined and justified in accordance with the provisions of article R.22-10-28 of the French Commercial Code. For the calculation of the quorum and the majority, the shareholders participating, as the case may be, to the shareholders' general meetings by proxy, by postal ballot, by videoconference or by any other means of telecommunication or remote data transmission are deemed present, in accordance with applicable French laws and regulations. Each of our shareholders may vote by postal ballot or by proxy (including by electronic means) in accordance with applicable legislation, and notably by means of a form filled in and sent to our company in the conditions set by applicable French laws and by regulations. Any shareholder may also participate in and vote at meetings by videoconference or any other means of telecommunication or electronic transmission (including by the transmission of an electronic voting form or a proxy form) allowing him/her to be identified, under the conditions and in accordance with the procedures stipulated in the legal and regulatory provisions in force. The decision of the board of directors to use telecommunication facilities or videoconferencing will be published in the meeting notice and the notice of summons.

Participation in shareholders' general meetings, in any form whatsoever, is subject to registration of shares under the conditions and time limits provided for applicable French laws and regulations.

The final date for returning voting ballots by correspondence is set by the board of directors and disclosed in the notice of meeting published in the French Journal of Mandatory Statutory Notices, or BALO *(Bulletin des Annonces Légales Obligatoires)*. This date cannot be earlier than three days prior to the meeting.

A shareholder who has voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

A shareholder may be represented at meetings by any individual or legal entity by means of a proxy form which we send to such shareholder either at the shareholder's request or at our initiative. A shareholder's request for a proxy form must be received at the registered office at least five days before the date of the meeting. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, and the other extraordinary, held on the same day or within a period of 15 days.

A shareholder may vote by correspondence by means of a voting form, which we send to such shareholder either at the shareholder's request or at our initiative, or which we include in an appendix to a proxy voting form under the conditions provided for by current laws and requirements. A shareholder's request for a voting form must be received at the registered office at least six days before the date of the meeting. The voting form is also available on our website at least 21 days before the date of the meeting. The voting form must be recorded by us three days prior to the shareholders' meeting, in order to be taken into consideration. The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

Notice of Annual Shareholders' Meetings. Shareholders' meetings are convened by our board of directors, or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances. Meetings are held at our registered offices or at any other location indicated in the convening notice (*avis de convocation*). A meeting announcement (*avis de réunion*) is published in the BALO at least 35 days prior to a meeting, as well as on our website at least 21 days prior to the meeting. In addition to the particulars relative to the company, it indicates, notably, the meeting's agenda and the draft resolutions that will be presented. The requests for recording of issues or draft resolutions on the agenda must be addressed to the company under the conditions provided for in the current legislation.

Subject to special legal provisions, the convening notice is sent out at least 15 days prior to the date of the shareholders' general meeting, by means of a notice inserted in a legal announcement bulletin of the registered office department and, if relevant, in the BALO. Further, the holders of registered shares for at least a month at the time of the latest insertion of the convening notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder after obtaining their agreement by post or by electronic means in accordance with legal and regulatory requirements. The latter may expressly request by post or by electronic means to the Company at least 35 days prior to the date of the insertion of the convening notice in a legal announcement bulletin and in the BALO that the aforementioned means of telecommunication should be replaced in the future by a mailing.

The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.

When the shareholders' meeting cannot deliberate due to the lack of the required quorum, the second meeting must be called at least ten days in advance in the same manner as used for the first notice.

Agenda and Conduct of Annual Shareholders' Meetings. The agenda of the shareholders' meeting shall appear in the convening notice of the meeting and is set by the author of the notice. The shareholders' meeting may only deliberate on the items on the agenda except for the removal of directors and the appointment of their successors which may be put to vote by any shareholder during any shareholders' meeting. Pursuant to French law and our current share capital, one or more shareholders representing 5% of our share capital may request the inclusion of items or proposed resolutions on the agenda. Such request must be received at the latest on the 25th day preceding the date of the shareholders' meeting, and in any event no later than the 20th day following the date of the shareholders' meeting announcement.

Shareholders' meetings shall be chaired by the Chairman of the board of directors or, in his or her absence, by a director elected for this purpose. Failing that, the meeting itself shall elect a Chairman. Vote counting shall be performed by the two members of the meeting who are present and accept such duties, who represent, either on their own behalf or as proxies, the greatest number of votes.

Ordinary Shareholders' Meeting. Ordinary shareholders' meetings are those meetings called to make any and all decisions that do not amend our bylaws. An ordinary meeting shall be convened at least once a year within six months of the end of each fiscal year in order to approve the annual and consolidated accounts for the relevant fiscal year or, in case of postponement, within the period established by court order. Upon first notice, the meeting may validly deliberate only if the shareholders present or represented by proxy or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission in accordance with the applicable laws and regulations, represent at least one-fifth of the shares entitled to vote. Upon second notice, no quorum is required. Decisions are made by a majority of the votes held by the shareholders present, or represented by proxy, or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission. Abstentions will have the same effect of a "no" vote. In addition, pursuant to the AMF recommendation applicable from June 15, 2015, French listed companies may be required to conduct a consultation of the ordinary shareholders' meeting prior to the disposal of the majority of their assets, under certain circumstances.

Extraordinary Shareholders' Meeting. Our bylaws may only be amended by approval at an extraordinary shareholders' meeting. Our bylaws may not, however, be amended to increase shareholder commitments without the approval of each shareholder. Subject to the legal provisions

governing share capital increases from reserves, profits or share premiums, the resolutions of the extraordinary meeting shall be valid only if the shareholders present, represented by proxy or voting by correspondence, by videoconference or by means of telecommunication or electronic transmission represent at least one-fourth of all shares entitled to vote upon first notice, or one-fifth upon second notice. If the latter quorum is not reached, the second meeting may be postponed to a date no later than two months after the date for which it was initially called. Decisions are made by a two-thirds majority of the votes held by the shareholders present, represented by proxy, or voting by correspondence, by videoconference or electronic transmission. Abstentions will have the same effect of a "no" vote.

Provisions Having the Effect of Delaying, Deferring or Preventing a Change in Control of Our Company

Provisions contained in our bylaws and French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. These provisions include the following:

- under French law, the owner of 95% of voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the EEA Agreement, including from the main French Stock Exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;

- under French law, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.;

- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;

- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;

- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;

- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;

- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;

- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;

- our board of directors can be convened by our chairman, including upon request from our managing director, if any, or, when no board meeting has been held for more than two consecutive months, from directors representing at least one third of the total number of directors;

- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;

- our shares are in registered form or in bearer form, if the legislation so permits, according to the shareholder's choice;

- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;

- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;

- our bylaws can be changed in accordance with applicable French laws and regulations;

- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the sections below titled "Rights, Preferences and Restrictions Attaching to Ordinary Shares (Articles 11, 12, 32, 40 and 41 of the Bylaws)—Requirements for Holdings Exceeding Certain Percentages" and "Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)";

- transfers of shares shall comply with applicable insider trading rules and regulations, and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and

- pursuant to French law, the sections of the bylaws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

Declaration of Crossing of Ownership Thresholds (Article 11 of the Bylaws)

Set forth below is a summary of certain provisions of the French Commercial Code applicable to us. This summary is not intended to be a complete description of applicable rules under French law.

Any individual or legal entity referred to in Articles L. 233-7, L. 233-9 and L. 223-10 of the French Commercial Code coming to directly or indirectly own, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater or equal to 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% and 95% shall inform us as well as the French Financial Markets Authority (AMF) of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time within a period of four trading days from the crossing of the said holding thresholds.

This obligation applies when crossing each of the above-mentioned thresholds in a downward direction.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared, such shares shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code.

In addition, any shareholder crossing, alone or acting in concert, the 10%, 15%, 20% or 25% threshold shall file a declaration with the AMF pursuant to which it shall expose its intention over the following 6 months, including notably whether it intends to continue acquiring shares of the company, it intends to acquire control over the company, its intended strategy for the company.

Further, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 30% threshold shall file a mandatory public tender offer with the AMF. Also, any shareholder holding directly or indirectly a number between 30% and 50% of the capital or voting rights and who, in less than 12 consecutive months, increases his/her/its holding of capital or voting rights by at least 1% company's capital or voting rights, shall file a mandatory public tender offer.

Pursuant to the provisions of Article 11 of our bylaws, such individual or legal entity acquiring directly or indirectly, alone or in concert, a number of shares representing a fraction of our capital or voting rights greater than or equal to 2% or a multiple of this percentage, must inform us of the total number of shares and voting rights and securities giving access to capital and voting rights it owns immediately or subsequently within a period of four trading days from the crossing of the said holding thresholds.

The individual or company required to provide the above information shall inform us of the objectives it intends pursuing during the next 12 months when the thresholds are crossed, either upwards or downwards, of a tenth, fifth or third of the capital or voting rights. This declaration specifies whether the purchaser is acting alone or in concert, if it intends stopping its purchases or sales or continuing them, or whether it intends acquiring or transferring control of our company, requesting its nomination or that of one or more other persons, or its registration, as a director of the Board of directors.

In case of failure to declare shares or voting rights exceeding the fraction that should have been declared in accordance with the provisions of Article 11 of our bylaws, such share shall be deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code, if the failure to make the declaration was recorded and if one or more shareholders holding at least 5% of the capital request it, their request being recorded in the minutes of the General Meeting.

Changes in Share Capital

Increases in Share Capital (Article 7 of the Bylaws). Pursuant to French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in our share capital.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; and
- exercising the rights attached to securities giving access to the share capital.

Increases in our share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;

- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; and
- subject to certain conditions, by way of offset against debt incurred by us.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings.

Reduction in Share Capital. Pursuant to French law, any reduction in our share capital requires shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

Preferential Subscription Right. According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights (*droits préférentiel de souscription*) to these securities on a *pro rata* basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe *pro rata* based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, our share capital by means of a cash payment or a set-off of cash debts. The preferential subscription rights are transferable during the subscription period relating to a particular offering. Further, the preferential subscription rights will be transferable during a period starting two days prior to the opening of the subscription period and ending two days prior to the closing of the subscription period.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of our shareholders or individually by each shareholder. Our board of directors and our independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

To the extent permitted under French law, we may seek shareholder approval to waive preferential subscription rights at an extraordinary general shareholders' meeting in order to authorize the board of directors to issue additional shares and/or other securities convertible or exchangeable into shares.

Form, Holding and Transfer of Shares (Articles 9 and 10 of the Bylaws)

Form of Shares. The shares are in registered form, until their full payment. When they are fully paid up, they may be in registered form or bearer, at the option of the shareholders.

Further, in accordance with applicable laws, we may request at any time from the central depository responsible for holding our shares, the information referred to in Article L. 228-2 of the French Commercial Code. Thus, we are, in particular and at any time, entitled to request the name and year of birth or, in the case of a legal entity, the name and the year of incorporation, nationality and address of holders of securities conferring immediate or long-term voting rights at its general meetings of shareholders and the amount of securities owned by each of them and, where applicable, the restrictions that the securities could be affected by.

Holding of Shares. In accordance with French law concerning the "dematerialization" of securities, the ownership rights of shareholders are represented by book entries instead of share certificates. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions.

Ownership of Shares by Non-French Persons. Neither the French Commercial Code nor our bylaws limit the right of non-French residents or non-French shareholders to own or, where applicable, to vote our securities. However,non-French residents must file a declaration for statistical purposes with the Bank of France (Banque de France) within 20 working days following the date of certain direct foreign investments in us, including any purchase of the ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross of such 10% threshold. Moreover, certain foreign investments in

companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

Assignment and Transfer of Shares. Shares are freely negotiable, subject to applicable legal and regulatory provisions. French law notably provides for standstill obligations and prohibition of insider trading.

Forum Selection Provision (Article 44 of the Bylaws)

Our bylaws also include a provision that applies to actions between shareholders and us and between shareholders themselves that are predicated on French corporate law. The competent court is the Commercial Court of Lille. This provision does not apply to actions arising under U.S. federal securities laws. In addition, it is possible that a court could find this provision in our bylaws inapplicable or unenforceable.

Differences in Corporate Law

We are a *société anonyme*, or S.A., incorporated under the laws of France. The laws applicable to French *sociétés anonymes* differ from laws applicable to Delaware corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to us and the Delaware General Corporation Law relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and French law.

	FRANCE	**DELAWARE**
Number of Directors	Under French law, a *société anonyme* must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the bylaws. In addition, the composition of the board of directors endeavors to seek a balanced representation of women and men. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied as well as the deliberations taken by the director irregularly appointed will be null and void. The directors are appointed at theshareholders' general meetings.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws, unless the certificate of incorporation fixes the number of directors.

Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its bylaws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the Chairman of the board of directors), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or bylaws.
Removal of Directors	Under French law, directors may be removed from office, with or without cause, by the shareholders at any shareholders' general meeting without notice or justification, by a simple majority vote.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death, resignation or removal, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification at the shareholders at the next shareholders' general meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors (even though less than a quorum).
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months following the end of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing which, by the statutory auditors, or by a court appointed agent (*mandataire ad hoc*) or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notice of General Meetings	A meeting announcement is published in the French Bulletin of Mandatory Legal Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the shareholders' general meeting. Subject to special legal provisions, the meeting notice is sent out at least 15 days prior to the date of the shareholders' general meeting, by means of a notice inserted both in a newspaper for legal notices (*journal d'annonces légales*) of the registered office department and, if relevant, in the BALO. Further, shareholders holding registered shares for at least a month at the time of the latest insertion of the notice shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice to shareholders holding registered shares may also be transmitted by electronic means of telecommunication, in place of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying their e-mail address. When the shareholders' general meeting cannot deliberate due to lack of required quorum, the second meeting must be called at least ten calendar days in advance in the same manner as used for the first notice. The notice shall specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Trade and Companies (*registre du commerce et des sociétés*), the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting). The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote, the record date for voting if it is different from the record date for determining notice and purpose or purposes of the meeting.

Proxy	Each shareholder has the right to attend the shareholders' general meetings and participate in the discussions (1) personally, or (2) by granting proxy to his/her spouse, his/her partner with whom he/she has entered into a civil union or to another shareholder or to any individual or legal entity of his choosing; or (3) by sending a proxy to the company without indication of the mandate, or (4) by voting by correspondence, or (5) by videoconference or another means of telecommunication in accordance with applicable French laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two shareholders' general meetings, one ordinary, and the other extraordinary, held on the same day or within a period of 15 days.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.
Shareholder Action by Written Consent	Under French law, shareholders' action by written consent is not permitted in a *société anonyme*.	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.
Preemptive Rights	Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights (***droits préférentiel de souscription***) to these securities on a *pro rata* of his/her share ownership unless such rights are waived by a two-thirds majority of the votes held by the shareholders present or represented at the extraordinary general meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such preferential subscription rights have not been waived by the shareholders' extraordinary general meeting, each shareholder may individually either exercise, assign or not exercise its preferential subscription rights. Further, preferential subscription rights may only be exercised during the subscription period. In accordance with French law, the exercise period cannot be less than five trading days in duration. Preferential subscription rights are transferable during the subscription period, but starting two business days prior to the start of the subscription period and ending two business days prior to its closing.	Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock or to any security convertible into such stock.

Sources of Dividends	Under French law, dividends may only be paid by a French *société anonyme* out of distributable profits (*bénéfices distribuables*) plus any distributable reserves and "distributable premium" that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law. "Distributable profits" (*bénéfices distribuables*) consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years. "Distributable premium" refers to the contribution paid by the shareholders in addition to the par value of their ordinary shares for their subscription that the shareholders decide to make available for distribution. Except in case of a share capital reduction, no distribution can be made to the shareholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the company's bylaws.	Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus as defined in and computed in accordance with Delaware law or (2) in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.

Repurchase of Ordinary Shares	Under French law, a corporation may acquire its own ordinary shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes: •to decrease its share capital, provided that such decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at the extraordinary general meeting deciding the capital reduction, in which case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer; •with a view to distributing within one year of their repurchase the relevant shares to employees or managers under a profit-sharing, free share or share option plan; not to exceed 10% of the share capital, in which case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled; or •to meet obligations arising from debt securities, that are exchangeable into equity instruments. A simple exemption is provided when the acquisition is made under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 225-209 of the French Commercial Code and in accordance with the General Regulations of the Financial Markets Authority (*Règlement Général de l'AMF)*. All other purposes, and especially share buy-backs for external growth operations by virtue of Article L. 225-209 of the French Commercial Code, while not forbidden, must be pursued in strict compliance of market manipulations and insider dealing rules. Under the MAR and in accordance with the General Regulations of the AMF, a corporation shall report to the competent authority of the trading venue on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.	Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.

Liability of Directors and Officers	Under French law, the company's bylaws may not include any provisions limiting the liability of directors. Civil liabilities of the directors may be sought for (1) an infringement of laws and regulations applicable to a company, (2) breach of the bylaws and (3) management failure.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: •any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	French law provides that, unless otherwise provided in the bylaws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder. Sinch March 2014, double voting rights are automatically granted to the shares held in registered form (*au nominatif*) for more than two years, unless provided otherwise in the bylaws.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder
Shareholder Vote on Certain Transactions	Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: •the approval of the board of directors; and •approval by a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant shareholders' meeting or, in the case of a merger with a non-EU company, approval of all shareholders of the corporation (by exception, the extraordinary general meeting of the acquiring company may delegate to the Board of Directors authority to decide a merger-absorption or to determine the terms and conditions of the merger plan).	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: •the approval of the board of directors; and •approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

Dissent or Dissenters' Appraisal Rights	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock. Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of merger or consolidation requires the holders to accept for their shares anything other than: •shares of stock of the surviving corporation; •shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders; •cash in lieu of fractional shares of the stock described in the two preceding bullet points; or •any combination of the above. In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.
Standard of Conduct for Directors	French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest (*intérêt social*) taking into consideration the social and environmental aspects of their activity, where applicable.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Shareholder Suits	French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's corporate interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders. The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.	Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must: •state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and •allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or •state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.
Amendment of Certificate of Incorporation	Under French law, corporations are not required to file a certificate of incorporation with the French Registry of Trade and Companies (*registre du commerce et des sociétés*) and only have bylaws (*statuts*) as organizational documents.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: •its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and •the amendment is adopted by the affirmative votes of a majority (or greater percentage as may be specified by the corporation) of the outstanding shares entitled to vote on the amendment and a majority (or greater percentage as may be specified by the corporation) of the outstanding shares of each class or series of stock, if any, entitled to vote on the amendment as a class or series.
Amendment of Bylaws	Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the bylaws.	Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal bylaws. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors

Listing

The ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "GNFT" and our ordinary shares are listed on Euronext Paris under the symbol “GNFT.”

Transfer Agent and Registrar

Uptevia (formerly known as BNP Paribas Securities Services) is the transfer agent and registrar for our ordinary shares. The Bank of New York Mellon is the depositary for our ADSs.

AI. AMERICAN DEPOSITARY SHARES

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

An investor may hold ADSs either (A) directly (i) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs, registered in the investor’s name, or (ii) by having uncertificated ADSs registered in the investor’s name, or (B) indirectly by holding a security entitlement in ADSs through the investor’s broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If an investor holds ADSs directly, he or she is a registered ADS holder, or an ADS holder. The description below assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. French law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will you receive dividends and other distributions on the ordinary shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

Cash. We do not expect to declare or pay any cash dividends or cash distributions on our ordinary shares for the foreseeable future. The depositary will convert any cash dividend or other cash

distribution we pay on the ordinary shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Ordinary Shares. The depositary may distribute additional ADSs representing any ordinary shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell ordinary shares which would require it to deliver a fraction of an ADS (or ADSs representing those ordinary shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new ordinary shares. The depositary may sell a portion of the distributed ordinary shares (or ADSs representing those ordinary shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional ordinary shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse unexercised. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of ordinary shares, new ADSs representing the new ordinary shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, ordinary shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited ordinary share or other security.

The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of France and the provisions of our articles of association or similar documents, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date and we confirm to the depositary that

- we wish to receive a discretionary proxy;
- as of the instruction cutoff date we reasonably do not know of any substantial shareholder opposition to the particular question; and
- the particular question would not be materially adverse to the interests of our shareholders,

then the depositary will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs as to that question.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the ordinary shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting*

rights and there may be nothing you can do if the ordinary shares represented by your ADSs are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

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

Holders of ADSs who wish to obtain double voting rights will need to surrender their ADSs for cancellation at the depositary's office. The depositary will in turn deliver the ordinary shares underlying such ADSs to you, and you must then inscribe those shares directly in registered form within the books of our transfer agent and registrar for the ordinary shares for two consecutive years in order to be entitled to double voting rights.

Except as described above, you will not be able to exercise your right to vote unless you withdraw the ordinary shares. However, you may not know about the shareholder meeting enough in advance to withdraw the ordinary shares.

Fees and Expenses

What fees and expenses will you be responsible for paying?

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

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

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

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate

assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

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

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs,

delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended*.

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our ordinary shares from an exchange on which they were listed and do not list the ordinary shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, *but*, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

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

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;

- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;.
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of ordinary shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Ordinary Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of ordinary shares is blocked to

permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our ordinary shares;

- when you owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.Each holder of ADSs may be required from time to time to provide certain information, including proof of taxpayer status, residence and beneficial ownership (as applicable), from time to time and in a timely manner as we, the depositary or the custodian may deem necessary or proper to fulfill obligations under applicable law.

Governing Law/Jury Trial Waiver

The deposit agreement, the ADSs, and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of France.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY BANK.

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the

depositary's compliance with U.S. federal securities laws or the rules and regulations promulgated thereunder.

Exhibit 4.5

Summary of 2022 Free Shares (AGA) Plans

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

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors, or as delegated to our Chief Executive Officer, determines the list of the beneficiaries, the grant dates, the number of AGA granted and the terms and conditions of the AGA, including their vesting schedule and, if any, lock-up period.

Grants. Our AGA were granted to our Chief Executive Officer and employees of our Company. A total of 58,900 AGA have been granted under two (2) plans in 2022. In 2022, we had one (1) AGA D plan for our Chief Executive Officer (AGA D 2022) and one (1) AGA S plan for employees (AGA S 2022), with different terms and conditions as set out below.

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

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

Standard terms. Our AGA will be definitively granted following a vesting period at the end of which the beneficiary must be effectively present in our Company or its consolidated subsidiaries (subject to exceptions) and subject to the realization of performance conditions that are assessed by our board of directors.

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

	Performance condition(s)	**Assessment date(s) of presence and performance conditions and end of vesting period**	**Lock-up period end date**
AGA D 2022	(i) Internal performance (1) (ii) External performance (2)	October 17, 2025	October 17, 2025
AGA S 2022	Internal performance (1)	October 17, 2025	October 17, 2025

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

Exhibit 4.6

Summary of 2023 Free Shares (AGA) Plans

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

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors determines, or delegates to the Chief Executive Officer to determine, the list of the beneficiaries, the grant dates, the number of AGA granted and the terms and conditions of the AGA, including their vesting schedule and, if any, lock-up period.

Grants. Our AGA were granted to our Chief Executive Officer and employees of our Company. A total of 40,900 AGA have been granted, and 40,100 accepted, under two (2) plans in 2023. In 2023, we had one (1) AGA D plan for our Chief Executive Officer (AGA D 2023) and one (1) AGA S plan for employees (AGA S 2022), with different terms and conditions as set out below.

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

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

Standard terms. Our AGA will be definitively granted following a vesting period at the end of which the beneficiary must be effectively present in our Company or its consolidated subsidiaries (subject to exceptions) and subject to the realization of performance conditions that are assessed by our board of directors.

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

	Performance condition(s)	**Assessment date(s) of presence and performance conditions and end of vesting period**	**Lock-up period end date**
AGA D 2023	(i) Internal performance (1) (ii) External performance (2)	March 14, 2026	March 15, 2026
AGA S 2023	Internal performance (1)	March 14, 2026	March 15, 2026

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

Exhibit 4.11

Summary of the 2022 Stock Options Plans

Stock options (*options de souscription et/ou d'achat d'actions*) are granted for free and entitle each holder to subscribe for new shares and/or purchase existing shares of our Company at an exercise price set at the time of grant.

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors determines the exercise price, the aggregate number of stock options granted and the terms and conditions of the stock options, including the number of shares underlying each stock option, their vesting schedule and exercise period and delegates to the Chief Executive Officer the determination of the list of the beneficiaries and the number of stock options granted to each beneficiary, with the exception of the grant to the Chief Executive Officer, which is decided our board of directors.

Grants. Our stock options were granted to our Chief Executive Officer, executive officers and employees of our Company. A total of 209,375 stock options have been granted and accepted by the beneficiaries under four (4) plans in 2022, with different terms and conditions as set out below. We have one (1) stock option plan for French beneficiaries (SO 2022 C), one (1) stock option plan for our Chief Executive Officer (SO 2022 D), one (1) stock option plan for U.S. beneficiaries that was designed to benefit from the "Incentive Stock Options" status (SO US 2022) and one (1) stock option plan for Swiss beneficiaries (SO SU 2022).

Underlying shares. The securities to which our stock options give rights are new ordinary shares of our Company. The number of ordinary shares to which each stock option gives right is one (1) new ordinary share.

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

Standard terms. Our stock options are exercisable during a period of seven (7) years following a three (3) year vesting period at the end of which the beneficiary must be effectively present in our Company or its consolidated subsidiaries (subject to exceptions) and subject to meeting the performance conditions that are assessed by our board of directors.

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

	Performance conditions	Assessment date(s) of presence and performance conditions	Lock-up period end date	Exercise price
SO 2022 C	Internal performance (1)	October 17, 2025	October 18, 2025	€3.91
SO 2022 D	Internal performance (1) External performance (2)	October 17, 2025	October 18, 2025	€3.12
SO US 2022	Internal performance(1)	October 17, 2025	October 18, 2025	€3.94
SO SU 2022	Internal performance(1)	December 3, 2025	December 4, 2025	€2.95

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

Exhibit 4.12

Summary of the 2023 Stock Options Plans

Stock options (*options de souscription et/ou d'achat d'actions*) are granted for free and entitle each holder to subscribe for new shares and/or purchase existing shares of our Company at an exercise price set at the time of grant.

Administration. Pursuant to delegations granted at our general meeting of the shareholders, our board of directors determines the exercise price, the aggregate number of stock options granted and the terms and conditions of the stock options, including the number of shares underlying each stock option, their vesting schedule and exercise period and delegates to the Chief Executive Officer the determination of the list of the beneficiaries and the number of stock options granted to each beneficiary, with the exception of the grant to the Chief Executive Officer, which is decided our board of directors.

Grants. Our stock options were granted to our Chief Executive Officer, executive officers and employees of our Company. A total of 190,200 stock options have been granted and accepted by the beneficiaries under four (4) plans in 2023, with different terms and conditions as set out below. We have one (1) stock option plan for French beneficiaries (SO 2023 C), one (1) stock option plan for our Chief Executive Officer (SO 2023 D), one (1) stock option plan for U.S. beneficiaries that was designed to benefit from the "Incentive Stock Options" status (SO US 2023) and one (1) stock option plan for Swiss beneficiaries (SO SU 2023).

Underlying shares. The securities to which our stock options give rights are new ordinary shares of our Company. The number of ordinary shares to which each stock option gives right is one (1) new ordinary share.

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

Standard terms. Our stock options are exercisable during a period of seven (7) years following a three (3) year vesting period at the end of which the beneficiary must be effectively present in our Company or its consolidated subsidiaries (subject to exceptions) and subject to meeting the performance conditions that are assessed by our board of directors.

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

	Performance conditions	Assessment date(s) of presence and performance conditions	Lock-up period end date	Exercise price
SO 2023 C	Internal performance (1)	March 13, 2026	March 14, 2026	€3.26
SO 2023 D	Internal performance (1) External performance(2)	March 13, 2026	March 14, 2026	€4.07
SO US 2023	Internal performance(1)	March 13, 2026	March 14, 2026	€4.05
SO SU 2023	Internal performance (1)	March 13, 2026	March 14, 2026	€3.26

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

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

Exhibit 4.16
Execution Version

SHARE PURCHASE AGREEMENT

dated September 29, 2022

between

[***]

(the "**Seller 1**")

[***]

(the "**Seller 2**")

[***]

(the "**Seller 3**")

[***]

(the "**Seller 4**")

[***]

(the "**Seller 5**")

[***]

(the "**Seller 6**")

[***]

(the "**Seller 7**")

[***]

(the "**Seller 8**")

[***]

(the "**Seller 9**")

[***]

(the "**Seller 10**")

[***]

(the "**Seller 11**")

[***]

(the "**Seller 12**")

[***]

(the "**Seller 13**")

[***]

(the "**Seller 14**")

[***]

(the "**Seller 15**")

[***]

(the "**Seller 16**")

[***]

(the "**Seller 17**")

[***]

(the "**Seller 18**")

[***]

(the "**Seller 19**")

[***]

(the "**Seller 20**")

[***]

(the "**Seller 21**")

[***]

(the "**Seller 22**")

[***]

(the "**Seller 23**")

[***]

(the "**Seller 24**")

[***]

(the "**Seller 25**")

[***]

(the "**Seller 26**")

(the Sellers 1 through 26 each a "**Seller**" and collectively the "**Sellers**")

and

GENFIT SA, company number 424 341 907 RCS. Lille Métropole
885 avenue Eugène Avinée Parc Eurasanté 59120 Loos

(the "**Buyer**")

(each of the Sellers and the Buyer each a "**Party**" and collectively the "**Parties**")

and

VISCHER AG
Aeschenvorstadt 4, 4010 Basel, Switzerland

(the "**Sellers' Representative**")

regarding the sale and purchase of all shares and options in
Versantis AG, Zurich, Switzerland

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PREAMBLE

A. Versantis AG is a stock corporation incorporated under the laws of Switzerland, registered under no. CHE-269.651.272 in the commercial register of the canton of Zurich, with registered office at Technoparkstrasse 1, 8005 Zurich, Switzerland (the "**Company**"). The Company has a fully paid-in share capital of CHF 343'484.00 divided into (i) 109'437 registered common shares with a nominal value of CHF 1 each (the "**Common Shares**"), (ii) 117'382 registered series A preferred shares with a nominal value of CHF 1 each (the "**Series A Preferred Shares**") and (iii) 116'665 registered series B preferred shares with a nominal value of CHF 1 each (the "**Series B Preferred Shares**" and together with the Series A Preferred Shares, the "**Preferred Shares**") (the Common Shares, the Series A Preferred Shares and the Series B Preferred Shares, collectively, the "**Shares**" and each individually a "**Share**").

B. The Sellers 1 through 17 are the legal owners of all Shares as set forth in Annex 0, save for 12'063 treasury shares which are owned by the Company. The Sellers 1, 2, 5

and 18 through 26 are the legal owners of all [***] Options as set forth in Annex 0 (collectively, the "**Options**" and each individually an "**Option)**".

C. The Company directly owns all 1'000 shares of common stock with a par value of USD 0.00001 per share in Versantis, Inc., a Delaware corporation.

D. The Buyer is a stock corporation incorporated under the laws of France, registered in the commercial register of Lille, France under the number 424 341 907, with registered office at 885 avenue Eugène Avinée Parc Eurasanté, 59120 Loos, France.

E. The Sellers individually intend to sell and, at the Closing Date, to transfer to the Buyer and the Buyer intends to buy and, at the Closing Date, to receive from the Sellers, all the Shares and all the Options, it being understood that certain Options shall be cancelled in accordance with Section 2.2.

F. Prior to the execution of this Agreement, the Buyer conducted a comprehensive due diligence on the Group Companies, their businesses and operations. In this context, the Buyer reviewed, inter alia, the information made available to the Buyer.

G. On [***] the Parties have entered into that certain negotiation and exclusivity agreement (the "**NEA**").

Therefore, the Parties have come to the following agreement (together with this Preamble and all Annexes the "**Agreement**"):

1. DEFINITIONS

Capitalized terms used in this Agreement shall have the meaning assigned to such terms in Annex 1.

2. OBJECT OF PURCHASE

2.1 Shares

Subject to the terms and conditions of this Agreement, each Seller holding Shares hereby agrees to sell and, at the Closing Date, to transfer to the Buyer, and the Buyer hereby agrees to purchase and accept from such Sellers, all the Shares at the Purchase Price as listed opposite the name of each such Seller in Annex 0.

2.2 Options

Subject to the terms and conditions of this Agreement, each Seller (other than a U.S. Seller) holding Options hereby agrees to sell at the Closing Date to the Buyer, and the Buyer hereby agrees to purchase from such Sellers, all the Options at the Purchase Price as listed opposite the name of each such Seller in Annex 0. The Company hereby agrees to such transfer. In addition, subject to the terms and conditions of this Agreement, each U.S. Seller holding Options hereby agrees to the cancellation of such Options (the "**U.S. Holder Options**") at the Closing Date in

exchange for the Purchase Price as listed opposite the name of each such U.S. Seller in Annex 0. The Company hereby agrees to such cancellation. For purposes of this Agreement, the "**U.S. Sellers**" are Seller 21 and Seller 26.

2.3 Benefit and Risk

The economic benefit and risk (*Nutzen und Gefahr*) with respect to the Shares and Options, respectively, shall pass to the Buyer with effect as of the Closing Date. Subject to Closing occurring, article 185 para. 3 of the CO is hereby expressly waived by the Parties.

2.4 Treatment of Options and Employee Shares

1.1.1 Purchase Price Treatment

For the Purchase Price for (i) each Option, (ii) each Common Share marked accordingly in Annex 0, the sale of which qualifies as income from employment (*unselbständige Erwerbstätigkeit*) as indicated in Annex 0 (the "**Employee Shares**") and (iii) each U.S. Holder Option, the following principles apply:

A) Options: each holder of Options (other than U.S. Sellers) shall have the right to receive from the Company as gross salary payment (i) an amount equal to the pay-out for a Common Share of the Base Purchase Price per Option net of the applicable Deductions in accordance with Section 2.4.3 less the applicable strike price and less any applicable employee portion of the Deductions (as defined below), as listed opposite the name of each such holder of Options in Annex 0 plus (ii) an amount equal to the pay-out for a Common Share per Option of any Milestone Payments less any applicable employee portion of the Deductions.

B) Employee Shares: each holder of Employee Shares shall have the right to receive, with respect to each Employee Share, the pay-out for a Common Share of the Base Purchase Price in accordance with this Agreement less any applicable employee portion of the Deductions plus an amount equal to the pay-out for a Common Share of any Milestone Payments less any applicable employee portion of the Deductions.

C) U.S. Holder Options: each U.S. Seller that holds U.S. Holder Options shall have the right to receive from the Company (i) an amount equal to the pay-out for a Common Share of the Base Purchase Price per Option in accordance with this Agreement less the applicable strike price and less any applicable employee portion of the Deductions, plus (ii) an amount equal to the pay-out for a Common Share per Option of any Milestone Payments, less any applicable employee portion of the Deductions. It is the intention of the Parties that, as of the Closing Date, any Milestone Payments shall be deemed subject to a substantial risk of forfeiture until such amounts become due and payable hereunder for U.S. tax purposes.

D) Employer Portion of Deductions: The aggregate applicable portion of the Deductions required to be contributed to the relevant authorities by the employer in connection with the sale of Options and Employee Shares and the cancellation of the U.S. Holder Options contemplated under this Agreement and the respective payments by the employer to the respective holder of Options and Employee Shares on the account of the employer (employer portion) shall be deducted from the relevant Base Purchase Price component (being the Initial Consideration (as defined below) and the Adjustment Amount (as defined below)) and the Milestone Payments, respectively and, thereby, are economically borne by all the Sellers. Such employer Deductions shall be paid to the Company Account (as defined below) in accordance with the procedures set forth in Section 2.4.3. The employer part of Deductions are treated like Transaction Costs reducing the overall payout.

1.1.2 Tax Deductions

Any applicable social security or pension contributions by the employer and the employee, any salary withholding tax (*Quellensteuer*) and any other Tax and other similar salary deductions required to be made and, for U.S. Sellers only, any applicable U.S. withholding Taxes, including the employer and employee portion of payroll Taxes (together the "**Deductions**") shall - when making the payment of the Base Purchase Price or any Milestone Payment - be deducted from such payment. All Deductions shall be calculated and made in accordance with the applicable legislation and practice by the competent authorities at the time of payment.

Annex 2.4.2 contains a calculation of the Deductions on the Initial Consideration and a sample calculation of the Deductions on the Adjustment Amount. Deductions in relation to the Initial Consideration to be made by the Company, shown as separate items as employer portion and employee portion is on page 1 of the Annex 2.4.2, and as aggregate figure on in the last section of Annex 3.2. Deductions to be made by Versantis Inc, are shown on page 2-4 of the Annex 2.4.2, and as aggregate figure on in the last section of Annex 3.2.

For the (final) Adjustment Amount and any Milestone Payments the applicable Deductions shall be determined by the Company and the Buyer in a way consistent with the process used in Annex 2.4.2 based on the net pay-out applicable to the Options, Employee Shares or U.S. Holder Options, respectively, in an amount determined in accordance with Section 2.4.1, subsection a), b) or c), respectively, as communicated by the Sellers' Representative upon request, it being understood that such an amount equal to the pay-out for a Common Share of the Base Purchase Price per Option net of the applicable Deductions in accordance with Section 2.4.3 less the applicable strike price and less any applicable employee portion of the Deductions, as listed opposite the name of each such holder of Options in Annex 0.

1.1.3 Purchase Price Payment Process

A) Base Purchase Price: The Buyer shall pay the Base Purchase Price to the Sellers' Representative Bank Account as per Section 3.3 net of the applicable Deductions and, and pay the applicable Deductions to the Company's bank account (the "**Company Account**") set forth in Annex 2.4.3a) and cause the Company (or the applicable Affiliate thereof) to pay the employer and employee portion of the Deductions to the relevant authorities.

B) Milestone Payment: The Buyer shall pay the relevant Milestone Payment to the Sellers' Representative Bank Account net of any applicable Deductions, pay the applicable Deductions to the Company Account (or the applicable account of an Affiliate thereof) and cause the Company (or the applicable Affiliate thereof) to pay the employer and employee portion of the applicable Deductions to the relevant authorities.

C) [***]

D) Options and Employee Shares: The Parties record that payment of the Base Purchase Price and the Milestone Payments, respectively, for the Options (excluding U.S. Holder Options) and the Employee Shares respectively, by the Buyer in accordance with Sub-Sections a) and b) constitutes a salary payment by the Company to the respective holder and employee.

E) U.S. Holder Options: Upon the Company (or the applicable Affiliate of the Company) having received the U.S. Sellers' individual portion of the Base Purchase Price and Milestone Payments respectively (in each case net of the employer portion of any applicable Deductions which will be deducted from the respective Purchase Price payable to all Sellers), the Company (or the applicable Affiliate of the Company) shall deduct from such individual allocated amount any applicable withholding Tax and pay the outstanding amount to the U.S. Sellers. The Buyer shall cause the Company (or the applicable Affiliate thereof) to pay the employer and employee portion of such Deductions to the relevant authorities.

F) Tax Ruling: If the Tax authorities have not formally approved the Tax Ruling requested regarding [***], the Sellers' Representative shall withhold [***] from their respective portion of the Initial Consideration (i.e. an amount which is equal to the maximum possible Deductions) and (once paid) [***] from their respective portion of the Adjustment Amount and [***] from their respective portion of any Milestone Payment (or such higher or lower percentage of Deductions as required by law from time to time) until a final assessment by the competent tax authorities [***]. If the payments for the Common Shares held by Sellers 1 and 2, respectively, are qualified as employment income or employment income subject to social security deductions in a final and not

appealable tax or social security assessment, [***] are treated as Employee Shares in accordance with this Agreement. The Sellers' Representative shall pay the withheld amount of Deductions to the Company Account and the Buyer shall cause the Company to pay the employer and employee portion of the Deductions to the relevant authorities. If the final assessment confirms that the payment in relation to [***] do not constitute employment income, the Sellers's representative shall release the respective withheld amounts to Sellers 1 and 2. If the Company receives an assessment from the Tax or social security authorities, the Buyer shall promptly notify the Sellers' Representative and shall appeal upon request of the Sellers' Representative such decision by either authorizing the Sellers' Representative or submitting the factual and legal arguments submitted by the Sellers' Representative; the fees of such procedures shall be advanced and covered by the Seller(s) 1 and/or 2.

2.5 Waiver

Each of the Sellers hereby expressly and irrevocably agrees, solely for the benefit of the other Sellers that (a) the methodology set forth in this Section 2 for determining the consideration payable to such Seller is, in all respects, consistent and in accordance with the Company's articles of association, the Stock Option and Incentive Plan Regulation 2018, the SHA, the IA and applicable law, (b) Annex 0 is complete and accurate in all respects and was calculated pursuant to and in accordance with this Section 2, the Company's articles of association, the Stock Option and Incentive Plan Regulation 2018, the SHA, the IA and applicable Law and (c) payment of the amounts of the Purchase Price in accordance with this Agreement shall satisfy all rights of such Seller under the Company's articles of association, the Stock Option and Incentive Plan Regulation 2018, the SHA, the IA and applicable law in connection with the transactions contemplated in this Agreement.

Each of the Sellers hereby agrees for the benefit of the Buyer that payment of the Purchase Price by the Buyer and (in case of the U.S. Holder Options) the Company, respectively, in accordance with the procedures set forth in this Agreement to the Sellers' Representative and the Company, respectively, are deemed to be in full performance and discharge of the obligations regarding the Purchase Price of the Buyer and the Company, respectively, towards such Seller.

3. PURCHASE PRICE

3.1 Amount

The purchase price for all the Shares and the Options shall be calculated as follows (the "**Purchase Price**"):

A) an initial consideration of CHF 40'000'000.00 (the "**Initial Consideration**");

plus

B) the aggregate amount of Cash as of the Closing Date plus: (i) all VS-01 Phase II costs incurred for the period starting [***], and paid until Closing, and (ii) all Company Group salary costs (including employer portion of any applicable social security for the period starting [***] until Closing, as listed on a best efforts basis in Annex 3.2;

minus

C) the aggregate amount of Debt as of the Closing Date less all VS-01 Phase II costs incurred for the period starting [***], and not yet paid as at the Closing Date, as a listed on a best efforts basis in Annex 3.2;

plus

D) the Milestone Payments, payable as set forth in Section 4.2.

The Initial Consideration plus the Adjustment Amount (as defined below) is hereinafter referred to as the "**Base Purchase Price**".

3.2 Calculation of Base Purchase Price

Annex 3.2 sets forth the good faith estimation of the Base Purchase Price and Adjustment Amount on the basis of Sections 3.1a) to c) indicating the items which are agreed and final and the items which will need to be updated, whereby in the calculation of Cash and Debt the items which are in agreed and final form are reflected as such. Annex 3.2 further sets out on a best efforts basis all VS-01 Phase II related items, it being understood that certain activities are ongoing.

3.3 Payment of Initial Consideration at Closing

At the Closing Date, the Buyer shall pay the Initial Consideration of CHF 40'000'000 (forty million Swiss francs) less Deductions in connection with the holders of Options and U.S. Options, respectively, and Employee Shares pursuant to Section 2.4 (for clarity the Deductions due thereon as set out in Annex 2.4.2 shall be simultaneously paid to the Company Account), to the bank account of the Sellers' Representative as set forth in Annex 3.3 (the "**Sellers' Representative Bank Account**"), in cash, in CHF, without any further deductions or set-off, by wire transfer in immediately available funds, with value date being the Closing Date.

The Sellers are not obliged to consummate the transactions contemplated hereunder unless the entire Initial Consideration is fully paid at Closing.

Payment to the Seller's Representative and the Company’s bank account of the amounts in accordance with this Section 3.3 shall fully discharge the Buyer from the obligation to pay the Initial Consideration and the Buyer shall have no responsibility for the internal allocation among the Sellers.

3.4 Waiver by Sellers

Upon Closing (i) all claims of any nature whatsoever, if any, of Sellers or any of their Related Persons against any Group Company shall be deemed fully and finally settled and (ii) each Seller shall not, and shall procure that none of their Related Persons will, raise claims against any Group Company. Subject to the occurrence of Closing, each Seller hereby irrevocably waives all claims of any nature whatsoever against any Group Company with effect as of Closing. Notwithstanding the above, the two preceding sentences shall not apply to any and all claims (x) a Seller or a Seller Related Party may have in their capacity as employee, director or consultant of a Group Company, under their respective written contract disclosed to the Buyer prior to the date hereof and referred to in Annex 6.17d) to the extent such contract has not been terminated as a result of Closing, (y) Seller 26 may have under the [***] and (z) the [***] may have under the [***], entered into in writing with the Company and attached as Annex 5.2e).

3.5 Payment of Adjustment Amount

Upon completion of the post-closing procedures pursuant to Section 3.6 (Post-Closing Determination of Adjustment Amount), Buyer shall pay the difference between the Initial Consideration and the Base Purchase Price as adjusted pursuant to Section 3.6 and corresponding to Cash minus Debt (the "**Adjustment Amount**") net of Deductions to the Sellers' Representative Bank Account and the respective Deductions to the Company Account.

1.1 Post-Closing Determination of Adjustment Amount

1.6.1 Closing Accounts

A) After the Closing, the Buyer shall cause the Company to establish and deliver to the Sellers' Representative within [***] calendar days after the Closing Date the calculation of the Adjustment Amount as per the Closing Date 9 (the "**Proposed Adjustment Amount**"), calculated in accordance with Annex 3.2.

B) The Sellers shall cooperate with, and support, the Buyer in connection with the determination of the Adjustment Amount.

C) The Buyer shall cause the Group Companies to give the Sellers' Representative and its advisors reasonably prompt access during regular business hours to the records, accounts and other information of relevance for the preparation and conduct of their review of the calculation of the Base Purchase Price and the Proposed Adjustment Amount and, if applicable, in the event of any subsequent objection and appraiser procedure pursuant to Section 3.6.2.

D) Unless the Sellers' Representative gives written notice (the "**Notice of Objection**") to the Buyer within [***] Business Days following receipt of the calculation of the Base Purchase Price and the Proposed Adjustment Amount that they disagree with any specific item set forth in the calculation of the Base

Purchase Price or the Proposed Adjustment Amount, stating in such notice in reasonable detail the reasons for their objections and their proposed calculation and amounts of such item (collectively, the "**Disputed Items**"), the calculation of the Base Purchase Price and the Proposed Adjustment Amount and all calculations set forth therein shall be deemed final and binding on the Parties for all purposes hereunder (upon becoming final and binding in accordance with this Section 3.6, the "**Final Adjustment Amount**", respectively).

1.1.1 Disputed Items

A) If the Sellers' Representative delivers a Notice of Objection in accordance with Section 3.6.1d), the Parties shall use reasonable endeavors in good faith to resolve any objection of the Sellers' Representative within [***] Business Days after the Buyer's receipt of the Notice of Objection. If, during such period, the Parties agree upon any of the Disputed Items, the Proposed Adjustment Amount shall be adjusted to reflect such agreement and shall become final and binding for all purposes hereunder. If the Parties are unable to reach such agreement on all Disputed Items in accordance with this Section 3.6.2, they shall promptly thereafter engage [***], or, if [***], is unable to serve [***], and if [***] is unable to serve and the Parties are unable to agree within [***] Business Days on another firm of independent certified public accountants of internationally recognized standing, a person nominated (directly or indirectly) by the president of the Zurich Chamber of Commerce upon the application of either the Sellers' Representative or the Buyer, to review the then remaining Disputed Items of the calculation of the Proposed Adjustment Amount (the "**Appraiser**"). In so doing, the Appraiser shall act as an expert (*Schiedsgutachter*) as that term is defined in article 189 of the Swiss Code of Civil Procedure, and not as an arbitrator, and its determination of any subject matter falling within the scope of its mandate shall be final and binding on the Parties, except in the event of manifest error on the part of the Appraiser (as a consequence of which the relevant part of its determination shall be void and the matter be remitted to the Appraiser for correction). The Appraiser shall consider only those Disputed Items that are not resolved by the Parties in accordance with this Section 3.6.2, and shall resolve each such remaining Disputed Item within the range of calculations proposed by the Parties. In determining the Disputed Items, the Appraiser shall limit its review to the written submissions of the Parties with respect to the Disputed Items.

B) The Sellers and the Buyer shall procure that the Appraiser will be furnished with all documents and information reasonably requested by the Appraiser for purposes of preparing and reviewing the calculations of the Disputed Items. Except to the extent that the Parties agree otherwise in writing, the Appraiser shall determine its own procedure, but apart from procedural matters and as

otherwise set out in this Agreement shall determine only whether the Disputed Items as set forth in the calculation of the Proposed Adjustment Amount are correct and in accordance with this Section 3.6; and if not so, what alterations should be made to the calculation of the Proposed Adjustment Amount or any specific items set forth therein in order to correct the relevant inaccuracy of such specific items.

C) The Sellers' Representative and the Buyer shall direct the Appraiser to prepare a report setting forth its calculation of the remaining Disputed Items in accordance with this Section 3.6 as soon as is reasonably practicable, but not later than [***] Business Days from the date of its appointment (provided that, for clarity, a delay shall not render the Appraiser's opinion ineffective).

D) The procedure of the Appraiser shall comply with the principles of due process and shall in particular:

A) give the Parties a reasonable opportunity to make written and, if so requested by a Party, oral presentations to it;

B) require that each Party supply the other with a copy of any written presentations at the same time as they are made to the Appraiser;

C) permit each Party to be present while oral submissions, if any, are being made by the other Party; and

D) be conducted in English.

E) Each Party and the Appraiser shall, and shall procure that its employees, accountants, assistants and other advisors will, keep all information and documents provided to them in accordance with this Section 3.6 confidential and shall not use the same for any purpose, except for disclosure or use in connection with the preparation of the Final Adjustment Amount, the proceedings before the Appraiser or otherwise in connection with the determination of the Final Adjustment Amount.

F) The costs and expenses (including VAT) of the Appraiser shall be allocated by the Appraiser between the Sellers and the Buyer [***] in the proceedings before the Appraiser. The Sellers on the one side and the Buyer on the other side shall pay in equal shares (i.e. the Sellers 50% and the Buyer 50%) advances on costs and expenses as the Appraiser may request.

1.6.2 Adjustment Amount

A) The Buyer shall pay an amount equaling the difference between the Base Purchase Price and the Initial Consideration (net of any applicable Deductions) to the Sellers' Representative Bank Account pursuant to Section 3.5 with the applicable Deductions paid to the Company Account.

B) If the Initial Consideration is higher than the Base Purchase Price according to the Final Adjustment Amount, Buyer may deduct any such difference due in favor of Buyer from [***].

4. MILESTONE PAYMENTS

4.1 In General

Each Milestone Payment shall be due and payable to the Sellers within [***] following the date on which the Sellers' Representative (on behalf of the Sellers) has received a notice from the Buyer informing them that the particular Milestone Event has been achieved, which notification by the Buyer shall be deemed made on the earlier to occur of: (i) the date of the Buyer's public announcement of the Milestone Event or (ii) if the Milestone Event is not publicly announced, a date that is no later than [***] after the Milestone Event has been achieved (the "**Milestone Notice Date**"). It is hereby understood that each Milestone Payment shall be paid only once and that the Buyer is released from any and all obligations under this Agreement with respect to each Milestone Payment upon payment in accordance with Section 2.4.3b). The total of all Milestone Payments is set at CHF 65 (sixty-five) million plus one third of the Net Proceeds (as defined below) resulting from the sale of the pediatric review voucher of VS-01 pediatric application.

Any Milestone Payment due to any Seller shall be paid, at the discretion of the Buyer, (i) in cash by wire transfer of immediately available funds or (ii) [***] (less Deductions pursuant to Section 2.4.3c) and subject to (y) sufficient [***] in the Buyer being immediately at the Buyer's free disposal and (z) the terms set forth in Section 2.4.3c), in each case to a bank or [***] account designated by the Party receiving the Milestone Payment or the Sellers' Representative on their behalf. For purposes of converting the Milestone Payment due to Sellers to [***] of the Buyer, the price [***] of the Buyer shall correspond to [***].

4.2 Milestone Events and Milestone Payments

As of the Closing Date, the Sellers shall be entitled to the following one-time, non-refundable, non-creditable milestone payments (each, a "**Milestone Payment**") upon achievement of the milestones as set forth below (each, a "**Milestone Event**"):

A) Milestone Payment of [***] in case of positive phase II clinical trial results in acute-on-chronic liver failure ("**ACLF**"). Positive phase II clinical trial results in ACLF means [***]. If VS-01 receives Regulatory Approval in ACLF, this Milestone-Event is deemed automatically achieved;

B) Milestone Payment of [***] in case of receipt of the first Regulatory Approval for the drug candidate VS-01. "**Regulatory Approval**" means, in any of the countries or jurisdictions listed under letters (a), (b) or (c) below, any approval, registration, license, or authorization that is required by the applicable

Governmental Authority to market and sell the Product in such countries or jurisdictions: [***];

C) Milestone Payment of [***] in case of Positive Phase II Clinical Trial Results in the first Liver Disease indication [***] in which VS-02 will be developed [***].

"**Positive Phase II Clinical Trial Results**" in the first Liver Disease indication (including, but not limited to [***]) in which VS-02 will be developed means phase II clinical trial results where [***]. If VS-02 receives Regulatory Approval in the first indication studied in phase II, this milestone is deemed automatically achieved; and

D) Milestone Payment in an amount equaling one third of the Net Proceeds in the event of a sale of the pediatric review voucher ("**PRV**") of VS-01 pediatric application or any active ingredients thereof. For the purpose of this Agreement the term "**Net Proceeds**" shall mean the aggregate sales price, less [***]. For clarity, in the event Buyer uses the PRV for an application relating to one of its own internal programs the Milestone Payment shall be equal to 1/3 of the then fair market value ([***]) of the PRV is paid to the Sellers hereunder.

4.3 Efforts to achieve the Milestone

A) The Buyer shall, and shall procure that the Company will, either directly or indirectly through an Affiliate or a third party, use Commercially Reasonable Efforts to reach each of the Milestones. Subject to the Buyer complying with its obligations under this Section 4.3a), it is agreed and understood that nothing in this Section or in the SPA shall prevent the Buyer and/or the Company, either directly or indirectly through an Affiliate, from acquiring products/technologies in the same, or in a similar, therapeutic area as that of the Products. The term "**Commercially Reasonable Efforts**" as used in this Section means that the Buyer shall, and shall procure that the Company will use at least comparable efforts, including without limitation [***].

B) In case of a Change of Control event or an exclusive licensing or a transfer of ownership of VS-01 or VS-02 to a third party for the territory of the USA or European Union, Buyer shall ensure that the Buyer's obligations under this Section 4.3a) are assumed by such third party.

4.4 Reporting and Assessment

A) As long as the Milestone Events for a respective Product are not reached, the Buyer shall, and shall procure that the Company will, deliver to the Sellers' Representative a report on clinical and regulatory development of the Products twice a year on [***] and [***], substantially in the form of Annex 4.4.

B) Without restricting the above paragraph, the Buyer shall inform the Sellers' Representative promptly, but in no event later than [***] following the occurrence of any event having a material adverse impact on any Milestone Event including, for clarity, [***].

C) In the event that a number of Sellers representing together at least a simple majority (50% plus 1) of the Shares and Options (including any Employee

Shares and U.S. Options) sold to the Buyer under this Agreement (the "**Sellers' Majority**") reasonably believes that the Buyer may potentially be in breach of its obligations under this Section 4.3, the Sellers' Representative may, if so instructed by the Sellers' Majority, request the Buyer at a maximum [***] per calendar year to respond to a specific set of questions. The Sellers' Representative shall share the answers to such questions only with persons representing Sellers who have been pre-approved by the Buyer and have signed confidentiality agreements in form and substance satisfactory to the Buyer. If the Sellers' Representative deems the answers provided as unsatisfactory, the Sellers' Representative may demand again not more than [***] per calendar year that the Buyer make available to a reputable third party (the "**Expert**") to review relevant documents to determine the facts relevant for the assessment whether the Buyer is in breach under Section 4.3 (whereby not disclosing a document to the Expert shall not be deemed a breach of this Agreement). The Expert shall be acceptable to the Buyer (such consent not to be unreasonably withheld, conditioned or delayed) and must enter a confidentiality agreement with the Buyer in form and substance satisfactory to the Buyer. The Expert shall first share his conclusions with the Buyer who may block the release of such information based on the ground that such information constitutes proprietary business secrets of the Company. Any information approved by the Buyer (including the information whether any information has been blocked) shall be released to the Sellers' Representative and those persons representing Sellers who have been pre-approved by the Buyer and have signed confidentiality agreements in form and substance satisfactory to the Buyer. The Expert's costs shall be borne by the Sellers, unless the Expert concludes that the information provided by the Buyer has been materially incorrect or incomplete in which instance the Expert's costs shall be borne by the Buyer.

D) If the Buyer and Sellers' Representative are unable to resolve any dispute, each Party may defer the dispute to arbitration according to Section 12.2 (Arbitration) below. For clarity, only the arbitral court shall have the authority to force the Buyer to submit information, which the Buyer had refused to disclose at the Expert's request.

4.5 Transfer of Claims to a Milestone Payment

If a Seller wishes to transfer its entitlement to receive a portion of the claim to a Milestone Payment to another person or entity, such Seller shall notify the Sellers' Representative who will in turn inform the Buyer thereof. The following rules shall apply to such a transfer:

A) if the Seller is a legal entity, such Seller shall be entitled to transfer its claim to a Milestone Payment (i), upon notification to the Buyer, to such Seller's

Affiliate, or (i) to any other Seller or, (iii) if the Seller is winding down its activities and/or distributing liquidation proceeds, to such Seller's legal or economic successor or stakeholders or (iv) if such Seller is winding down its activities and/or distributing liquidation proceeds to any third party other than (y) a direct competitor the Buyer or the Company or (x) an entity operating in any Sanctioned Country or otherwise meeting the criteria in Section 6.18(e)(ii) herein, or (iv), subject to the Buyer's prior consent (not to be unreasonably withheld, conditioned or delayed), to a third party.

B) if the Seller is an individual, such Seller shall be entitled to transfer its claim to a Milestone Payment (i), upon notification to the Sellers' Representative, to such Seller's heirs or beneficiaries as part of the Seller's estate planning or to any other Seller or (ii), subject to the Buyer's consent (not to be unreasonably withheld, conditioned or delayed), to a third party.

5. CLOSING

5.1 Date and Place of Closing

Subject to the terms and conditions of this Agreement, the consummation of the transactions contemplated in Sections 5.2 and 5.3 (the "**Closing**") occur on the date hereof being the date on which the Closing actually occurs, as provided for in this Section 5 (the "**Closing Date**"). The Closing shall take place at the offices of VISCHER AG in Zurich, or at such other location as the Parties may agree.

5.2 Closing Actions by the Sellers

At the Closing, the Sellers shall simultaneously (*Zug um Zug*) with the closing actions of the Buyer pursuant to Section 5.3 deliver to the Buyer:

A) a power of attorney (certified copy) under which any of the documents referred to in this Section 5.2 are executed, including evidence reasonably satisfactory to the Buyer of the authority of any Person signing on behalf of the Sellers;

B) written assignment declarations (in form and substance reasonably satisfactory to the Buyer) duly signed by the respective Seller (and acknowledged by the Company) or its attorney assigning all outstanding Shares or Options (excluding the U.S. Options which are deemed cancelled as per the Closing Date) held by such Seller to the Buyer;

C) a board resolution of the Company (in form and substance reasonably satisfactory to the Buyer) approving, subject to the occurrence of Closing, (i) the transfer of the Shares from the Sellers to the Buyer and the registration of the Buyer in the Company's share register (original), (ii) the cancellation of the U.S. Options and transfer of any outstanding and vested Options from the Sellers to the Buyer;

D) the combined share register and register of beneficial owners of the Company evidencing the Buyer as the sole shareholder in the Company, save for the treasury shares owned by the Company (original);

E) a copy of the executed transfer agreements between [***] and the Company related to the sale and transfer of the intellectual property relating to VS-01 and VS-02 (the "**IP Transfer Agreements**") and the executed license agreement amendment between [***] and the Company relating to TS-01 as per the forms set forth in Annex 5.2e);

F) transfer deeds duly signed by [***] reflecting the transfer of intellectual property under the IP Transfer Agreements to the Company and evidence satisfactory to the Buyer that the respective purchase price has been paid to [***];

G) duly signed separation agreement and release of claims (the "**CEO Separation Agreement**") between the CEO and the Company and the US subsidiary as per the form set forth in Annex 5.2g);

H) duly signed addendum to the engagement letter with Torreya Partners (Europe) LLP which confirms that (i) the Sellers agree to assume payment of all transaction fees that the Company is obligated to pay under such letter and (ii) Torreya Partners (Europe) LLP releases the Company from the payment obligation which is assumed and paid by the Sellers as set forth in Annex 5.2h) an all other obligations of the Company under or in connection with such engagement letter) and a written confirmation by Vischer AG that its fees are paid by the Sellers and that the Company is released from all obligations in connections with its engagement; and

I) duly signed resignation letters, effective as of Closing, of all members of the board of directors of the Company, with the exception of Vincent Forster, and Meriam Kabbaj, who shall continue serving as a member of such board.

5.3 Closing Actions by the Buyer

At the Closing, the Buyer shall simultaneously (*Zug um Zug*) with the closing actions of the Sellers pursuant to Section 5.2:

A) deliver to the Sellers' Representative a power of attorney under which any of the documents referred to in this Section 5.3 are executed, including evidence reasonably satisfactory to the Sellers of the authority of any person signing on behalf of the Buyer, including a passport copy of any such person, a Kbis extract of the Buyer and resolutions of the board of directors of the Buyer (copy);

B) deliver to the Sellers' Representative a notification of beneficial owners in the agreed form in accordance with article 697j CO); and

C) pay the Initial Consideration in accordance with Section 3.3 confirmed by the recipient bank (copy).

5.4 Simultaneous Closing Actions

The Parties agree that the closing actions pursuant to Sections 5.2 and 5.3 shall take place simultaneously and that the transactions contemplated by this Agreement shall only be completed if all said transactions have happened in accordance with the provisions hereof.

If the Closing cannot be completed and the respective missing closing action has not been waived by the respective Party in writing, then all closing actions or declarations that have already been made or fulfilled shall be deemed null and void (but without affecting the validity and binding effect of this Agreement). In this event, the Parties undertake to reinstate forthwith the status as it was immediately before the Closing and to return, retransfer and reassign respectively any documents delivered or any payments or assets already transferred prior to or during the Closing.

5.5 Closing Memorandum

The Parties record that they have signed a closing memorandum which documents the closing actions undertaken pursuant to Sections 5.2 and 5.3 above.

6. REPRESENTATIONS OF EACH SELLER

Subject to the limitations set forth in Section 8, each Seller hereby represents and warrants individually (but not jointly or jointly and severally) to the Buyer that the representations and warranties as set forth in this Section 6 (*Representations of the Sellers*) are true and correct as of the date of Signing the NEA (except to the extent such representations and warranties relate to the IP Transfer Agreement and the IP License Agreement) and Closing Date, it being understood that the representations made under Sections 6.1 and 6.2 (the "**Fundamental Warranties**") are made by each Seller with respect to himself/herself/itself exclusively.

6.1 Title to the Shares and Options; Capital of the Company

A) Each Seller (excluding Seller 15) is the sole legal and economic owner of the Shares and Options, respectively, set forth against its/his/her name in Annex 0 free and clear of any Liens and has the full right to sell, convey and deliver these Shares and Options, respectively, free and clear of any Liens and the Buyer will at Closing receive good and valid title to such Shares and Options, respectively, free and clear of any Liens, with the exception of the Options of the U.S. Sellers which are being cancelled at Closing in accordance with the Company's Board resolution referred to in Section 5.2c). Seller 15 is the sole legal owner of Shares set forth against Seller 15's name in Annex 0 and holds

such Shares for the account, risk and benefit of several investors acting through [***]. The Shares owned by Shareholder 15s are free and clear of any Liens and Seller 15 has the full right to sell, convey and deliver these Shares free and clear of any Liens on behalf of these investors and the Buyer will at Closing receive good and valid title to such Shares free and clear of any Liens. All Shares and Options referred to in this Section 6.1a), respectively, are validly issued and fully paid in and the share capital has not been repaid in whole or in part.

B) No concealed contributions have been made to the Company or contributions repaid by the Company or hidden distributions occurred in each case to such Seller.

C) The Company has an authorized capital and a conditional capital in the amount of CHF 16'739.00 and CHF 32'868.00, respectively and an issued share capital of CHF 343'484.00 divided into (i) 109'437 Common Shares of which 12'063 are held in treasury, (ii) 117'382 Series A Preferred Shares and (iii) 116'665 Series B Preferred Shares. Except for the Options, there are no outstanding rights, contracts, resolutions or other commitments that could require the Company to increase its share capital or to issue or sell any shares or other equity-linked securities.

6.2 Due Authorization; Valid and binding Effect

A) If a Seller is a Corporate Seller, it is duly incorporated, organized and validly existing under the laws of its incorporation or seat and has the full corporate power, authority and all necessary approvals to carry on its business as now being conducted

B) Each Seller has the absolute and unrestricted right, power, authority and capacity to execute this Agreement and to perform its respective obligations under this Agreement and, if a Seller is a Corporate Seller, is duly authorized by all necessary corporate action.

C) This Agreement constitutes the legal, valid, and binding obligation of such Seller, enforceable against such Seller in accordance with its terms. There are no limitations under applicable law or any contracts by which such Seller is bound that would prevent such Seller from entering into and performing its respective obligations under this Agreement.

D) There are no actions, suits or proceedings pending against such Seller before any court or administrative board, agency or commission which involve a claim by a Governmental Authority or regulatory authority, or by a third party, which would operate to hinder or substantially impair the consummation of the transactions contemplated by this Agreement. There are no actions, suits or

proceedings which have been threatened in writing to be filed against such Seller.

E) No winding-up, bankruptcy, insolvency or judicial composition proceedings are pending or have been initiated or applied for against the relevant Seller under any applicable law.

6.3 The Company

A) The Company is duly incorporated, organized and validly existing under the laws of Switzerland and has the full corporate power and authority to own or use its assets and to carry on its business as now being conducted.

B) The Company is not subject to any bankruptcy, insolvency (*Konkursverfahren*), moratorium (*Nachlassstundung*) or any composition proceedings (*Nachlassverfahren*) under any applicable law, nor have any such proceedings been initiated or applied for, and no resolution is pending or has been passed for the liquidation or winding-up of the Company. The Company is not over-indebted (*überschuldet*) or insolvent (*insolvent*).

6.4 Organization and shares of Versantis, Inc.

A) Versantis, Inc. is duly incorporated, organized and validly existing under the laws of Delaware and has the full corporate power and authority to own or use its assets and to carry on its business as now being conducted.

B) There are no outstanding rights, contracts, resolutions or other commitments that could require Versantis, Inc. to increase its share capital or to issue or sell any equity or equity-linked securities to any Person other than the Company.

C) No petition is pending or order has been made to declare Versantis, Inc. insolvent (*Konkurs*), to grant a moratorium (*Nachlassstundung*) or to initiate composition proceedings (*Nachlassverfahren*) in respect of Versantis, Inc., and no resolution is pending or has been passed for the winding-up of Versantis, Inc.

D) Other than Versantis, Inc., the Company does not own directly or indirectly other equity or voting interest in any other company or entity.

E) The Company is the sole legal direct or indirect owner of all the shares in Versantis, Inc.

6.5 Financial Statements

A) The audited statutory financial statements of the Company for the business year ended 31 December 2021 (the "**Financial Statements**", contained in Annex 6.5a)) (i) have been prepared in accordance with the Accounting Principles; and (ii) are complete and correctly represent the financial position of

the Company as at 31 December 2021, all in accordance with the Accounting Principles.

B) The Company has no liabilities (including any off-balance sheet items or contingent liabilities such as royalty payment or milestone obligations) that under the Accounting Principles have to be included in the Financial Statements and which were not disclosed in the Financial Statements and the notes thereto.

C) The books of the accounts and all supporting books and records of the Company have been properly kept as required under applicable legal, regulatory and accounting requirement and are up-to-date and reflect all assets, liabilities and expenditures of the Company and are in the possession of the Company.

6.6 Ownership and Condition of Assets

A) The Group Companies have good and valid title to the tangible and intangible assets that are material or otherwise relevant for the business of the Group as currently conducted, free and clear of any Lien (except for Liens resulting by operation of law in the ordinary course of business).

B) The Group Companies have valid right to use and possession of all tangible and intangible assets (including buildings and premises) necessary for the conduct of the business of the Group as currently conducted. There has been no termination, or threat of termination, of such Group Company's right to use such assets, nor are there any circumstances likely to result in such termination.

C) All assets are in good operating condition, taking into account ordinary wear and tear and comply with all applicable laws and regulations.

This representation shall not concern any of the Company's Intellectual Property Rights. The sole representation, concerning the Company's Intellectual Property Rights is contained in Section 6.7.

6.7 Intellectual Property Rights

A) The Company is at Closing the sole and exclusive owner of the Intellectual Property Rights as set forth in Annex 6.7a)(i) (the "**Owned Intellectual Property Rights**") free of any Lien and none of the Owned Intellectual Property Rights are subject to any pending transfer of ownership. Registration and maintenance fees for the Company’s Intellectual Property Rights listed in Annex 6.7a)(i) have been paid, and until the Closing Date will be paid, if finally due. The Company has not granted any exclusive licenses to Owned Intellectual Property Rights and no non-exclusive licenses to Owned Intellectual Property Rights except for those listed to manufacturers in Annex 6.7a)(ii).

B) To the Sellers' Knowledge, no inventors other than the inventors listed in the patents and patent applications listed in Annex 6.7a)(i) have contributed to the Owned Intellectual Property Rights.

C) The Company has rights to use pursuant to the terms of license agreements, service contracts or similar contracts, the Intellectual Property Rights (other than any commercially available standard computer software applications used generally in the Company and that are licensed for an aggregate license fee of no more than CHF 50'000 per year per license) listed in the agreements set forth in Annex 6.7c) (the "**Licensed Intellectual Property Rights**" and together with the Owned Intellectual Property Rights, the "**Company's Intellectual Property Rights**").

D) The licensing agreements giving the Company rights to the Licensed Intellectual Property Rights listed in Annex 6.7c) are fully valid and in force and the Company is not in breach of obligations that have been or are due under these agreements.

E) No proceedings have been served on the Company nor, to the Sellers' Knowledge, any proceedings are threatened that challenge the ownership or use by the Company of any of the Company's Intellectual Property Rights.

F) To the Sellers' Knowledge, none of its activities carried out within the scope of its present businesses as conducted on the Closing Date, infringe any patent rights of any third party.

G) To the Sellers' Knowledge, no third party (including, without limitation, any Sellers or any Sellers' Affiliates) infringes any of the Company's Intellectual Property Rights.

H) The Company has taken commercially reasonable steps for a company of like size and resources to protect its Intellectual Property Rights. Current or former employees, consultants and contractors of the Company who have participated in the creation of any such Intellectual Property Rights have entered into employment agreements, confidentiality agreements, or assignment agreements. To the Sellers' Knowledge no employee, consultant or contractor is in violation thereof.

6.8 GCP or Good Clinical Practices

The Group Companies have complied with all applicable regulatory standards, practices and procedures in the development and manufacturing of its products, including any applicable ICH, GCP and GLP promulgated and enforced by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other regulatory authorities applicable to the territories where the Group Companies do business. The Company has not received any written notifications from

any regulatory authority raising any material issues in any jurisdiction requiring the termination or suspension of any clinical studies conducted by, or on behalf of, the Company.

6.9 Information Technology

A) The Company has sufficient rights, either by ownership, valid licenses or otherwise to use all of the software and hardware currently required by it to conduct its business. Such IT systems (i) are in good working condition and have been properly maintained, and (ii) operate and perform as necessary to conduct the business as conducted at the date hereof.

B) The Company has in place and maintains (a) sufficient market standard back-up-procedures contingency plans (external back-up provider) in place for proper protection against loss of data, (b) an adequate cybersecurity processes and infrastructure, including anti-virus and malware protection, which protect it from cyber-attacks such as hacking or other fraudulent actions, and (c) adequate measures to protect and safeguard business data, customer data and employee data against illegal or unauthorized access or use by its personnel or third parties, in each case as customary for the business as performed by the Company. To the Sellers' Knowledge, the Company has in the past 2 years not suffered a security incident (in particular unauthorized access to the IT systems) with a material adverse effect or has in the past 2 years been materially adversely affected by any virus, ransomware malware or (other) cyber-attacks, or denial-of-service attacks on any IT systems.

6.10 Real Estate and Environment

A) The Group Companies do not own real estate properties.

B) The Group Companies have the valid and unrestricted right (except as provided for by Applicable Law and applicable lease agreements) to use as a renter all real property used or required for the purposes of the Group's business.

C) The Group Companies are in compliance with applicable environmental laws in all material aspects.

D) Neither environmental investigations nor claims related to environmental matters exist or are threatened against the Group Companies.

6.11 Conduct of Business

Since 1 January 2022 each of the Group Companies

A) has carried on its business in the ordinary course of business;

B) has not declared, authorised, paid or made, any dividend, distribution of profits or assets, direct or indirect return or repayment of equity;

C) has not issued or agreed to issue any share capital or other similar interest;

D) has not repaid any borrowing or indebtedness nor incurred any such borrowing or indebtedness except intercompany balances;

E) has not performed or agreed to perform any of the actions listed in Section 6.11,

in each case other than any transaction or circumstance that is permitted under this Agreement. From the period from 1 January 2022 until the Closing Date, no extraordinary or significant events have occurred that could have substantial adverse effects on the market position or the development of the Company or could otherwise substantially adversely affect the value of the Group Companies.

Since the signing of the NEA, the Group Companies have been in compliance with the Interim Covenants as listed in Section 3.1 and Section 3.2 of the NEA.

6.12 Litigation

A) There are no actions, suits, claims or litigation, arbitration or administrative proceedings (the "**Litigation**") pending or threatened in writing against any of the Group Companies by or before any court, arbitral tribunal, or Governmental Authority which involve a claim by a Governmental Authority or regulatory authority, including Tax authority, or a third party against the Group Companies.

B) There is no claim, suit or proceeding pending or threatened in writing against any of the Sellers or the Company before or by any Governmental Authority, or by a third party, which in each case would prohibit the Closing. There are no circumstances which are likely to give rise to any of the foregoing.

6.13 Taxes

A) Each of the Group Companies has timely filed all Tax declarations and Tax Returns, which are true, correct and complete, as required by law with the competent Tax authorities (taking in-to account any permitted extensions). No claim, action or proceeding regarding Taxes is pending or threatened by any authority, body or beneficiary. No Tax Return is currently under audit by any authority or body and no communication of any such audit has been received.

B) The Company has, except for Taxes that are disputed in good faith, timely paid, disbursed or withheld all Taxes payable relating to any time period up to the Closing Date when due or if not due, or fully provisioned for in the Financial Statements or its books in accordance with Accounting Principles.

C) Since 31 December 2021, Taxes with respect to each of the Group Companies have only occurred in the ordinary course of business in line with past accounting periods.

D) The Group Companies have all supporting documents in connection with (i) all filed Tax returns and other filings, and (ii) all Tax returns and other filings still to be filed which refer to assessment periods (partially or fully) before the Closing Date, in each case in form and substance in accordance with Applicable Law. All such accounts, books, registers, ledgers, records and supporting documents of the Company are up to date and have been properly and accurately kept, in accordance with all applicable laws, regulations and directives.

E) All transactions entered by the Group Companies with affiliated parties are at arm's length and that no hidden profit distributions have been made.

F) All payments made by the Company to employees and self-employed individuals have been correctly handled regarding Taxes in accordance with Applicable Law.

G) The signing of this Agreement and the consummation of the Transaction at signing do not result in any Taxes being levied on the Company except for any applicable Deductions, income tax and stamp duty tax levied as a result of the payment of the Base Purchase Price to holders of Employee Shares, Options and U.S. Options.

6.14 Employment

A) Except for [***] ([***]), no employee is entitled to receive (i) a contractual termination compensation for regular termination by the employer exceeding the equivalent of 3 months' gross salary, or (ii) a contractual severance or other payment due to the consummation of the Transaction payable by the Company and exceeding CHF 25,000 in aggregate.

B) Except for [***] ([***]), none of the Key Employees has given or received written notice of termination at the date of this Agreement.

C) No current or past contractor or freelancer of the Company ever claimed to have an employment relationship with the Company or made any claims in relation thereto, both from a Tax or employment law perspective. To the Sellers' Knowledge, there are no circumstances that are likely to give rise to the foregoing.

D) All officers, employees, directors or independent contractors of the Group Companies are lawfully authorized to work in the respective jurisdictions where they perform their work according to applicable immigration laws. The Group Companies are in compliance with all applicable laws relating to documentation and recordkeeping of its employees' work authorization status.

E) There are no disputes or other proceedings pending or overtly threatened between the Group Companies and any of its employees in connection with

their employment. The Company has not received notice of the intent of any governmental entity responsible for the enforcement of any labor law to conduct an investigation with respect to the Company, and no such investigation is in progress.

F) The Group Companies are not a party to or otherwise bound by collective bargaining agreements, contracts or other agreements or understandings with labor unions or similar organizations, and there are no orders of general applicability (*Allgemeinverbindlichkeitserklärungen*) which have an effect on the Company. There are no disputes with unions or work councils and there are no negotiations going on with them.

6.15 Social Security and Pensions

A) Other than any mandatory government or social security pension arrangements and the pension arrangements set out in Annex 6.15, there is no scheme, arrangement or agreement to which a Group Company is a party or by which a Group Company is bound or under which it has an obligation or liability (whether actual, contingent or prospective) to contribute or to provide funding for the provision of life assurance, retirement, death, disability or other like benefits (in the form of a pension, lump sum, gratuity or otherwise) in respect of any Employee. There is no funding deficit (*Unterdeckung*) under any of the occupational pension plans, funds, contracts, schemes or arrangements relating to the Company or its employees

B) All material agreements or arrangements for the payment of pensions, allowances, lump sums or other similar benefits upon retirement or death or during periods of sickness or disablement for the benefit of any current or former director, officer or employee of the Group Companies or such person's dependents (the "**Pension Plans**") have been established in compliance with applicable laws and regulations.

C) All deductions from employee salaries for social security and Pension Plans have been made and all such deductions and all premiums due to be paid by the Company to the social security authorities or a Pension Plan as of the Closing Date have been fully and timely paid or fully provided for in the books and accounts of the Group Companies in accordance with the Accounting Principles.

D) Each of the Pension Plans which are pre-funded (whether by means of a book reserve or otherwise) are fully insured.

E) To the Sellers' Knowledge, there are no actions, claims, investigations, proceedings or suits pending or threatened in writing against the Group Companies by any social security authority or by any employee under any Pension Plan.

6.16 Permits and Authorizations

A) The Group has all the permits and authorizations necessary to carry on its business as presently conducted.

6.17 Material Contracts

A) As of the date of this Agreement, the Disclosed Information to the Buyer contains the following written contracts of the Group Companies (the "**Material Contracts**"):

A) contain prohibitions or restrictions on any Group Company from competing in any line of business or which otherwise restrict any Group Company, in any material respect, from engaging in its business;

B) contain any agreement or series of agreements which provide for an annual aggregate payment obligation (*Zahlungsverpflichtung*) of the Company of an amount exceeding [***];

C) contain any agreement that involves performance of services or delivery of goods to or by the Company of an amount or value exceeding [***] *per annum*;

D) loan agreements, bonds, notes or any other instruments of debt in an amount exceeding CHF [***] per case or CHF [***] in the aggregate;

E) guarantees, suretyships (*Bürgschaften*), indemnities, letters of comfort (*Patronatserklärungen*) issued by the Company;

F) requires the Company to provide more than 6 months' notice to terminate the contract or requires the payment of a termination fee greater than CHF [***];

G) are not at arm's length;

H) relate to a joint-venture, alliance or other form of cooperation agreements with third parties;

I) contain any Change of Control provision;

J) contain any agreement or series of agreements which relate to the Intellectual Property other than Off-the Shelf Intellectual Property obtained from a third Person on general commercial terms that was licensed for payments of less than CHF [***] in the aggregate and requires license, maintenance, support and other ongoing fees of less than CHF [***] per year;

K) are entered into by the Company and any governmental, quasi-governmental or government-controlled counterparty; or

L) contain any lease agreements regarding premises.

M) To the Sellers' Knowledge, the Material Contracts are valid, binding, enforceable in accordance with their terms and are in full force and effect, except as may be limited by bankruptcy, insolvency, reorganization, moratorium, civil procedure or other similar laws now or hereafter in effect relating to or affecting the enforcement of creditors' rights in general and subject to general principles of equity (good faith) and similar general principles of Applicable Law.

N) The Company has performed all material obligations arising out of such contracts in accordance with its terms and no notice of termination has been received or given or, to the Sellers' Knowledge, is reasonably likely to be given. The counterparties have performed all material obligations arising out of such contracts and to the Sellers' Knowledge no grounds for early termination exist.

O) Except as disclosed in Annex 6.17d), the Company is not a party to any contract, agreement, arrangement or understanding with any Seller or any person related to or connected with a Seller or in which any such person is interested (whether directly or indirectly). No director or manager, former director or manager, shareholder, or employee or former employee of, or any person not dealing at arm's length with, the Company is engaged in any transaction or arrangement with or is a party to a contract with, or has any indebtedness, liability or obligation to, the Company.

6.18 Compliance & Data Protection

A) The Company (i) has complied with all Applicable Laws in all material respects, including applicable provisions of employment, environmental, sanctions, competition and antitrust laws, rules and regulations, and no material action, suit or proceeding by any third party or any Governmental Authority or administrative authority is pending or threatened in writing against the Company alleging any failure to comply with any laws and regulations in effect as of the date of this Agreement, and (ii) is and has been in substantial compliance in all material respects with all of the terms and conditions of all Permits required under any laws and regulations.

B) To the Sellers' Knowledge, no employee of the Company or any third party acting on behalf of the Company has, in violation of any applicable law, offered, promised or granted, directly or indirectly, any benefit (*e.g.*, bribes, payments in kind or kick-backs) to any person (e.g., a natural or legal person or his/her/its representative(s)), in return for obtaining unfair favorable treatment vis-à-vis competitors in the supply of goods or commercial services or for any other reason, or demanded, allowed him- or herself to be promised or accepted such benefit for him- or herself or a third party for the purpose of obtaining unfair

favorable treatment vis-à-vis competitors in the supply of goods or commercial services or for any other reason.

C) To the Sellers' Knowledge,

A) the processing of any information relating to an identified or identifiable natural person (the "**Personal Data**") by the Company is lawful;

B) the Company has complied with the requirements of applicable data protection laws as regards the processing of Personal Data;

C) in the last 3 years prior to the date of this Agreement, the Company (x) has not received any process, notice or other formal or informal communication from any competent governmental, administrative, regulatory authority or court alleging that the Company has not complied with applicable data protection laws, (y) has not received any complaints from third parties (including data subjects) for the breach of any data protection laws, (z) nor was the subject to a data breach which resulted in a loss, damage, unauthorized access, use, modification or other misuse of Personal Data. No individual nor any Governmental Authority has made any claim or commenced any action with respect to loss, damage, or unauthorized access, use, modification, or other misuse of any Personal Data;

D) the Company has implemented the appropriate technical and organizational measures to ensure (w) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services, (x) the ability to restore the availability and access to Personal Data in a timely manner in the event of a physical or technical incident, (y) timely notification of data breach events to a competent Governmental Authority or administrative or regulatory authority and (z) a process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

E) None of the Group Companies and, to the Sellers' Knowledge, none of their respective representatives has, directly or indirectly:

A) improperly or unlawfully made any payment or offered anything of value to any foreign or domestic officials or employees or to any foreign or domestic political parties or campaigns, whether to obtain or retain business or otherwise;

B) made or authorized any payment, contribution or gift of money, property or services involving the direct or indirect use of funds of the Seller or any Group Company (including entertainment or other expenses), whether or

not in contravention of Applicable Law, (A) as a "kickback" or bribe to any Person or (B) to any political organization or the holder of (or person who seeks) any elective or appointive public office related to political activity or otherwise related to political activity; or

C) violated any applicable export control, money laundering or anti-terrorism law or taken any action that could reasonably be expected, individually or in the aggregate, to cause any of the Seller or any Group Company to be in violation of the U.S. Foreign Corrupt Practices Act of 1977, as amended, any law enforced by the Office of Foreign Asset Control of the U.S. Department of Treasury ("**OFAC**") or any Applicable Law of similar effect.

D) Without limiting the generality of the foregoing, none of the Group Companies and, to the Sellers' Knowledge, none of their respective representatives, at any time since the date that is five (5) years prior to the date hereof:

A) has been (A) the subject of any Sanctions administered by the US government, including those of OFAC and the US Department of State, the United Nations Security Council or any other applicable Sanctions Authority; (B) operating, organized or resident in, or directly or indirectly owned or controlled by the government of any country or territory that is, or whose government is, the target of comprehensive country- or territory-wide sanctions (e.g., Crimea, Cuba, Iran, North Korea, Syria, and since February 21, 2022 the Donetsk People's Republic, and the Luhansk People's Republic (collectively, "**Sanctioned Countries**"); or has been (C) directly or indirectly owned fifty percent (50%) or more in the aggregate, or controlled (as defined by the relevant Sanctions Authority) by a Person which is the subject of the foregoing restrictions;

B) has, directly or indirectly, engaged in, or is now engaged in, any dealings or transactions, including the sale, purchase, import, export, re-export or transfer of products or services to or from any Sanctioned Country, or with any Person targeted by trade regulations, including but not limited to Persons who are (A) owned or controlled by the government of a Sanctioned Country, (B) designated on the OFAC list of Specially Designated Nationals and Blocked Persons, any other sanctions-related list maintained by OFAC, any sanctions- or export controls-related list maintained by the US Department of State, the US Commerce Department’s Entity List, Denied Persons List, or Unverified List, the EU Consolidated Financial Sanctions List, the UK Sanctions List, or any other similar restricted party list maintained by relevant regulators under applicable sanctions and export controls, or (C) owned or controlled by any of the foregoing (collectively, "**Restricted Parties**"), to the extent

such dealings or transactions would have been or would be prohibited or restricted by then-applicable or applicable trade regulations. Neither Sellers nor the Group Companies are a party to or beneficiary of, or have interest in, any franchise, license, management or other Contract with any Person, either public or private, in the Sanctioned Countries or with any Restricted Parties, or are a party to any investment, deposit, loan, borrowing or credit arrangement or involved in any other financial dealings, directly or indirectly, with any Person, either public or private, in the Sanctioned Countries or who is a Restricted Party, that remains in effect that would be blocked or frozen by applicable trade regulations if the Seller or the Acquired Companies were a person required to comply with such trade regulations. Neither the Group Companies, nor, to the Sellers' Knowledge, any director, manager, officer nor employee of the Group Companies, is a Restricted Party;

C) has, directly, or indirectly through a third-party intermediary, entered into any contract that remains in effect and that contains provisions reflecting participation in, or cooperation with, a foreign boycott that is not sanctioned by the United States, including without limitation the Arab League boycott of Israel; or

D) has (A) conducted or initiated an internal review or investigation related to potential or alleged violations of anti-corruption laws, anti-money laundering or anti-tax evasion laws, or trade regulations, (B) made any voluntary or involuntary disclosure to any Governmental Authority or other Person with respect to any possible violation or any actual or potential non-compliance of any anti-corruption laws, anti-money laundering or anti-tax evasion laws, or trade regulations or (C) received any written government prosecution, enforcement, investigation, subpoena or other inquiry related to potential non-compliance with anti-corruption laws, anti-money laundering or anti-tax evasion laws, or trade regulations.

6.19 Insurance

A) The Company maintains adequate insurance coverage, in line with Applicable Law and industry standards and market practice for companies conducting a similar business. The Disclosed Information to the Buyer contains all material insurance policies of the Group Companies. All premiums due with respect to such insurance policies for the period ending as of Closing are paid when due and, to the Sellers' Knowledge, each such policy is in full force and effect as at the date hereof.

B) No act or omissions have occurred which could render any insurance policy void or entitle the insurer to decline or reduce insurance coverage. At the date hereof, no insurance policy has been terminated, amended or declined nor have premiums increased (other than in the ordinary course of business in line with market conditions) nor are there, to the Sellers' Knowledge, any circumstances likely to result in any termination, amendment or non-renewal.

C) At the date hereof and in the past 5 years, there have been no insurance claims and to the Sellers' Knowledge there are no circumstances likely to give rise to such claim.

6.20 Transaction Fees

Except for the obligations pursuant to certain agreement dated [***] between the Company and Torreya Partners (Europe) LLP which will be settled by the Sellers as further outlined in Annex 5.2h), none of the Group Companies is obligated to pay or will pay a broker's, finder's or transaction fee or commission in connection with, or as a result of, the signing of this Agreement or the execution of the transactions contemplated herein.

6.21 No Further Representations

The Company does not make any further representations or warranties (neither express nor tacit or by implication) other than those expressly made in this Section 6.

Without limiting the generality of the foregoing, the Buyer specifically acknowledges that the Company makes no representations, express or implied, with respect to the future development of the Products or the Company or with respect to budgets, business plans, forward-looking statements and other projections of a financial, technical or business nature relating to the Company or its business.

7. REPRESENTATIONS OF THE BUYER

The Buyer represents (*sichert zu*) that the statements set forth in this Section 7 are true and correct as of the date of this Agreement and as of the Closing Date.

7.1 Corporate Matters

The Buyer is a corporation validly incorporated, duly organized and lawfully existing under the laws of France and is neither in liquidation nor in composition proceedings or in any other similar procedure.

7.2 Binding Agreement

The Buyer has full power and authority to enter into and perform this Agreement and no authorizations, permits, approvals or consents are required from any corporate body of the Buyer, from any Governmental Authority, or from any other party

(including any shareholders, board of directors (or the like) or creditors of the Buyer) for the transactions contemplated by this Agreement other than as set out herein.

This Agreement and the transactions contemplated hereby will constitute valid and binding obligations of the Buyer enforceable in accordance with its terms.

In particular, no injunction issued by any court or Governmental Authority relating to the Buyer in order to restrain or prohibit the consummation of the transactions contemplated by this Agreement is in effect, and no suit, action or other legal or administrative proceeding relating to the Buyer is threatened in writing or pending before any court or governmental agency in which it is sought to restrain or prohibit or to obtain damages or other relief in connection with this Agreement or the consummation of the transactions contemplated herein.

7.3 Purchase in Own Name

The Buyer confirms to buy the Shares in its own name and for its own account.

7.4 Funding of Purchase Price; Compliance with Anti-Money Laundering Laws

The Buyer has arranged that on the Closing Date it will have the necessary funds to finance the transaction contemplated by this Agreement on an unconditional basis (subject to Closing only). The funds which the Buyer shall use to finance the present transaction originate from lawful sources and the use of such funds in the present transaction does not violate any Applicable Laws of any relevant jurisdiction. In particular, the funding of the Purchase Price and other payments under or in connection with this Agreement fully comply with all applicable anti-money laundering laws and regulations.

The Buyer has the necessary funds to finance the transaction contemplated by this Agreement. The funding of the Purchase Price and other payments under or in connection with this Agreement fully comply with all applicable anti-money laundering laws and regulations.

7.5 No disqualification

Neither the Buyer nor any officer, employee, or agent of the Buyer has been:

A) excluded from participation in Federal healthcare programs under 42 U.S.C. § 1320a-7 or convicted of an offense for which such exclusion is mandatory or permissive;

B) debarred from Federal procurement or non-procurement contracts or convicted of any offense for which such debarment is mandatory or permissive;

C) disqualified, debarred, or restricted by FDA, including but not limited to under 21 CFR §§ 312.70, 511.1, 812.119, or under 21 U.S.C. § 335a, or convicted of any offense for which FDA debarment is mandatory or permissive; or

D) otherwise disqualified, excluded, debarred, prohibited, restricted, or suspended from performing activities under this Agreement.

7.6 No Further Representations

The Buyer does not make any further representations (neither express nor tacit or by implication) other than those expressly made in this Section 7.

8. REMEDIES

8.1 Sellers' Right to Cure and Sellers' Liability

A) With respect to a misrepresentation or breach of a warranty set forth in Section 6 (Representations of each Seller) notified by the Buyer to the Sellers pursuant to Section 8.3 (Notice of Breach), the Seller (or the Sellers' Representative acting on behalf of a Seller)shall have the right, within [***] after the receipt of the Notice of Breach, to put Buyer or the Company in the same position in which it would have been if no such breach had occurred.

B) If the breach is not cured within [***] following receipt of the Notice of Breach, the Sellers shall, subject to the conditions, limitations and exclusions set forth in this Section 8 (Remedies), be liable in proportion to their respective direct holdings in Shares or Options, and not jointly (*nicht solidarisch*), to the Buyer for any damage, expense or cost (in all cases including interests but excluding loss of profit and/or punitive damages incurred and sustained by the Buyer or a Group Company (the "**Damage**") as a result of such misrepresentation or breach of warranty; such amount to be calculated as being the amount which would be necessary to put the Buyer and the Group Company (without double counting) into the financial position which would have existed if such warranty had been true and correct.

8.2 W&I Insurance

A) Buyer agrees that it will not be entitled to recover, and hereby irrevocably and unconditionally waives any and all rights to recover for, any claim for any Damage in excess of the Warranty Cap against a Seller arising out of or relating to a misrepresentation or a breach of a warranty set forth in Section 6 (Representations of each Seller) by such Seller except for (i) a claim arising out of or relating to a breach of a Fundamental Warranty, and (ii) except in case of fraud (*Betrug*) or intent (*Absicht*) or deceit (*vorsätzliche Täuschung* in the sense of art. 28, 41 (not including negligence), 192 para. 3 or to the extent mandatorily applicable art. 199 CO) or criminal act by such Seller. Buyer's sole remedy and recourse with respect to such claims will be against the W&I Insurance Policy. Any liability of any Seller in excess of the Warranty Cap is herewith excluded, including if no W&I Insurance Policy is obtained by Buyer or if a specific breach is not covered by the W&I Insurance Policy

B) Buyer agrees and acknowledges that the validity and collectability risk with respect to the W&I Insurance Policy as well as the risk that not all of Seller's representations and warranties set forth in Section 6 (Representations of each Seller) are covered by the W&I Insurance Policy shall solely and irrevocably rest with Buyer.

C) Buyer confirms to the Sellers that pursuant to the terms of the W&I Insurance Policy, the W&I Insurer will only be entitled to subrogate against a Seller in respect of a payment under the W&I Insurance Policy which arises in whole or in part out of Damage caused by such Seller's fraud (*Betrug*) or intent (*Absicht*) or deceit (*vorsätzliche Täuschung* in the sense of art. 28, 41 (not including negligence), 192 para. 3 or to the extent mandatorily applicable art. 199 CO) or criminal act.

8.3 Notice of Breach

A) The Buyer shall deliver a written notice to the Sellers' Representative describing and substantiating the underlying facts in reasonable detail (including the amount of the reasonably anticipated Damage) of a claim for misrepresentation or breach of a warranty set forth in Section 6 (Representations of each Seller)and which shall specify the representation allegedly breached, as well as disclosing to the Sellers' Representative (to the extent known or available) documents and information in support of such claim (the "**Notice of Breach**") no later than [***] after the Buyer becomes actually aware of a misrepresentation pursuant to Section 6 (Representations of each Seller)

B) Failure to deliver a Notice of Breach within the time period set forth in Section 8.3a) shall not exclude or limit Sellers' liability related to such breach, except to

the extent the Buyer's failure to duly and timely notify the Sellers caused an increase or non-reduction of the Damage.

C) The regimen provided for in this Section 8.3 shall be in lieu of the Buyer's duty to immediately inspect and notify Sellers in accordance with article 201 CO.

D) The Sellers confirm that they have reviewed immediately prior to the Closing Date, but no earlier than [***] before the Closing Date, the representations and warranties in Section 6 (Representations of each Seller) and have enquired with [***] in order to identify any facts or circumstances that have become known after the date of signing of the NEA (irrespective of when the underlying events have occurred) and render Insured Warranties and Tax Indemnities, that were held to be true and accurate as of the date of signing of the NEA, to be no longer true and accurate on the Closing Date ("**Bring-Down of Disclosures**"). The Sellers have disclosed the results of the Bring-Down of Disclosures to the Buyer substantially in the form attached hereto as Annex 8.3d). The Sellers note that in the Bring-Down of Disclosures qualifies the insured warranties and tax indemnities to which the disclosed facts or circumstances relate and relieve the Sellers from any liability for a breach of the respective insured warranties and tax indemnities resulting from the disclosed facts or circumstances.

8.4 Term

A) Any claims by the Buyer for misrepresentations shall be time barred (*verjährt*) and forfeited (*verwirkt*) unless and to the extent the Buyer delivers to the Sellers a Notice of Breach within the following time limits:

(i) unless otherwise set forth in this Section 8.4, before the lapse of eighteen months from the Closing Date;

(ii) with regard to the Fundamental Warranties, before the lapse of a period of seven years from the Closing Date;

(iii) with regard to the representations pursuant to Section 6.7 (Intellectual Property Rights), before a lapse of a period of five years from the Closing Date;

(iv) with regard to the representations pursuant to Section 6.13 (Taxes), before the lapse of a period of three months from the date on which the relevant statute of limitation has expired, but in any case five years from the Closing Date.

B) The time periods set forth above are (only) complied with if the Sellers' Representative receives a Notice of Breach in accordance with Section 8.3;

C) Further, claims of the Buyer shall be time barred (*verjährt*) and forfeited *(verwirkt*) if the Buyer does not commence formal proceedings against the Sellers with respect to such breach and claim within [***] from the lapse of the applicable limitation period set forth in Section 8.4a). For clarity, it is understood that the filing of an application for conciliation (*Einreichung eines Schlichtungsgesuches*) does not qualify as commencement of a formal action for performance.

D) The provisions of this Section 8.4 (Term) shall be in lieu of, and supersede, the provisions of article 210 CO which does not apply to this Agreement.

8.5 Third Party Claims

If any claim is brought or threatened to be brought after the Closing Date by a third party (including a Tax authority or other Governmental Authority or body), against the Buyer or the Company, which may qualify as a breach of a representation or warranty under this Agreement by the Sellers, the Buyer shall notify the Sellers' Representative of such claim (a "**Third Party Claim**") according to Section 8.3 (Notice of Breach), it being understood that the Buyer shall be free in the conduct of proceedings with respect to Third Party Claims provided, however, that the Buyer shall not settle any such Third Party Claim without the prior written consent of the Sellers (such consent not to be unreasonably withheld, delayed or conditioned), except where on-settlement would be materially prejudicial to the Company's business in which case the Buyer shall be free to settle Third Party Claims without the consent of the Sellers.

8.6 Exclusion of Liability

Seller's liability under this Agreement relating to a misrepresentation or a breach of a warranty set forth in Section 6 (Representations of each Seller) shall be excluded or reduced to the extent that:

A) a breach has been cured pursuant to Section 8.1 (Sellers' Right to Cure and Sellers' Liability);

B) the matter giving rise to a claim has been specifically provided for in the Financial Statements or an amount has specifically been taken into account in connection with the calculation of the Base Purchase Price;

C) Buyer has recovered or could have recovered from a third party (including recovery under any insurance policy other than the W&I Insurance Policy) after deduction of all reasonable costs and expenses incurred in making such;

D) with respect to Taxes, a tax loss carry forward (*Verlustvortrag*) can be used to set-off any such Taxes;

E) the Buyer (including, following Closing, the Group Companies) failed to use its best efforts to mitigate the Damage (*Schadensminderungspflicht*);

F) such liability is resulting from or attributable to any act, omission, transaction or voluntary arrangement of the Buyer or any of its Affiliates (including, following Closing, the Group Companies);

G) the claim arises or increased as a result of the passing of or any change in any legislation, regulation or rule of law or administrative practice of any Governmental Authority or regulatory body after the Closing Date;

H) the Buyer would recover from the Sellers, under this Agreement or otherwise, more than the amount of Damage actually incurred by the Buyer and/or the Company; or

I) except for Fundamental Warranties, the facts, matters or circumstances giving rise to a claim have been Fairly Disclosed to the Buyer.

For the avoidance of any doubt, the Buyer is not entitled to any double recovery of the same damage under any provision or title of this Agreement or otherwise.

8.7 Threshold and De Minimis Amount; Liability Cap

A) Except for claims brought against the Sellers for breach or misrepresentation of Fundamental Warranties, none of the Sellers shall be liable to the Buyer for claims asserted by the Buyer against any of the Sellers for breach or misrepresentation of Sellers' representations under Section 6 (Representations of the Sellers), unless

(i) each such claim exceeds, on a stand-alone basis, the amount of CHF [***] (the "**De Minimis**"), it being understood that for the calculation of the De Minimis, a series of claims shall be regarded as one single claim if such claims are based on substantially the same factual circumstances, irrespective of whether they are brought by one or several claimants; and

(ii) the amount of claims by the Buyer, on an aggregate basis, exceeds CHF [***] (the "**Threshold Amount**"), in which case, subject to the limitations set forth in this Agreement, all Damages may be claimed by the Buyer.

B) The maximum aggregate liability of a Seller for any Damage incurred by the Buyer or any Group Company

(i) as a result of a breach or misrepresentation of a warranty set forth in Section 6 (Representations of each Seller) other than a Fundamental Warranty or in the circumstances set forth in (ii) below shall be limited to, and shall in no event exceed, CHF [***] (the "**Warranty Cap**")

(ii) as a result of a breach of a Fundamental Warranty or in case of fraud (*Betrug*) or intent (*Absicht*) or deceit (*vorsätzliche Täuschung* in the sense of art. 28, 41 (not including negligence), 192 para. 3 or to the extent mandatorily applicable art. 199 CO) or criminal act by a Seller shall in no event exceed 100% of the Purchase Price paid to the relevant Seller on a net, after Tax basis.

8.8 Exclusive Remedies

The remedies of the Buyer in this Section 8 for breach of representations, shall be in lieu of, and not in addition to, the remedies and termination rights provided for by Applicable Law. All other remedies, including, without limitation, (i) any and all rights pursuant to articles 192 et seq. CO and articles 197 et seq. CO and any rights of a similar nature, (ii) the right to rescind this Agreement (*Wandelung*) or the right of purchase price reduction (*Minderung*) under article 205 CO or otherwise, (iii) the right to challenge the validity of this Agreement for fundamental error (*Grundlagenirrtum*) or invalidity (*Nichtigkeit*) or partial invalidity (*Teilnichtigkeit*) under articles 23 et seq. CO, and (iv) any remedies under the theory of *culpa in contrahendo* shall not apply and are hereby expressly waived to the greatest extent permissible under Applicable Law. For clarity, this Section does not exclude the mandatory articles 28 CO and 199 CO.

8.9 Remedies of the Sellers

The provisions of this Section 8 shall apply *mutatis mutandis* with respect to any misrepresentation by the Buyer.

9. TAX INDEMNITY

The Sellers shall, irrespective of any fault (v*erschuldensunabhängig*) or knowledge and without any limitations by this Agreement or the CO, indemnify and hold harmless the Buyer and the Company up to the maximum of the Adjustment Amount from and against, and shall compensate and reimburse the Buyer, or at the election of the Buyer, the Company at the Buyer's first demand for any and all Tax liability (including expenses for investigations and costs and expenses of attorneys, accountants, and other professional advisors) resulting from the following:

A) for any business events or transactions occurred in and of the Group Companies prior to the date hereof; and

B) relating to the assumption of a permanent establishment of the Company outside of Switzerland by any non-Swiss local Tax authority; and

C) relating to the freelancers qualified as employees of the Company by the competent Tax authorities; and

D) relating to Swiss and U.S. taxation [***], including social security deductions and salary withholding tax prior to and after the Closing Date; and

E) relating to Deductions or Taxes, including social security contributions and salary tax withholdings) imposed on or otherwise incurred by the Company in connection with the payment of the Purchase price (to the extent not deducted from the Purchase Price in accordance with Section 2.4).

Above indemnification obligation shall be limited to and deducted from the Adjustment Amount, and after payment of the Adjustment Amount, from the Milestone Payments.

A claim against the Sellers in accordance with the preceding paragraph shall be the sole remedy of Buyer in respect of any breach of the undertaking in Section 9.

10. FURTHER UNDERTAKINGS

10.1 Confidentiality

The Parties agree that the terms of this Agreement are confidential and shall continue to keep confidential the contents of this Agreement and shall not inform any third party about its content unless required to do so under Applicable Law, including stock exchange regulations and disclosure requirements under applicable accounting standards or rules or mutually agreed upon by the Parties (the "**Confidentiality Undertaking**"); it being understood and agreed that the foregoing Confidentiality Undertaking shall not restrict the Sellers or the Buyer from pursuing their rights and obligations under this Agreement and a Seller wishing to transfer its entitlement to receive a portion of the claim to a Milestone Payment under Section 4.5 shall be entitled to disclose a copy of this Agreement to a potential buyer being made aware of, and agreeing to comply with, the obligation of confidence owed in respect of this Agreement. Notwithstanding the aforesaid, any Seller which is an investment fund shall have the right to disclose to their limited partners and any co-investors this Agreement, provided such limited partners and any co-investors are subject to confidentiality. When disclosing information to the Sellers, the Buyer may notify the Sellers which materials (or individual portions thereof) are (i) publicly available information not subject to this Section 10.1, (ii) confidential information under this Section 10.1, which can be shared by the Sellers with Person subject to a customary confidentiality, or (iii) confidential information, which can only be shared with a third-party after receipt of Buyer's prior written approval.

The Parties acknowledge that the Buyer may be obligated to file under Applicable Laws a copy of this Agreement with Governmental Authorities, including, without limitation, the French *Autorités des Marchés Financiers* (the "**AMF**") and U.S. Securities and Exchange Commission. Sellers agree that Buyer and its Affiliates shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available. In the event of any such filing, Buyer will provide the Sellers Representative with a copy of this Agreement marked

to show provisions for which Buyer intends to seek confidential treatment and shall reasonably consider and incorporate the Sellers Representative's timely comments thereon to the extent consistent with the legal requirements governing disclosure of material agreements and material information that must be publicly filed.

10.2 Information Policy

The Parties will agree in good faith on the contents of all public announcements or press releases concerning this Agreement which will be published after signing of the NEA and/or Closing or at such time as may be agreed upon by the Parties, save for any specific disclosures contained therein required under Applicable Law or by any Governmental Authority (including any securities exchange) as determined solely by Buyer. Consent to such public announcements or press releases shall not be unreasonably withheld by either Party.

Simultaneously with any public announcement, the employees of the Group shall be informed by the Sellers in an appropriate manner about this Agreement.

10.3 No Recourse; Discharge

A) Without prejudice to the remedies of Buyer against the Sellers and each of the Sellers, respectively, under this Agreement, Buyer shall from and after the Closing Date not, and shall procure that its Affiliates (including, after Closing, the Company and any other Group Company) shall not, make any claim against any of the current members of the board of directors and/or officers of the Company or any of its subsidiaries in connection with their acts or omissions up to and including the Closing Date, except in cases of fraud (*Betrug*) or deceit (*vorsätzliche Täuschung* in the sense of art. 28, 192 para. 3 or to the extent mandatorily applicable art. 199 CO) or criminal act.

B) Promptly following the Closing, the Buyer shall cause:

(i) each Group Company to call and hold an extraordinary shareholders' meeting or the equivalent thereof; and

(ii) a resolution to be passed at each such extraordinary shareholders' meeting granting unconditional discharge to the directors and officers of the relevant Group Company for their acts or omissions as directors and officers of such Group Company before (and including) the Closing Date (the "**Discharge**").

C) Granting of Discharge to the directors and officers of each Group Company shall be repeated on the occasion of the next ordinary shareholders' meeting or equivalent meeting of each Group Company following the Closing and any further ordinary shareholders meeting or equivalent meeting covering the period until the Closing Date.

D) A copy of each resolution of the shareholders of a Group Company granting Discharge shall be delivered to the Sellers' Representative within ten Business Days after the date of the relevant meeting.

E) The Buyer shall procure that each Group Company will, as soon as practicable but not later than ten Business Days after the Closing Date, take the necessary steps to file with the respective commercial register authorities an application for deregistration of their directors and officers who resign as of the Closing Date in the respective commercial register.

F) The Buyer acknowledges that, if (to the extent permissible under this Section 10.3) legal action is taken against any former director or officer of any Group Company in respect of their acts or omissions in that capacity, the Buyer shall permit, and shall procure that the Group Companies will grant, such directors and officers access to the Group Companies' records and otherwise cause the relevant Group Company to use reasonable endeavors to assist that director or officer in defending any such action.

10.4 Retention of and Access to Documents

The Buyer agrees that it shall keep and cause the Company to keep all books and records of the Company until the longer of (i) 10 years from the Closing Date or (ii) the period required by applicable mandatory law (in each case, without prejudice to any mandatory provision of applicable law requiring earlier deletion). During such period, the Buyer shall procure that the Company grants the Sellers access, during normal business hours, to such books and records (and allows them to make necessary copies at their expense) to the extent relevant in connection with any proceeding regarding actual or alleged breaches of this Agreement or with a third party, tax filing or audit or preparation of financial statements. The Parties shall, and shall procure that their Affiliates, fully cooperate with the other Party and its Affiliates regarding any such proceeding, tax filing or audit or preparation of financial statements.

10.5 Termination of Certain Agreement

A) At the date hereof, certain Sellers are parties to the shareholders' agreement dated [***], as amended by addendum signed on [***] (the "**SHA**") and the investment agreements dated [***] (together the "**IA**"). Subject to the occurrence of Closing, the relevant Sellers herewith expressly and irrevocably waive any rights under the SHA or IA or any similar agreement that limit, restrict or forbid the execution, delivery and performance of this Agreement or the transactions contemplated hereby or that would grant to any of the Sellers any right to keep, purchase, or sell to a third party, any of the Shares. Subject to, and with effect as of, Closing, the Sellers herewith irrevocably terminate the SHA and the IA. For clarity, the foregoing is without prejudice to the rights of

the Sellers among themselves under the SHA (e.g. distribution of exit proceeds) which do not affect the transaction contemplated under this Agreement.

B) At the date hereof, the Parties are parties to that certain NEA. Subject to, and with effect as of, Closing, the Parties herewith agree that any outstanding obligation under the NEA shall be replaced by, and superseded with, the Parties' obligations under this Agreement. Accordingly, the NEA shall at Closing no longer have any force or effect.

11. GENERAL PROVISIONS

11.1 Notices

All notices and other communications to be given under or in connection with this Agreement shall be made in writing and shall be delivered by registered mail (return receipt requested) or by an internationally recognized courier, in all cases additionally as a matter of courtesy in advance by e-mail, to the following address:

If to any of the Sellers, to the Sellers' Representative as follows:

VISCHER AG
Dr. Matthias Staehelin
Aeschenvorstadt 4, P.O. Box, CH-4010 Basel, Switzerland
[***]

with a copy (which shall not constitute notice under this Agreement) to:

[***]

If to the Buyer:

GENFIT SA,
attn. Pascal Prigent
885 avenue Eugène Avinée Parc Eurasanté
59120 Loos, France
[***]

with a copy (which shall not constitute notice under this Agreement) to:

Niederer Kraft Frey Ltd
Philipp Haas
Bahnhofstrasse 53, CH-8001 Zurich, Switzerland
[***]

Each Party may at any time change its address by giving notice to the other Parties in the manner described above.

11.2 Waiver

The failure of any of the Parties to enforce any of the provisions of this Agreement or any rights with respect thereto shall (i) in no way be considered as a waiver of such provisions or rights and (ii) not in any way affect the validity of this Agreement. The waiver of any breach of agreement by any Party shall not operate to be construed as a waiver of any other prior or subsequent breach.

11.3 Entire Agreement

Subject to the Confidentiality Undertaking which shall survive as stated in Section 10.1 (Confidentiality), this Agreement constitutes the entire agreement and understanding among the Parties with respect to the subject matter hereof, and shall supersede all prior oral and written agreements or understanding of the Parties relating hereto.

For clarity, the preceding sentence shall not apply to, nor affect, the CEO Separation Agreement set out in Annex 5.2g).

11.4 Amendment

This Agreement (including this Section 11.4) may be amended only in writing through a document duly signed by the Buyer and each Seller.

11.5 Severability

If any provision of this Agreement is held to be invalid or unenforceable for any rea-son it shall be revised rather than rendered void, if possible, in order to achieve the intent of the Parties to this Agreement to the fullest extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the fullest extent possible.

11.6 No Assignment

Subject to Section 4.5, neither this Agreement nor any rights or obligations thereunder shall be assigned by any Party, including pursuant to a transfer of assets (*Vermögensübertragung*) or divestiture (*Abspaltung*), without the prior written consent of the other Parties.

11.7 Taxes and Expenses

Unless provided otherwise herein, each Party shall bear all Taxes, costs and expenses incurred by it in connection with the negotiation, execution and consummation of this Agreement or for which it is statutorily liable.

11.8 No Set-Off

Unless provided otherwise in this Agreement, no Party may set off any claim or payment under or in connection with this Agreement with any counterclaim.

11.9 Relationship between the Sellers and the Buyer

All obligations of the Sellers under this Agreement are several (*Teilschuldnerschaft*) and only in proportion to the shareholding of each Seller in the Company and not joint (*keine Solidarschuldnerschaft*), and no Seller shall be responsible for the obligations of any other Seller, it being understood and agreed that the shareholding of each Seller in the Company is as set forth in Annex 0.

The Sellers' rights under this Agreement are several (*Teilgläubigerschaft*).

11.10 Sellers' Representatives

By virtue of their execution of this Agreement, (i) the Sellers designate and appoint VISCHER AG as their authorized representative and general attorney-in-fact under this Agreement with the right of substitution, to exercise any rights and to give and receive notices and communications on behalf of the relevant Sellers under this Agreement. Notices or communications to or from the Sellers' Representative constitute notice to or from the Sellers for all purposes under this Agreement.

In the event of the liquidation, incapacity or resignation of the Sellers' Representative, a successor sellers' representative will be appointed promptly by the Sellers, and the Sellers will so notify the Buyer. Each successor sellers' representative has all of the power, authority and rights conferred by this Agreement upon the original Sellers' Representative.

A decision, act, consent or instruction of the Sellers' Representative constitutes a decision of the relevant Sellers and is final, binding and conclusive upon the relevant Sellers, and the Buyer may rely upon any such decision, act, consent or instruction of the Sellers' Representative as being the decision, act, consent or instruction of the relevant Sellers.

The Sellers' Representative will have no liability to any person for any act done or omitted under this Agreement while acting in good faith and not in a manner constituting gross negligence or willful misconduct.

This appointment and grant of power and authority by the Sellers to the Sellers' Representative pursuant to this Section is irrevocable and may not be terminated by the act of any Seller or by operation of law, whether upon any insolvency event of any Seller, or by the occurrence of any other event.

12. GOVERNING LAW / ARBITRATION

12.1 Governing Law

This Agreement and any claim arising out of or in connection therewith shall be governed by, and construed in accordance with, the substantive laws of Switzerland, excluding its rules on conflict of laws and excluding international treaties or

international conventions (in particular the Vienna Convention on the International Sale of Goods dated 11 April 1980; CISG).

12.2 Arbitration

Any dispute, controversy or claim arising out of, or in relation to, this Agreement, including the validity, invalidity, breach, or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Arbitration Center in force on the date on which the notice of arbitration is submitted in accordance with these rules. The number of arbitrators shall be three. The seat of the arbitration shall be in Zurich. The arbitral proceedings shall be conducted in the English language.

[SIGNATURE PAGE FOLLOWS]

This Agreement so agreed on the date set forth on the cover page of this Agreement.

Seller 1:

[***]

Seller 2:

[***]

Seller 3:

[***]

Seller 4:

[***]

Seller 5:

[***]

Seller 6:

[***]

Seller 7:

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Seller 8:

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Seller 9:

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Seller 10:

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Seller 11:

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Seller 12:

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Seller 13:

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Seller 14:

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Seller 15:

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Seller 17:

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Seller 18:

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Seller 19:

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Seller 20:

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Seller 21:

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Seller 22:

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Seller 23:

[***]

Seller 24:

[***]

Seller 25:

[***]

Seller 26:

[***]

The Buyer:

GENFIT SA

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Pascal Prigent
Chief Executive Officer:

ANNEXES

Annex 0	Sellers' holding of Shares and Options
Annex 1	Definitions
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Annex 1: Definitions

Accounting Principles	means the CO as correctly and consistently applied in the past with correctness prevailing over consistency.
ACLF	means Acute-on-Chronic Liver Failure.
Adjustment Amount	shall have the meaning assigned to such term in Section 3.5.
Affiliate(s)	shall mean any Person that directly or indirectly controls, is controlled by or is under common control with the Person in question. For purposes of this definition, control of a Person means the power, direct or indirect, to direct the management and policies of such Person, whether by contract or otherwise; in any case control by a Person is given if it holds more than 50% of the voting rights of another Person.
Agreement	shall have the meaning assigned to such term in the Preamble.
AMF	shall have the meaning assigned to such term in Section 10.1.
Annex	shall mean any annex to this Agreement.
Applicable Law	shall mean, with respect to any Person, any domestic or foreign, federal, state, cantonal or local statute, law, ordinance, regulation, authorization, decision, injunction, decree, judgment, award of, or any agreement with, any Governmental Authority binding upon such Person or any of its businesses or assets.
Appraiser	shall have the meaning assigned to such term in Section 3.6.2a).
Base Purchase Price	shall have the meaning assigned to such term in Section 3.1.
Business Day(s)	shall mean any day, other than a Saturday or a Sunday, on which banks in the city of Zurich, Switzerland, are open for business to the public.
Buyer	shall have the meaning assigned to such term on the cover page.
Cash	shall mean on a consolidated basis cash and cash equivalents as the aggregate amount of (i) cash on hand, (ii) immediately available amount of demand deposits with banks, financial or other similar institutions, (iii) certified cheques, (iv) all cash equivalents freely available to the Company, including interest bearing short and long-term receivables (each in the meaning of Swiss GAAP) and (v) prepayments for liabilities to be incurred post Closing (including amounts paid for invoices issued by third parties where services or products have not yet been provided to Versantis); (vi) receivables due and recoverable from tax authorities and (vii) receivables from third parties which are actually paid to the Company within 60 days of Closing

CEO Separation Agreement	shall have the meaning assigned to such term in Section 5.2g).
Change of Control	means (i) the sale or transfer of a substantial portion of the assets held by the Company that constitute or are otherwise related to [***] and having a material and adverse impact on the attainability of any Milestone Event, (ii) upon a merger, consolidation, listing or acquisition of the Company in which the Buyer and its Affiliates collectively cease to own more than 50% of the voting equity securities of the Company.
CHF	shall mean Swiss Francs being the lawful currency of Switzerland.
Closing	shall have the meaning assigned to such term in Section 5.1.
Closing Date	shall have the meaning assigned to such term in Section 5.1.
CO	shall mean the Swiss Code of Obligations (SR 220).
Commercially Reasonable Efforts	shall have the meaning assigned to such term in Section 4.3a).
Common Shares	shall have the meaning assigned to such term in the Preamble A.
Company	shall have the meaning assigned to such term in the Preamble A.
Company Account	shall have the meaning assigned to such term in Section 2.4.3a).
Company's Intellectual Property Rights	shall have the meaning assigned to such term in Section 6.7c).
Confidentiality Undertaking	shall have the meaning assigned to such term in Section 10.1.
Damage	shall have the meaning assigned to such term in Section 8.1b).
De Minimis	shall have the meaning assigned to such term in Section 8.7a)(i).

Debt

means mean on a consolidated basis any third party debt, including but not limited to bank debt, factoring facilities, accrued outstanding interest, mezzanine or hybrid capital, shareholder loans or similar items, plus the sum of any (i) third party accounts payables, (ii) accruals for invoices outstanding; (iii) Taxes actually due and payable (all in the meaning of Swiss GAAP) excluding any operating lease commitments, except any pending amounts due at time of closing which should be added back, plus any Transaction Expenses which is not yet reflected as Deduction or Debt, and (iv) any accruals and/or provisions for bonuses, overtime compensation and holidays.

In addition, Debt shall include:

A) any Swiss withholding tax payment obligation incurred by the Company as a result of a payment or benefit (in cash or kind) made/conferred, or agreed to be made/conferred, by a Group Company (or on their behalf) to, on behalf of, or for the benefit of, a Seller or an Affiliate or a Related Person of a Seller since July 1, 2022, until the Closing Date, including without limitation:

   (i) any dividend, distribution of profits or assets, direct or indirect return or repayment of equity or loan capital declared, made or agreed to be made;

   (ii) any assumption or discharge (whether conditional or not) by any Group Company of any Liability of such Seller or Related Person;

   (iii) any waiver of any Liability owed by such Seller or Related Person, directly or indirectly, to a Group Company;

   (iv) any transaction with, or payment to or for the economic benefit of, any Seller or Related Person, effected by any Group Company;

B) any invoice which should have been issued to the Company between July 1, 2022, and the Closing Date but which was requested by the Company or any of the Sellers to be issued after the Closing Date and relates to a service rendered to or an obligation of the Company prior to the Closing Date.

Deductions

shall have the meaning assigned to such term in Section 2.4.2.

Discharge

shall have the meaning assigned to such term in Section 10.3b).

Disclosed Information	shall mean all information contained in the virtual data room maintained by the Company, the complete contents of which are contained in the USB-stick with the table of content listed in Annex A.
Disputed Items	shall have the meaning assigned to such term in Section 3.6.1d).
Employee Shares	shall have the meaning assigned to such term in Section 2.4.1.
Expert	shall have the meaning assigned to such term in Section 4.4c).
Fairly Disclosed	shall mean the fair, specific and non-misleading disclosure of a fact or circumstance made prior to the signing of the NEA in a manner which allowed the Buyer, without performing factual or additional inquiries or cross-examinations of other documents, to reasonably identify the impact of such fact or circumstance on the business operations, the financial situation and the prospects of the Company and its and its subsidiaries business. The concept of fair disclosure as defined herein shall supersede article 200 of the CO.
Final Adjustment Amount	shall have the meaning assigned to such term in Section 3.6.1d).
Financial Statements	shall have the meaning assigned to such term in Section 6.5a).
Fundamental Warranties	shall have the meaning assigned to such term in Section 6.
Governmental Authority	shall mean any domestic, foreign, state, federal, cantonal, municipal or local governmental authority, quasi-governmental authority, court, government organization, self-regulatory organization, supervisory authority, tribunal, arbitration tribunal or supranational organization (including the European Union).
Group / Group Companies	shall mean the Company and Versantis, Inc. collectively.
Group Company	shall mean any of the Company or Versantis, Inc..
IA	shall have the meaning assigned to such term in Section 10.5.
Initial Consideration	shall have the meaning assigned to such term in Section 3.1a).

Intellectual Property Rights	shall mean patents, patent applications (including provisional and non-provisional applications) including all patent cooperation treaty (PCT) applications, divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, supplemental protection certificates, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, trademarks, copyrightable works, designs, corporate names and domain names.
IP Transfer Agreements	shall have the meaning assigned to such term in Section 5.2e).
Key Employees	shall mean [***].
Licensed Intellectual Property Rights	shall have the meaning assigned to such term in Section 6.7c).
Lien	shall mean any lien, encumbrance or other security interest, irrespective of whether such lien arises under an agreement, by operation of law or by means of a judgment or decree.
Litigation	shall have the meaning assigned to such term in Section 6.12a).
Material Contracts	shall have the meaning assigned to such term in Section 6.17a).
Milestone Event(s)	shall have the meaning assigned to such term in Section 4.2.
Milestone Payment(s)	shall have the meaning assigned to such term in Section 4.2.
Milestone Notice Date	shall have the meaning assigned to such term in Section 4.1.
NEA	shall have the meaning assigned to such term in Preamble G.
Net Proceeds	shall have the meaning assigned to such term in Section 4.2c).
Notice of Breach	shall have the meaning assigned to such term in Section 8.3a).
Notice of Objection	shall have the meaning assigned to such term in Section 3.6.1d).

OFAC	shall have the meaning assigned to such term in Section 6.18d)(iii).
Option(s)	shall have the meaning assigned to such term in Preamble B.
Owned Intellectual Property Rights	shall have the meaning assigned to such term in Section 6.7a).
Party / **Parties**	shall have the meaning assigned to such term on the cover page.
Pension Plans	shall have the meaning assigned to such term in Section 6.15b).
Permits	shall mean governmental licenses, permits, approvals, clearances, certificates, consents, waivers, concessions, exemptions, orders, registrations, notices, listings, designations or other authorizations that are necessary for the conduct of the business and operations of the Company as conducted on the date of this Agreement.
Person	shall mean any natural person, corporation, limited liability company, general or limited partnership, trust, unincorporated organization, government agency or department, joint venture or any other person or entity doing business.
Personal Data	shall have the meaning assigned to such term in Section 6.18c)(i).
Positive Phase II Clinical Trial Results	shall have the meaning assigned to such term in Section 4.2c).
Preamble	shall mean the preamble to this Agreement.
Preferred Shares	shall have the meaning assigned to such term in the Preamble A.
Products	shall mean any biological or drug candidate, compound or product being researched, tested, developed, manufactured and/or distributed, generated using or which incorporates the Group's technology whereby any drug candidate, compound or product licensed by the Company to a third party prior to the date of this Agreement shall not be considered as a Product.

Proposed Adjustment Amount	shall have the meaning assigned to such term in Section 3.6.1a).
PRV	shall have the meaning assigned to such term in Section 4.2c).
Purchase Price	shall have the meaning assigned to such term in Section 3.1.
Regulatory Approval	shall have the meaning assigned to such term in Section 4.2b).
Related Person	shall mean an employee, officer, director, manager or member of any corporate body, including shareholders, (and their respective immediate family) or, as regards individuals, the immediate family of such individuals.
Restricted Parties	shall have the meaning assigned to such term in Section 6.18e)(ii).
Sanctioned Countries	shall have the meaning assigned to such term in Section 6.18e)(i).
Sanctions	shall mean any economic or financial sanctions, export controls, trade restrictions, embargoes or other similar laws, regulations, rules, measures or restrictions, including any restricted or designated party lists, orders or requirements, in each case, in force from time to time and imposed, administered or enforced by a Sanctions Authority.
Sanctions Authority	shall mean any (a) the United States of America; (b) the United Nations; (c) the European Union or any of its member states; (d) the United Kingdom; (e) the applicable Governmental Authorities of any of the foregoing including the OFAC, the United States Department of State and Her Majesty's Treasury; and (f) any other Governmental Authority with jurisdiction over the Group Companies that imposes, administers or enforces Sanctions.
Section	shall mean any section of this Agreement.
Seller(s)	shall have the meaning assigned to such term on the cover page.
Sellers 1 to 26	shall have the meaning assigned to such term on the cover page.

Sellers' Knowledge	or any similar knowledge qualification means the actual knowledge of any of [***] at or prior to the Closing Date or the knowledge they should have, had they made due inquiry with the respective employee or consultant entrusted with such matter.
Sellers' Majority	shall have the meaning assigned to such term in Section 4.4c).
Sellers' Representative	shall have the meaning assigned to such term on the cover page.
Sellers' Representative Bank Account	shall have the meaning assigned to such term in Section 3.3.
Series A Preferred Shares	shall have the meaning assigned to such term in the Preamble A.
Series B Preferred Shares	shall have the meaning assigned to such term in the Preamble A.
SHA	shall have the meaning assigned to such term in Section 10.5.
Share(s)	shall have the meaning assigned to such term in Preamble A.
Tax	shall mean (i) all taxes,, including corporate or personal income and profit taxes, capital taxes, stamp duties (both on the issuance and on the transfer of securities), withholding and source taxes, VAT, gains, sales, transfer, license, payroll, employment, social security, pensions, customs, equity, stamp, estimated taxes and all other taxes, duties, charges, levies or imposts imposed by a Governmental Authority and (ii) all interest, penalties, fines, additions to tax or additional amounts imposed in connection with any item described in paragraph (i).
Tax Ruling	shall mean the tax rulings regarding "[***]" filed with the Zurich and Grisons cantonal Tax authorities on [***].
Third Party Claim	shall have the meaning assigned to such term in Section 8.5.
Threshold Amount	shall have the meaning assigned to such term in Section 8.7a)(ii).

Transaction Expenses	means without duplication and, to the extent not paid and remaining payable, the aggregate amount of any and all fees and expenses (excluding Sellers' expenses) incurred by or on behalf of, or paid or to be paid directly by, the Company or any person that the Company pays or reimburses or is otherwise legally obligated to pay or reimburse in connection with the negotiation, preparation or execution of this Agreement or the performance or consummation of the transactions contemplated hereby or thereby, including (i) all fees and expenses of counsel, advisors, consultants, investment bankers, accountants, auditors and any other experts in connection with the transactions contemplated hereby; (ii) any fees or expenses associated with obtaining the release and termination of any Lien in connection with the transactions contemplated hereby; (iii) all brokers', finders' or similar fees specifically required in connection with the transactions contemplated hereby; (iv) other than amounts payable pursuant to Section 2.4, any liability resulting from any cancellation of Options (except such cancellation is reflected in the Purchase Price), change of control payments or similar amounts payable by the Company and specifically triggered by the transactions contemplated hereby.
U.S. Holder Options	shall have the meaning assigned to such term in Section 2.2.
U.S. Seller	shall have the meaning assigned to such term in Section 2.2.
VAT	shall mean value added tax (*Mehrwertsteuer*).
VS-01	shall mean an intraperitoneal liposomal formulation for which intellectual property is defined by patent family entitled "[***]" (see e.g. [***]).
VS-02	shall mean an urease inhibitor for which intellectual property is defined by patent family entitled "[***]" (see e.g. [***]).
W&I Insurance Policy	shall mean any buyer-side warranty and indemnity insurance policy entered into by the Buyer in respect of this Agreement and the transactions contemplated herein.
W&I Insurer	shall mean the provider of the W&I Insurance Policy.
Warranty Cap	shall have the meaning assigned to such term in Section 8.7a)8.7b)(i).

GENFIT

French *société anonyme* with a board of directors with a share capital of € 7,791,609.25

Registered office: Parc Eurasanté, 885, avenue Eugène Avinée, 59120 Loos, France

424 341 907 R.C.S. Lille Métropole

GENFIT 3.50 per cent. bonds issue for a nominal amount of € 179,999,997.60 due 16 October 2025 convertible into new Shares and/or exchangeable for existing Shares of GENFIT

AMENDED AND RESTATED TERMS AND CONDITIONS OF THE BONDS DATED 25 JANUARY 2021

THE AMENDED AND RESTATED TERMS AND CONDITIONS AMEND AND RESTATE THE TERMS AND CONDITIONS DATED 11 OCTOBER 2017.

THE AMENDED AND RESTATED TERMS AND CONDITIONS HAVE BEEN CREATED SOLELY AS A MATTER OF RECORD TO EVIDENCE THE CURRENT TERMS AND CONDITIONS OF THE BONDS AS AMENDED WITH EFFECT FROM 25 JANUARY 2021 TO AMEND THE TERMS AND CONDITIONS OF THE BONDS FOLLOWING DECISIONS OF THE MEETINGS OF THE BONDHOLDERS AND THE COMPANY'S SHAREHOLDERS CONVENED ON 25 JANUARY 2021 IN ORDER TO APPROVE CERTAIN MODIFICATIONS OF TERMS AND CONDITIONS OF THE BONDS.

NO OFFER OF ANY OF THE BONDS IS BEING MADE BY THE COMPANY (AS DEFINED BELOW) PURSUANT TO THIS DOCUMENT OR OTHERWISE AND THE COMPANY DOES NOT ACCEPT ANY ADDITIONAL OBLIGATIONS TO BONDHOLDERS IN RELATION TO THIS DOCUMENT.

The following text contains the terms and conditions of the Bonds (as defined below) (the "**Terms and Conditions**").

The combined general meeting (ordinary and extraordinary) of GENFIT of 16 June 2017, under resolution eleventh, delegated to the Board of Directors of the Company the authority to issue the Bonds. The Board of Directors, during its meeting of 22 September 2017, decided to authorise the issue of the Bonds and granted powers to the Chairman of the Board of Directors and Chief Executive Officer (*Président-Directeur Général*) of the Company to issue the Bonds and determine the terms and conditions of the Bonds.

For the purposes of these Terms and Conditions:

"Bonds" means the Company's 3.50 per cent. bonds due 16 October 2025 convertible into new Shares and/or exchangeable for existing Shares of GENFIT;

"Bondholders" means the holders of the Bonds;

"Business Day" means a day (other than a Saturday or a Sunday) on which banks are open for business in Paris (France) and on which Euroclear France and the trans-european automated real-time gross settlement express transfer system ("**TARGET**"), or any succeeding system operate;

"Calculation Agent" means Aether Financial Services, 36 rue de Monceau, 75008 Paris, France;

"Centralising Agent" means BNP Paribas Securities Services, 3, rue d'Antin, 75002 Paris, France;

"**Condition**" means a condition of these Terms and Conditions;

"Euronext Access™" means the Euronext Access™ (Open Market) of Euronext Paris (as defined below), a non-regulated market, pursuant to the terms of the 2004/39/CE Directive dated 21 April 2004 relating to the financial market instruments within the European Economic Area (or any succeeding regulation);

"**GENFIT**" and "**Company**" means GENFIT, a French *société anonyme* with a board of directors, with a share capital of € 7,791,609.25, having its registered office at Parc Eurasanté, 885, avenue Eugène Avinée, 59120 Loos, France and registered under number 424 341 907 R.C.S. Lille Métropole;

"Independent Expert" means an independent financial institution of international repute or independent financial adviser with appropriate expertise (which may be the initial Calculation Agent acting in such Independent Expert capacity), chosen by the Company at its sole discretion;

"Masse" has the meaning ascribed to such term in Condition 12 (*Representation of Bondholders*) below.

"Regulated Market" means any regulated market pursuant to the terms of the 2004/39/CE Directive dated 21 April 2004 relating to the financial market instruments within the European Economic Area (or any succeeding regulation);

"**Relevant Exchange**" means (A) in respect of the Shares, (i) the Regulated Market of Euronext in Paris ("**Euronext Paris**") or (ii) (if the Shares are no longer listed on Euronext Paris at the relevant time) the Regulated Market or similar market on which the Share has its principal listing, and (B) in respect of any other security, the Regulated Market or any other market on which such security has its principal listing;

"Representative of the Masse" has the meaning ascribed to such term in Condition 12 (*Representation of Bondholders*) below.

"Shares" means the shares of the Company with a nominal value of € 0.25 each;

"Trading Day" means a day on which the Shares are capable of being traded on the Relevant Exchange in respect thereof other than a day on which such trading ceases prior to the usual closing time (whether such closing is scheduled (as it is often the case regarding trading on Euronext Paris on 24 December and 31 December) or unscheduled);

"**Volume-Weighted Average Price**" means, in respect of a Share or other security, on any Trading Day, the order book volume-weighted average price of such Share or other security as published by or derived from (i) Bloomberg page HP (or any successor page) (setting "Weighted Average Line", or any successor setting) in respect of the Relevant Exchange in respect thereof (such page being as at the Issue Date of the Bonds, in the case of the Share, GNFT:FP Equity HP), provided that in the case of a Volume-Weighted Average Price to be observed over a period of several Trading Days, such Volume-Weighted Average Price shall be equal to the volume-weighted average of the relevant daily Volume-Weighted Average Prices (the daily volumes to be used for the purpose of determining such weighted average being the volumes as published on Bloomberg page HP (or any successor page), setting "VWAP Volume" (or any successor setting)), as determined by the Calculation Agent, or, (ii) if the Volume-Weighted Average Price cannot be determined as aforesaid, such Relevant Exchange in respect thereof.

For the avoidance of doubt, in these Conditions, references to "day" or "days" are to calendar days unless the context otherwise specifies.

1. **NATURE AND CLASS OF THE BONDS**

The Bonds which will be issued by the Company constitute securities that confer certain rights to receive Shares within the meaning of Articles L. 228-91 *et seq*. of the French Commercial Code (*Code de commerce*).

2. **NOMINAL AMOUNT OF THE ISSUANCE – PAR VALUE OF THE BONDS – ISSUE PRICE OF THE BONDS – ISSUE DATE OF THE BONDS**

The nominal amount of the issuance will be € 179,999,997.60 represented by 6,081,081 Bonds each with a par value of € 29.60, representing an issue premium of 30.0% over the reference price of the Share used at the time of determination of the final terms of the Bonds and corresponding to the Volume-Weighted Average Price of the Shares on Euronext Paris between the launch of the offering on 11 October 2017 and the time of determination of the final terms of the Bonds on the same day.

The Bonds are expected to be issued on 16 October 2017 (the "**Issue Date of the Bonds**"). This date is also the entitlement and single settlement-delivery date of the Bonds.

3. **HARDSHIP (*IMPRÉVISION*)**

In relation to these Conditions, the Company, the Representative of the Masse and each Bondholder waive any right under Article 1195 of the French Civil Code (*Code civil*).

4. **GOVERNING LAW AND JURISDICTION**

The Bonds are governed by French law.

The courts having jurisdiction in the event of a dispute are those where the registered office of the Company is located (at the date hereof the registered office of the Company is located in Loos, France) when the Company is the defendant and are designated according to the nature of the dispute, unless otherwise provided by the French Code of Civil Procedure (*Code de procédure civile*).

5. **FORM AND METHOD OF REGISTRATION IN BONDS ACCOUNTS**

The Bonds may be held in registered or bearer form, at the Bondholders' option.

In accordance with Article L. 211-3 of the French Monetary and Financial Code (*Code monétaire et financier*), the Bonds shall be registered in securities accounts held, as the case may be, by the Company or an authorized intermediary.

Consequently, the rights of the Bondholders will be represented via book entries in securities accounts opened in their name in the registries of:

- BNP Paribas Securities Services, appointed by the Company for Bonds held in fully registered form (*forme nominative pure*);
- an authorised financial intermediary chosen by the Bondholder and BNP Paribas Securities Services, appointed by the Company, for the Bonds held in administered registered form (*forme nominative administrée*); or
- an authorised financial intermediary chosen by the Bondholder for the Bonds held in bearer form (*forme au porteur*).

No document evidencing the ownership of the Bonds (including representative certificates under Article R. 211-7 of the French Monetary and Financial Code (*Code monétaire et financier*)) will be issued relating to the Bonds.

In accordance with Articles L. 211-15 and L. 211-17 of the French Monetary and Financial Code (*Code monétaire et financier*), the Bonds are transferred from one account to another, and the transfer of ownership of the Bonds will occur upon their book entry in the purchaser's securities account.

A request for the admission of the Bonds to the operations of Euroclear France will be made and Euroclear France will be responsible for the clearing of the Bonds between entities managing securities accounts. In addition, a request will also be made for the admission of the Bonds to the operations of Euroclear Bank S.A. /N.V. and/or Clearstream Banking, *société anonyme* (Luxembourg). The ISIN of the Bonds is FR0013286903.

It is expected that the Bonds will be registered in securities accounts from 16 October 2017, date of the settlement-delivery of the Bonds and Issue Date of the Bonds and admitted to trading on Euronext Access™ within 30 calendar days following the Issue Date of the Bonds.

6. CURRENCY OF THE ISSUANCE OF THE BONDS

The Bonds will be denominated in euros.

7. RANKING OF THE BONDS

7.1 Status

The principal and the interest in respect of the Bonds constitute senior, direct, unconditional, unsubordinated and (subject to Condition 7.2 (*Negative Pledge*) below) unsecured obligations of the Company, ranking equally among themselves and, subject to legal mandatory exceptions, *pari passu* with all other present or future unsecured and unsubordinated obligations of the Company.

The servicing of the Bonds in terms of interest, amortisation payments, taxes, costs and other amounts in respect of the Bonds is not guaranteed nor secured.

7.2 Negative pledge

7.2.1 So long as any of the Bonds remains outstanding (as defined below), the Company undertakes that it will not and will ensure that none of its Material Subsidiaries will create or permit to subsist any mortgage, charge, lien, pledge or other security interest (*sûreté réelle*) (a "**Security**"), other than a Permitted Security, upon the whole or any part of the Company's or any Material Subsidiary's present or future assets or revenues for the benefit of any holders of any Relevant Debt to secure (a) payment of any sum in respect of any such Relevant Debt or (b) any payment under any guarantee relating to any Relevant Debt, unless the Bonds are equally and rateably secured by such Security.

7.2.2 For the purposes of this Condition 7.2,

"**Group**" means the Company and its Subsidiaries taken as a whole.

“**Material Subsidiaries**” means any Subsidiary of the Company which represents at any time 5 % or more of the consolidated net revenues (excluding any intra-group revenues) or total consolidated assets (excluding any intra-group assets) of the Group, such determination being (i) made by reference to the most recent annual financial statements of that Subsidiary, consolidated where applicable, used for the purpose of the most recent annual audited consolidated financial statements of the Company and (ii) certified by the Company's statutory auditors.

"**Relevant Debt**" means (i) any present or future indebtedness of the Company and its Material Subsidiaries represented or evidenced by notes, bonds, debentures or other securities which are for the time being, or are capable of being, quoted, listed or ordinarily dealt with on any stock exchange, over-the-counter-market or other securities market and (ii) any financial debt (including, for the avoidance of doubt, bank debt) of the Company and its Material Subsidiaries at any time outstanding.

"**Subsidiary**" means in relation to any person or entity at any time, any other person or entity (whether or not now existing) controlled directly or indirectly by such person or entity within the meaning of Article L. 233-3 of the French Commercial Code (Code de commerce). At the date hereof, the Company has two wholly-owned subsidiaries: Genfit Corp, a Delaware corporation and Genfit Pharmaceutical SAS, a French corporation.

"**outstanding**" means, in relation to the Bonds, all the Bonds issued other than: (a) those which have been redeemed in accordance with the Conditions, (b) those in respect of which the date for redemption in accordance with the Conditions has occurred and the redemption moneys have been duly paid to the Centralising Agent and (c) those which have been purchased and cancelled as provided in Condition 10.7 (*Cancellation of the Bonds*).

"**Permitted Security**" means any Security created by the Company or any Material Subsidiary:

(i) in existence as at the Issue Date of the Bonds;

(ii) over or affecting any asset acquired by a member of the Group after the Issue Date of the Bonds created in contemplation of the acquisition of that asset by that member of the Group, if the Security is created in order to secure the financing of the acquisition of that asset;

(iii) over or affecting any asset of any company which becomes a member of the Group after the Issue Date of the Bonds, where the Security is created prior to the date on which that company becomes a member of the Group;

(iv) arising as a consequence of any present or future finance or capital lease contracted in the course of the Company’s ordinary course of business;

(v) arising under any retention of title, hire purchase or conditional sale arrangement or arrangements having similar effect in respect of goods supplied to a member of the Group in the ordinary course of trading and on the supplier's standard or usual terms and not arising as a result of any default or omission by any member of the Group;

(vi) any lien arising by operation of law and in the ordinary course of trading;

(vii) which result from the operation of provisions under standard business terms of banks or saving banks; or

(viii) securing indebtedness the principal amount of which (when aggregated with the principal amount of any other indebtedness which has the benefit of Security given by any member of the Group other than any permitted under paragraphs (i) to (vii) above) does not exceed € 25,000,000 (or its equivalent in another currency or currencies).

7.3 **Further issues**

If the Company subsequently issues new bonds with rights identical in all respects to those of the Bonds (except, if applicable, the related first interest payment and the issue date thereon), the Company may, without the consent of the Bondholders and provided that the terms and conditions of such bonds so permit, consolidate the Bonds with the bonds of any subsequent issuances, thereby treating such bonds as the same issue for purposes of financial agency services and trading. All holders of such bonds would in this case be grouped into a single Masse.

8. RIGHTS AND RESTRICTIONS ATTACHED TO THE BONDS AND TERMS OF EXERCISE OF SUCH RIGHTS

The Bonds entitle their holders to semi-annual interest payments in accordance with Condition 9 (*Interest*) and will be redeemed at par at their maturity date or at their early redemption date in accordance with the provisions of Condition 10 (*Redemption of the Bonds*).

Furthermore, in the event of exercise of the Conversion/Exchange Right, as defined in Condition 15.1 (*Nature of the Conversion/Exchange Right*), the Bondholders will have the right to receive new and/or existing Shares. The terms and conditions of the Conversion/Exchange Right are set out in Condition 15.3 (*Terms of allocation pursuant to the Conversion/Exchange Right*).

The exercise of the Conversion/Exchange Right results in the cancellation of the Bonds for which it was exercised.

9. **INTEREST**

The Bonds will bear interest on their outstanding principal amount from (and including) the Issue Date of the Bonds at the rate of 3.50 per cent. *per annum* payable semi-annually in arrear in equal instalments of EUR 0.518 per Bond on 16 April and 16 October in each year (or if it is not a Business Day, the following Business Day and in any such case the Bondholders will not be entitled to further interest or to any other sum in respect of such postponed payment) (inclusive) (each, an "**Interest Payment Date**"), commencing on 16 April 2018.

Any amount of interest relating to an interest period of less than a full half-year will be calculated by applying to the par value per Bond the product of (a) the above mentioned Interest Rate and (b) the ratio between (x) the exact number of days since the last Interest Payment Date (or, as the case may be, since the Issue Date of the Bonds) (exclusive) to the early redemption date (inclusive) and (y) 365, or 366 (in case of a leap year), depending on the exact number of days included between the next Interest Payment Date (exclusive) and the same date in the preceding year (inclusive).

Subject to the provisions of Condition 15.6 (*Bondholders' rights to interest on the Bonds and to dividends with respect to Shares delivered - listing of the Shares delivered*), interest will cease to accrue from the Maturity Date of the Bonds or early redemption date of the Bonds.

10. **REDEMPTION OF THE BONDS**

10.1 **Redemption at maturity**

Unless the Bonds have been the subject of an early redemption or purchase pursuant to the terms set out below and in the absence of the exercise of the Conversion/Exchange Right, the Bonds will be redeemed in full at par on 16 October 2025 (the **"Maturity Date of the Bonds"**).

If the Maturity Date of the Bonds is not a Business Day, the redemption price shall be paid on the next following Business Day.

The term of the Bonds from the Issue Date of the Bonds to the Maturity Date of the Bonds is eight years.

10.2 **Early redemption by repurchase or tender or exchange offers at the Company's option**

The Company shall have the right to purchase all or part of the Bonds at any time before the Maturity Date of the Bonds, without any limitation on price or number, either by repurchasing them through on-market or off-market transactions, or through repurchase or exchange offers.

Any such transaction shall not affect the normal schedule for the redemption of any outstanding Bonds.

The Bonds so purchased by the Company will be (i) cancelled or, (ii) subject to change of law as described in Condition 10.7 (iii), held by the Company in accordance with applicable laws, re-sold on the market or sold to a subsidiary or affiliate of the Company.

10.3 **Early redemption at the Company's option**

10.3.1 The Company may, at any time and at its option, from 6 November 2023 and until the Maturity Date of the Bonds subject to a minimum 30 calendar days' prior notice as set out in Condition 10.6 (*Publication of information in the event of redemption at maturity or early redemption of the Bonds and exercise of the Conversion/Exchange Right*), redeem early all (but not some only) the outstanding Bonds, at par plus accrued interest from the immediately preceding Interest Payment Date (or, if applicable, the Issue Date of the Bonds) to the date set for early redemption if the arithmetic mean (calculated over a period of 20 consecutive Trading Days chosen by the Company from among the 40 consecutive Trading Days immediately preceding the date of publication of the early redemption notice) of the daily product:

(A) of the Volume-Weighted Average Price of the Share traded on Euronext Paris (or, in the absence of listing on Euronext Paris, on any other Regulated Market or any other similar market where the Share has its principal listing); and

(B) the Conversion/Exchange Ratio (as defined in Condition 15.1 (*Nature of the Conversion/Exchange Right*)) applicable at each date;

exceeds 150% of the par value of the Bonds, as verified by the Calculation Agent upon request by the Company.

10.3.2 The Company may, at any time and at its option, subject to a minimum 30 calendar days prior notice as set out in Condition 10.6 (*Publication of information in the event of redemption at maturity or early redemption of the Bonds and exercise of the Conversion/Exchange Right*), redeem early all, but not some only, of the outstanding Bonds at par plus accrued interest from the immediately preceding Interest Payment Date (or, if applicable, the Issue Date of the Bonds) to the date set for early redemption, if the total number of Bonds still outstanding represents 15% or less of the number of Bonds originally issued.

10.3.3 In the events described in paragraphs 10.3.1 and 10.3.2 above, the Bondholders will retain the ability to request the exercise of their Conversion/Exchange Right pursuant to Condition 15.3 (*Terms of allocation pursuant to the Conversion/Exchange Right*) until the end of the seventh Trading Day (inclusive) preceding the early redemption date, as provided in Condition 15 (*Conversion/Exchange Right*).

10.3.4 The interests shall cease to accrue on the effective date on which the Bonds are redeemed by the Company.

10.4 **Events of Default**

If any of the following events (each an "**Event of Default**") shall have occurred and be continuing:

i. default by the Company in any payment when due of principal or interest on any of the Bonds, if such default shall not have been remedied within 15 calendar days thereafter; or

ii. default by the Company in the performance of, or compliance with, any other obligation under the Bonds, other than as referred to in paragraph 10.4 i above, if such default shall not have been remedied within 15 Business Days after receipt by the Company of written notice of such default given by a Bondholder; or

iii. any present or future indebtedness for borrowed money or guarantee thereof of the Company or any Subsidiary in excess of € 6,000,000 (or its equivalent in any other currency) whether individually or in aggregate, (x) is not paid when due or (as the case may be) within any originally applicable grace period or (y) becomes (or becomes capable of being declared) following, where applicable, the expiry of any originally applicable grace period, due and payable (*exigible*) prior to its stated maturity as a result of a default thereunder; or

iv. a judgement is issued for the judicial liquidation (*liquidation judiciaire*) or for a transfer of the whole of the business (*cession totale de l'entreprise*) or substantially the whole of the business of the Company or any Material Subsidiary; or, to the extent permitted by law, the Company or any Material Subsidiary is subject to any other insolvency or bankruptcy proceedings under any applicable laws or the Company or any Material Subsidiary makes any conveyance, assignment or other arrangement for the benefit of its creditors or enters into a composition with its creditors; or

v. if the Company or any Material Subsidiary is wound up or dissolved or ceases to carry on all or substantially all of its business or disposes of all or substantially all of its business except (i) in connection with a merger, consolidation, amalgamation or other form of reorganisation pursuant to which the surviving entity shall be the transferee of or successor to all or substantially all of the business of the Company or any Material Subsidiary and assumes all of the obligations of the Company with respect to the Bonds and, in the case of the Material Subsidiary, if such surviving entity is controlled (within the meaning of Article L.233-3 of the French Commercial Code (*Code de commerce*) directly or indirectly by the Company or (ii) on such other terms approved by a resolution of the General Meeting of Bondholders; or

vi. if the Shares are no longer admitted to trading on Euronext Paris or on any other Regulated Market;

then any Bondholder may give written notice to the Company at its registered office with a copy to the Centralising Agent that such Bond is immediately due and repayable, at par plus interest accrued from the last Interest Payment Date (or, if applicable, the Issue Date of the Bonds) until the date set for early redemption, without further formality, unless such event shall have been remedied prior to the receipt of such notice by the Centralising Agent.

10.5 **Early redemption at the Bondholders' option upon Change of Control of the Company**

10.5.1 If at any time while any Bond remains outstanding, there occurs a Change of Control (as defined below), the holder of each Bond will have the option (the "**Change of Control Put Option**") (unless, prior to the giving of the Change of Control Put Notice (as defined below), the Company gives notice to redeem the Bonds under Condition 10.3 (*Early redemption at the Company's option*)) to require the Company to redeem or, at the Company's option, to procure the purchase of that Bond, at par plus accrued interest from the immediately preceding Interest Payment Date (or, if applicable, the Issue Date of the Bonds) (exclusive) to the date set for early redemption (inclusive).

10.5.2 Upon the Company becoming aware that a Change of Control has occurred, the Company shall inform within a 30 calendar-day period starting from such Change of Control the Bondholders by means of a notice published by the Company on its website (www.genfit.fr) (a "**Change of Control Put Notice**"). The Change of Control Put Notice will specify (i) the nature of the Change of Control and the circumstances giving rise to it, (ii) the redemption date that will be between the 25th and the 30th Business Day following the date of the publication of the Change of Control Put Notice (the "**Change of Control Redemption Date**"), (iii) the redemption amount and (iv) the procedure for exercising the Change of Control Put Option and the Change of Control Put Period.

10.5.3 To exercise the Change of Control Put Option to require redemption or, as the case may be, purchase of the Bonds under this Condition 10.5, Bondholders must make a request to the financial intermediary holding their Bonds in a securities account and cause to be transferred their Bonds to be so redeemed or purchased to the account of the Centralising Agent specified in the Change of Control Put Notice for the account of the Company within the period beginning on the date of the publication of the Change of Control Put Notice and ending five Business Days prior to the Change of Control Redemption Date (the **"Change of Control Put Period"**).

The request transmitted by the financial intermediary in whose accounts the Bonds are held must have been received and the corresponding Bonds transferred to the Centralising Agent by the relevant financial intermediary by 5:00 p.m., (Paris time) at the latest on the last day of the Change of Control Put Period.

10.5.4 Once given to the relevant financial intermediary a request of redemption shall be irrevocable. The Company shall redeem or, at the option of the Company procure the purchase of, the Bonds in respect of which the Change of Control Put Option has been validly exercised as provided above, and subject to the transfer of such Bonds to the account of the Centralising Agent for the account of the Company as described above, on the Change of Control Redemption Date. Payment in respect of such Bonds will be made on the Change of Control Redemption Date by transfer to the financial intermediary of the Bondholders for credit of the Bondholders' bank account. For the avoidance of doubt, the Company shall have no responsibility for any cost or loss of whatever kind (including breakage costs) which the Bondholder may incur as a result of or in connection with such Bondholder's exercise or purported exercise of, or otherwise in connection with, any Change of Control Put Option (whether as a result of any purchase or redemption arising there from or otherwise).

For the purpose of the Terms and Conditions, a "**Change of Control**" shall be deemed to have occurred at each time that any person or persons acting in concert come(s) to legally or beneficially own or acquire(s), directly or indirectly, (i) such number of shares in the share capital of the Company carrying more than 40% of the voting rights attached to the Shares or (ii) 40% of the share capital of the Company.

For the purpose of this definition:

"**acting in concert**" has the meaning given in Article L. 233-10 of the French Commercial Code (*Code de commerce*).

10.6 **Publication of information in the event of redemption at maturity or early redemption of the Bonds and exercise of the Conversion/Exchange Right**

Information relating to the number of Bonds repurchased, redeemed, or for which the Conversion/Exchange Right has been exercised, and to the number of Bonds remaining outstanding, shall be provided to Euronext Access™ (or its successor). This information may also be obtained from the Company or from the Centralising Agent.

The decision of the Company to redeem outstanding Bonds upon or prior to their maturity shall be published on its website via a notice including the necessary information and informing the Bondholders of the redemption date, no later than 30 calendar days prior to the Maturity Date of the Bonds or early redemption date by the Company and made available on its website (www.genfit.fr).

10.7 **Cancellation of the Bonds**

Shall cease to be considered outstanding and shall be cancelled in accordance with applicable law (i) the Bonds redeemed at or prior to maturity, (ii) the Bonds for which the Conversion/Exchange Right has been exercised, as well as (iii) the Bonds repurchased on or off the market or by way of repurchase or exchange offers, except in case of a change of laws, applicable after the Issue Date of the Bonds, authorising the issuers to hold Shares or securities giving access to the company's capital (which is not currently the case, in particular pursuant to Article L. 225-149-2 of the French Commercial Code (*Code de commerce*)), in which case the Company will have the ability to hold the Bonds thus repurchased.

11. PRESCRIPTION

11.1 Interests

Any claims filed against the Company for the payment of interests due under the Bonds will be prescribed after a period of five years from the date on which such interests become due. In addition, the interests will be prescribed to the benefit of the French State at the expiration of a period of five years from the date on which it becomes due.

11.2 Redemption

Any claims filed against the Company seeking redemption of the Bonds will be time barred at the expiration of a period of ten years from the normal or early redemption date. In addition, the redemption price will be forfeited to the benefit of the French State at the expiration of a period of ten years from the normal or early redemption date.

12. REPRESENTATION OF BONDHOLDERS

In accordance with Article L. 228-103 of the French Commercial Code (*Code de commerce*), the Bondholders will be grouped together in a collective group with a legal personality to defend their common interests (the "**Masse**").

The Bondholders' general meeting is competent to authorise amendments to the terms and conditions of the Bonds and to vote on all decisions that require its approval under applicable law. The general meeting of Bondholders also deliberates on merger or demerger proposals presented by the Company pursuant to the applicable provisions of Articles L. 228-65, I, 3°, L. 236-13, L. 236-18 and L. 228-73 of the French Commercial Code (*Code de commerce*).

Under current law, each Bond carries the right to one vote. The general meeting of Bondholders may not validly deliberate unless the Bondholders present or represented hold at least one-quarter of the Bonds carrying voting rights at the first meeting convocation and at least one-fifth at the second meeting convocation. Decisions made by the general meeting of Bondholders are only valid if approved by a majority of two-thirds of the votes of the Bondholders present or represented.

Appointed Representative of the Masse of Bondholders

In accordance with Article L. 228-47 of the French Commercial Code (*Code de commerce*), the designated appointed representative of the Masse of Bondholders (hereinafter referred to as the "**Representative of the Masse**") will be:

Aether Financial Services
36 rue de Monceau
75008 Paris
agency@aetherfs.com

The Representative of the Masse will have the power, subject to any contrary resolution of the general meeting of Bondholders, to carry out, on behalf of the Masse all actions of an administrative nature that may be necessary to protect the common interests of the Bondholders.

The Representative will exercise its duty until its dissolution, resignation or termination of its duty by a general meeting of Bondholders or until it becomes unable to act. Its appointment shall automatically cease on the Maturity Date of the Bonds, or if no Bonds remain outstanding prior to the Maturity Date of the Bonds. His appointment shall automatically cease on the date of total redemption of the Bonds, whether at or prior to maturity. This term may be automatically extended, as the case may be, until the final resolution of any legal proceedings in which the Representative of the Masse is involved and the enforcement of any judgments rendered or settlements made pursuant thereto, if applicable.

General

The Representative of the Masse will be entitled to a remuneration of € 500 (VAT excluded) per year, with the first payment at the Issue Date of the Bonds calculated on a prorata basis until the end of the calendar year, the next payment for each subsequent calendar year on the 1st of January, and the last payment on the calendar year of the Maturity Date of the Bonds on the 1st of January and on a prorata basis until the date of such redemption, provided that there are still Bonds outstanding at any such time.

The Company will bear the cost of compensation of the Representative of the Masse and the expenses of calling and holding general meetings of the Bondholders, the costs related to publishing the decisions thereof, as well as any fees related to the appointment of the Representative of the Masse under Article L. 228-50 of the French Commercial Code (*Code de commerce*), and, more generally, all duly incurred and justified administrative and operational expenses of the Masse.

General meetings of the Bondholders will be held at the registered office of the Company or such other place as will be specified in the notice convening the meeting. Each Bondholder will have the right, during the 15 calendar-day period preceding such meeting, to review or procure a written copy, whether on his own or by proxy, at the registered head office of the Company or any other location specified in the notice of the meeting, of the resolutions to be proposed and reports to be presented at such meeting.

In the event that future issuances of bonds give subscribers identical rights to those under the Bonds and if the terms and conditions of such future bonds so permit, the holders of all such bonds shall be grouped together in a single Masse.

13. RESTRICTIONS ON THE TRANSFERABILITY OF THE BONDS

Subject to applicable selling restrictions, there are no restrictions imposed by the terms and conditions of the issue on the free transferability of the Bonds.

14. TAXATION

14.1 Withholding Tax

Payment of principal, interest or any other payment by or on behalf of the Company in respect of the Bonds shall be made free and clear of, and without withholding or deduction for, any taxes, duties, assessments or governmental charges of whatever nature imposed, levied, collected, withheld or assessed by or within any jurisdiction or any authority therein or thereof having power to tax, unless such withholding or deduction is required by law. If any law should require that payments of principal, interest or any other payment by or on behalf of the Company in respect of any Bonds be subject to withholding or deduction in respect of any present or future taxes, duties, assessments or governmental charges of whatever nature, the Company will not be required to pay any additional amounts in respect of any such deduction or withholding.

14.2 French tax on financial transactions

14.2.1 Pursuant to Article 235 *ter* ZD of the French *Code général des impôts* as in force and applicable on the date hereof*,* the financial transactions tax (the "**FTT**") applies to acquisitions for consideration of equity stocks (*titres de capital*) or assimilated securities (*titres de capital assimilés*) admitted to trading on a Regulated Market when issued by a company whose head office is in France with a market capitalisation of over one billion euros on the 1st of December of the year preceding the acquisition. On 1 December 2016, the market capitalisation of the Company did not exceed this threshold.

Under French law as in force and applicable on the date hereof, when the FTT is not due, registration duties would apply to the acquisition of existing Shares when it is established by a deed (*acte*).

14.2.2 Under French law as in force and applicable on the date hereof, Bondholders are advised that:

- the acquisition of the Bonds is exempt from the FTT;

- the delivery of existing Shares as a result of the exercise by the Bondholders of their Conversion/Exchange Right may be subject to the FTT (currently at a rate of 0.3%, based on the conversion/exchange price fixed in these Terms and Conditions) if the market capitalisation of the Company exceeds one billion euros on the 1st of December of the year preceding the delivery of the existing Shares, for which the financial intermediaries with whom the Bondholders have exercised their Conversion/Exchange Right or their custodian are accountable for. Depending on the contractual provisions governing the relationship between the Bondholders, their financial intermediaries and custodians, Bondholders are likely to bear the cost of the FTT when it is applicable; and

- the delivery of new Shares following the exercise by the Bondholders of their Conversion/Exchange Right is exempt from the FTT.

The Company is not required to assume or indemnify the Bondholders for the cost of the FTT or any registration duties that may be applicable with respect to the delivery of the new Shares to be issued upon conversion of the Bonds or the existing Shares to be delivered upon exchange of the Bonds.

Investors are invited to contact their usual tax advisor to assess the tax consequences of exercising their Conversion/Exchange Right.

15. CONVERSION/EXCHANGE RIGHT

15.1 Nature of the Conversion/Exchange Right

15.1.1 The Bondholders will have the right (the **"Conversion/Exchange Right"**) to receive during the time period defined in Condition 15.2 (*Period of the Conversion/Exchange Right*) and in accordance with the terms of Condition 15.3 (*Terms of allocation pursuant to the Conversion/Exchange Right*) a number of new and/or existing Shares (at the option of the Company) equal to the Conversion/Exchange Ratio in effect on the Exercise Date (as defined below) multiplied by the number of Bonds for which the Conversion/Exchange Right has been exercised (subject to the terms of paragraph 15.5.5 and Condition 15.9 (*Aggregation, Treatment of fractional entitlements*)).

Exercise of the Conversion/Exchange Right results in the cancellation of the Bonds for which it was exercised.

15.1.2 For the purpose of these Terms and Conditions:

The **"Conversion/Exchange Ratio"** is equal to 5.5 Shares for 1 Bond and may be subject to future adjustments in accordance with Condition 15.7 (*Preservation of Bondholders' rights*).

15.2 Period of the Conversion/Exchange Right

15.2.1 The Bondholders may request at any time the exercise of their Conversion/Exchange Right until the seventh Trading Day (inclusive) preceding the Maturity Date of the Bonds or, as the case may be, until the seventh Trading Day (inclusive) preceding the relevant early redemption date. It being specified that, as necessary, the Bonds for which the Bondholders requested the exercise of their Conversion/Exchange Right prior to the seventh Trading Day (inclusive) preceding the Maturity Date of the Bonds or the early redemption date will not give a right to redemption at the Maturity Date of the Bonds or at the early redemption date of the Bonds respectively.

15.2.2 Any Bondholder who has not requested the exercise of its Conversion/Exchange Right within the time period indicated above will be reimbursed in cash at the Maturity Date of the Bonds or at the early redemption date in accordance with Condition 10.1 (*Redemption at maturity*) or Condition 10.3 (*Early redemption at the Company's option)* respectively.

15.3 Terms of allocation pursuant to the Conversion/Exchange Right

Upon exercise of its Conversion/Exchange Right, each Bondholder will receive new and/or existing Shares.

The total number of new and/or existing Shares (the mix of which shall be determined by the Company at its sole discretion) shall be determined by the Calculation Agent and be equal, for each Bondholder, to the Conversion/Exchange Ratio in effect on the Exercise Date (as defined in paragraph 15.5.1) multiplied by the number of Bonds transferred to the Centralising Agent and for which the Conversion/Exchange Right has been exercised (subject to the terms of paragraph 15.5.5 and Condition 15.9 (*Aggregation, Treatment of fractional entitlements*)).

15.4 **Suspension of the Conversion/Exchange Right**

In the event of a share capital increase or issuance of new Shares or securities conferring rights to receive Shares, or any other financial transactions conferring preferential subscription rights or reserving a priority subscription period for the benefit of the shareholders of the Company, the Company shall be entitled to suspend the exercise of the Conversion/Exchange Right for a period not too exceed three months or such other period as may be established by applicable regulations. Any such suspension may not cause the Bondholders to lose their Conversion/Exchange Right.

The Company's decision to suspend the Conversion/Exchange Right of the Bondholders will be published in a notice in the *Bulletin des annonces légales obligatoires* (**"BALO"**). This notice shall be published at least seven calendar days before the suspension of the Conversion/Exchange Right becomes effective. The notice shall specify the dates on which the suspension period begins and ends. This information will also be published by a notice of the Company on its website (www.genfit.fr).

15.5 **Conditions of exercise of the Conversion/Exchange Right**

15.5.1 To exercise any Conversion/Exchange Right, Bondholders must make a request to the financial intermediary holding their Bonds in a securities account. Any such request to exercise the Conversion/Exchange Right is irrevocable once received by the relevant financial intermediary. The Centralising Agent will provide and ensure centralisation of the request.

The date of the request will correspond to the Business Day on which both paragraphs (A) and (B) below will have been satisfied, if satisfied at or prior to 3:00 p.m. (Paris time), or the following Business Day if satisfied after 3:00 p.m. (Paris time) (the **"Date of the Request"**):

(A) the Centralising Agent will have received the exercise request transmitted by the financial intermediary in the books of which the Bonds are held in a securities account;

(B) the Bonds will have been transferred to the Centralising Agent by the relevant financial intermediary.

Any request for the exercise of any Conversion/Exchange Right received by the Centralising Agent will take effect, subject to the provisions of Condition 15.7.3 "*Public offers*" on the earlier of the following two dates (the "**Exercise Date**"):

- the last Business Day of such calendar month; or
- the seventh Business Day preceding the date set for redemption.

All Bondholders with Bonds having the same Exercise Date will be treated equally and will each receive an allocation for their Bonds of new and/or existing Shares, in the same proportion, subject to rounding.

15.5.2 The Bondholders will receive delivery of new and/or existing Shares no later than the seventh Trading Day following the Exercise Date.

15.5.3 Notwithstanding the foregoing, in the case of the exercise of the Conversion/Exchange Right during the Adjustment Period in case of a Public Offer, the Exercise Date will be deemed to be the Request Date and the Bondholders will receive delivery of new and/or existing Shares no later than the third Trading Day following the Exercise Date.

15.5.4 In the circumstances described in paragraphs 15.5.2 and 15.5.3 above, any delivery of Shares occurring on a Trading Day that is not a Business Day shall take place on the next Business Day.

15.5.5

(A) In the event of a transaction constituting an adjustment event (see Condition 15.7 (*Preservation of Bondholders' rights*)) where the Record Date (as defined in Condition 15.7 (*Preservation of Bondholders' rights*)) occurs between the Exercise Date and the delivery date (exclusive) of the Shares issued and/or allocated upon exercise of the Conversion/Exchange Right, the Bondholders will have no right to participate and will have no right to indemnification, subject however, as the case may be, to their adjustment right (as set forth in Condition 15.7 (*Preservation of Bondholders' rights*)) until the delivery date (exclusive) of the Shares.

(B) If the Record Date of a transaction constituting an adjustment event referred to in Condition 15.7 (*Preservation of Bondholders' rights*) occurs:

(1) on an Exercise Date or prior to such date but, in either case for which, the Conversion/Exchange Ratio in effect as of such date does not reflect the adjustment (if any) resulting from this transaction pursuant to Condition 15.7 (*Preservation of Bondholders' rights*), or

(2) between an Exercise Date and the delivery date of the Shares (exclusive),

the Company will deliver a number of additional Shares determined by the Calculation Agent such that the total number of Shares delivered will be equal to the number that would have been determined if the Conversion/Exchange Ratio initially applied had taken into account the adjustment resulting, as the case may be, from this transaction pursuant to Condition 15.7 (*Preservation of Bondholders' rights*), subject to the provisions of Condition 15.9 (*Aggregation, Treatment of fractional entitlements*).

The delivery of these additional Shares will occur as soon as possible following the initial delivery of the Shares issued and/or allocated upon exercise of the Conversion/Exchange Right.

15.6 **Bondholders' rights to interest on the Bonds and to dividends with respect to Shares delivered - listing of the Shares delivered**

15.6.1 **Rights to interest on the Bonds**

In the event of the exercise of the Conversion/Exchange Right, no interest will be payable to Bondholders in respect of the period from the last Interest Payment Date (or, if applicable, the Issue Date of the Bonds) until the date on which the shares are delivered.

15.6.2 **Right to dividends of the Shares issued or allocated upon exercise of the Conversion/Exchange Right.**

(A) **New Shares issued upon exercise of the Conversion/Exchange Right**

The new Shares issued upon exercise of the Conversion/Exchange Right will carry dividend rights and confer upon their holders, from their date of delivery, all the rights attached to Shares (including the right to receive a dividend or an interim dividend declared during the fiscal year in which they are issued with respect to the distributable income of the prior fiscal year), it being specified that in the event that a Record Date for a dividend (or interim dividend) occurs between the Exercise Date (exclusive) and the delivery date of the Shares (inclusive), the Bondholders will not be entitled to such dividend (or interim dividend) nor to any compensation therefor, subject to the right to an adjustment provided for in Condition 15.7 (*Preservation of Bondholders' rights*).

It should be noted that in accordance with Condition 15.5 (*Conditions of exercise of the Conversion/Exchange Right*) and Condition 15.7 (*Preservation of Bondholders' rights*), the Bondholders will have the right to an adjustment of the Conversion/Exchange Ratio up to the date of the delivery of the Shares (exclusive).

(B) **Existing Shares allocated upon exercise of the Conversion/Exchange Right**

The existing Shares allocated upon exercise of the Conversion/Exchange Right will be existing ordinary Shares carrying dividend rights and conferring upon their holders, from their date of delivery, all the rights attached to Shares, it being specified that in the event that a Record Date for a dividend (or interim dividend) occurs between the Exercise Date (exclusive) and the delivery date of the Shares (inclusive), the Bondholders will not be entitled to such dividend (or interim dividend) nor to any compensation therefor, subject to the right to an adjustment provided for in Condition 15.7 (*Preservation of Bondholders' rights*).

It should be noted that in accordance with Condition 15.5 (*Conditions of exercise of the Conversion/Exchange Right*) and Condition 15.7 (*Preservation of Bondholders' rights*), the Bondholders will have the right to an adjustment of the Conversion/Exchange Ratio up to the date of the delivery of the Shares (exclusive).

15.6.3 **Listing of the new or existing Shares issued or allocated upon exercise of the Conversion/Exchange Right**

(A) **New Shares issued upon exercise of the Conversion/Exchange Right**

Applications will be made for the admission to trading on Euronext Paris of the new Shares issued upon exercise of the Conversion/Exchange Right. Accordingly, the new Shares will immediately become fungible with the existing Shares listed on Euronext Paris and tradable, as from the date on which they are admitted to trading, on the same listing line as such existing Shares under the same ISIN code FR0004163111.

(B) **Existing Shares allocated upon exercise of the Conversion/Exchange Right**

The existing Shares allocated upon exercise of the Conversion/Exchange Right will be immediately tradable on Euronext Paris.

15.7 **Preservation of Bondholders' rights**

15.7.1 **Specific provisions**

In accordance with the provisions of Article L. 228-98 of the French Commercial Code (*Code de commerce*),

(A) the Company may change its form or its corporate purpose without requesting the approval of the general Bondholders' meeting;

(B) the Company may, without requesting the approval of the general Bondholders' meeting, redeem its share capital, or modify the allocation of its profit and/or issue voting or non-voting preference Shares or other preferred equity instruments provided that, as long as any Bonds are outstanding, it takes the necessary measures to preserve the rights of the Bondholders;

(C) in the event of a capital reduction resulting from losses and realised through a decrease of the par value or of the number of Shares comprising its share capital, the rights of the Bondholders will be reduced accordingly, as if they had exercised them prior to the date on which such share capital reduction occurred. In the event of a reduction of the share capital by a decrease in the number of Shares, the new Conversion/Exchange Ratio will be determined by the Calculation Agent and will be equal to the product of the Conversion/Exchange Ratio in effect prior to the decrease in the number of Shares and the following ratio:

Number of Shares in the share capital after the transaction

Number of Shares in the share capital prior to the transaction

The new Conversion/Exchange Ratio will be calculated to three decimal places by rounding to the nearest one-thousandth (with 0.0005 being rounded up to the nearest thousandth, i.e. 0.001). Any subsequent adjustments will be carried out on the basis of such newly calculated and rounded Conversion/Exchange Ratio. However, because the Conversion/Exchange Ratio may only result in the delivery of a whole number of Shares, fractional entitlements will be settled as specified in Condition 15.9 (*Aggregation, Treatment of fractional entitlements*).

In accordance with article R. 228-92 of the French Commercial Code (*Code de commerce*), if the Company decides to issue, in any form whatsoever, new Shares or securities giving access to the share capital with a preferential subscription right reserved for shareholders, to distribute reserves, in cash or in kind, and issue premiums or to modify the allocation of its profits by creating preferred Shares, it will inform (if so required by applicable regulations) the Bondholders by a notice published in the BALO.

15.7.2 **Adjustments to the Conversion/Exchange Ratio in the event of financial transactions of the Company**

Following each of the following transactions:

(1) financial transactions with listed preferential subscription rights or by free allocation of listed subscription warrants;

(2) free allocation of Shares to shareholders, Share split or reverse split of Shares;

(3) incorporation into the share capital of reserves, profits or premiums by an increase in the par value of the Shares;

(4) distribution of reserves or premiums, in cash or in kind;

(5) free allocation to the Company's shareholders of any securities other than Shares;

(6) merger (*absorption* or *fusion*) or demerger (*scission*);

(7) repurchase by the Company of its own Shares at a price higher than the market price;

(8) redemption of share capital;

(9) modification of allocation of the profits of the Company through issuance of voting or non-voting preference shares or other preferred equity instruments; and

(10) distribution of a dividend;

which the Company may carry out as from the Issue Date of the Bonds, for which the Record Date (as defined below) occurs before the delivery date of the new

and/or existing Shares upon exercise of the Conversion/Exchange Right, the rights of the Bondholders will be maintained up to the delivery date (exclusive) by means of an adjustment to the Conversion/Exchange Ratio in accordance with the provisions set forth below.

The **"Record Date"** is the date on which the holding of the Shares is established so as to determine which shareholders are the beneficiaries of a given transaction or may take part in a transaction and, in particular, to which shareholders a dividend, a distribution or an allocation, announced or voted as of this date or announced or voted prior to this date, should be paid, delivered, or completed.

Such adjustment will be carried out so that, to the nearest thousandth of a Share, the value of the Shares that would have been delivered upon exercise of the Conversion/Exchange Right immediately before the completion of any of the transactions mentioned above, is equal to the value of the Shares to be delivered upon exercise of the Conversion/Exchange Right immediately after the completion of such a transaction.

In the event of adjustments carried out in accordance with paragraphs (A) to (J) below, the new Conversion/Exchange Ratio will be calculated to three decimal places by rounding to the nearest one-thousandth (with 0.0005 being rounded up to the nearest thousandth, i.e. 0.001). Any subsequent adjustments will be carried out on the basis of such newly calculated and rounded Conversion/Exchange Ratio. However, because the Conversion/Exchange Ratio may only result in the delivery of a whole number of Shares, fractional entitlements will be settled as specified in Condition 15.9 (*Aggregation, Treatment of fractional entitlements*).

In the event that the Company carries out transactions in respect of which no adjustment has been made in accordance with paragraphs (A) to (J) below and a subsequent law or regulation requires an adjustment, the Company will apply such adjustment in accordance with applicable laws or regulations and the relevant market practice in effect in France.

In the event that the Company carries out a transaction likely to be subject to several adjustments, legal adjustments will apply by priority.

(A) Financial transactions with listed preferential subscription right or with the free allocation of listed subscription warrants

(a) In the event of financial transactions with a listed preferential subscription right, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share ex right} + \text{Value of the preferential subscription right}}{\text{Value of the Share ex right}}$$

For the purpose of the calculation of this formula, the Value of the Share ex right and the Value of the preferential subscription right will be equal to

the arithmetic average of the opening prices quoted on Euronext Paris (or, in the absence of a listing on Euronext Paris, on any other Regulated Market or similar market on which the Share or the preferential subscription right has its principal listing) on each Trading Day included in the subscription period.

(b) In the event of financial transactions with free allocation of listed subscription warrants to the shareholders with the corresponding ability to sell the securities resulting from the exercise of warrants that were unexercised by their holders at the end of their subscription period[1], the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share after the detachment of the warrant} + \text{Value of the warrant}}{\text{Value of the Share after the detachment of the warrant}}$$

For the purpose of the calculation of this formula:

- the Value of the Share after the detachment of the warrant will be equal to the volume-weighted average of (i) the prices of the Share traded on Euronext Paris (or, in the absence of a listing on Euronext Paris, on any other Regulated Market or similar market on which the Share has its principal listing) on each Trading Day during the subscription period, and (ii) (a) the sale price of the securities sold in connection with the offering, if such securities are fungible with the existing Shares, applying the volume of Shares sold in the offering to the sale price, or (b) the prices of the Share traded on Euronext Paris (or, in the absence of a listing on Euronext Paris, on any other Regulated Market or similar market on which the Share has its principal listing) on the date on which the sale price of the securities sold in the offering is set, if such securities are not fungible with the existing Shares;
- the Value of the warrant will be equal to the volume-weighted average of (i) the prices of the warrants traded on Euronext Paris (or, in the absence of a listing on Euronext Paris, on any other Regulated Market or similar market on which the warrant has its principal listing) on each Trading Day during the subscription period, and (ii) the subscription warrant's implicit value as derived from the sale price of the securities sold in the offering, which shall be deemed to be equal to the difference (if positive) adjusted for the exercise ratio of the warrants, between the sale price of the securities sold in the

[1] Are only concerned warrants which are "substitutes" of preferential subscription rights (exercise price usually lower than the market price, term of the warrant similar to the subscription period of the capital increase with upholding of the shareholders' preferential subscription right, option to "recycle" the non-exercised warrants). The adjustment as a result of a free allocation of standard warrants (exercise price usually greater than the market price, term usually longer, absence of option granted to the beneficiaries to "recycle" the non-exercised warrants) should be made in accordance with paragraph E.

offering and the subscription price of the securities through exercise of the warrants by applying to this amount the corresponding amount of warrants exercised in respect of the securities sold in the offering.

(B) In the event of the free allocation of Shares to shareholders, or a Share split or reverse Share split, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Number of Shares included in the share capital after the transaction}}{\text{Number of Shares included in the share capital prior to the transaction}}$$

(C) In the event of a capital increase by incorporation of reserves, profits or premiums achieved by increasing the par value of the Shares, the par value of the Shares that will be delivered to the Bondholders exercising their Conversion/Exchange Right will be increased accordingly.

(D) In the event of a distribution of reserves or premiums, in cash or in kind (portfolio securities, etc.), the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share prior to the distribution}}{\text{Value of the Share prior to the distribution} - \text{Amount distributed per Share or Value of the securities or assets distributed per Share}}$$

For the purpose of the calculation of this ratio:

- the Value of the Share prior to the distribution will be equal to the Volume-Weighted Average Price of the Share over the period of three Trading Days ending on the last Trading Day preceding the date on which the Shares are first traded ex-distribution;
- if the distribution is made in kind:
  - in the event of a distribution of securities that are already listed on a Regulated Market or similar market, the value of the distributed securities will be determined as provided above;
  - in the event of a distribution of securities that are not yet listed on a Regulated Market or similar market, the value of the distributed securities will be equal, if they are expected to be listed on a Regulated Market or similar market within the ten Trading Days' period starting on the date on which the Shares are first traded ex-distribution, to the Volume-Weighted Average Price of such securities over the period of the first three Trading Days included

in such ten Trading Days period during which such securities are listed; and

- in other cases (distribution of securities that are not listed on a Regulated Market or a similar market or traded for less than three Trading Days within the period of ten Trading Days referred to above or in the case of a distribution of assets), the value of the securities or assets allocated per Share will be determined by an Independent Expert.

(E) In the event of a free allocation to the shareholders of the Company of financial instruments other than Shares and other than in the circumstances the subject of paragraph (A)(b) above, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share ex-right of free allocation + Value of the financial instruments allocated to each Share}}{\text{Value of the Share ex-right of free allocation}}$$

For the purpose of the calculation of this formula:

- the Value of the Share ex-right of free allocation will be equal to the Volume-Weighted Average Price of the Share over the period of the first three Trading Days starting on the date on which the Shares are first traded ex-right of free allocation;
- if the financial instrument allocated is listed or may be listed on Euronext Paris (or, in the absence of a listing on Euronext Paris, or any other Regulated Market or similar market) within the ten Trading Days period starting on the date on which the Shares are first traded ex-right of free allocation, the value of such instrument will be equal to the Volume-Weighted Average Price over the period of the first three Trading Days of such ten Trading Days' period in which the instrument is listed.
- If the financial instrument allocated is not listed on a Regulated Market or a similar market or is traded for less than three Trading Days within the ten Trading Days period referred to above, the value of such instrument will be determined by an Independent Expert.

(F) In the event that the Company is merged into another company (*absorption*) or is merged with one or more companies forming a new company (*fusion*) or is demerged (*scission*), the Bonds will be convertible

into and/or exchangeable for Shares of the merged or new company or of the beneficiary companies of such demerger.

The new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the commencement of the relevant transaction by the exchange ratio of Shares in the Company to the shares of the merging company or the beneficiary companies of the demerger. These companies will automatically be substituted for the Company for the purpose of the performance of its obligations towards the Bondholders.

(G) In the event of a repurchase by the Company of its own Shares at a price higher than the market price, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the repurchase by the following formula:

$$\frac{\text{Value of the Share x (1- Pc\%)}}{\text{Value of the Share – (Pc\% x Repurchase price)}}$$

For the purpose of the calculation of this formula:

- **"Value of the Share"** means the Volume-Weighted Average Price of the Share over the period of the three Trading Days preceding the repurchase (or the repurchase option);
- **"Pc%"** means the percentage of share capital repurchased; and
- **"Repurchase Price"** means the actual price at which any Shares are repurchased.

(H) In the event of a redemption of the share capital, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share before the redemption}}{\text{Value of the Share before the redemption – Amount of the redemption per Share}}$$

For the purpose of the calculation of this formula, the value of the Share before the redemption will be equal to the Volume-Weighted Average Price of the Share over the period of the three Trading Days preceding the Trading Day on which the Shares are first traded ex-redemption.

(I) (a) In the event the Company changes its profit distribution and/or creates preferred Shares resulting in such a change, the new Conversion/Exchange Ratio will be determined by the Calculation Agent by multiplying the Conversion/Exchange Ratio in effect prior to the relevant transaction by the following formula:

$$\frac{\text{Value of the Share prior to the modification}}{\text{Value of the Share prior to the modification} - \text{Reduction per Share of the right to profits}}$$

For the purpose of the calculation of this formula:

- the Value of the Share prior to the modification will be equal to the Volume-Weighted Average Price of the Share over the period of the three Trading Days preceding the date on which the Shares are first traded ex-modification; and
- the Reduction per Share of the right to profits will be determined by an Independent Expert.

(b) In the case of creation of preferred Shares which do not result in a modification of allocation of the Company's profits, the adjustment of the Conversion/Exchange Ratio, if any, will be determined by an Independent Expert.

(c) Notwithstanding the foregoing, if such preferred Shares are issued with upholding of the preferential subscription rights of the shareholders or by way of a free allocation to the shareholders of warrants exercisable for such Shares, the new Conversion/Exchange Ratio will be adjusted in accordance with paragraphs (A) or (E) above, as applicable,

(J) Adjustment in the event of distribution of a Dividend:

In the event of the payment by the Company of any dividend, interim dividend or any distribution paid in cash or in kind to shareholders (prior to any withholdings and without taking into account any deductions or tax credits that may be applicable) (hereinafter referred to as the "**Dividend**"), the new Conversion/Exchange Ratio will be calculated by the Calculation Agent as follows, it being specified that any dividend or distribution (or fraction of a dividend, interim dividend or distribution) leading to an adjustment in the Conversion/Exchange Ratio by virtue of paragraphs (A) through (I) above will not be taken into account for the adjustment under the terms of this paragraph (J):

$$NCR = CR \times \frac{STP}{STP - ADD}$$

where:

- **"NCR"** means the new Conversion/Exchange Ratio;

- **"CR"** means the last Conversion/Exchange Ratio previously applicable;
- **"ADD"** means the amount of the Dividend distributed per Share; provided that;
  - in the case of a Dividend payable solely in cash, ADD shall be equal to the cash amount distributed per Share;
  - in the case of a Dividend payable either in cash or in kind (including but not limited to Shares) at the option of shareholders of the Company (including but not limited to pursuant to articles L. 232-18 et seq. of the French Commercial Code (*Code de commerce*), ADD shall be equal to the cash amount distributed per Share;
  - in the case of a Dividend payable solely in kind, ADD shall be equal to the value of such Dividend determined in the same way as that of the distribution of securities pursuant to paragraph (D) above; and
- **"STP"** means the Share trading price, defined as being equal to the Volume-Weighted Average Price of the Share over the last three Trading Days preceding the Trading Day on which the Shares are traded for the first time ex-Dividend.

15.7.3 **Public offers**

In the event that the Shares would be targeted by a public offer (in cash or in securities, in cash and securities, etc.) which may result in a Change of Control (as defined in paragraph 10.5) or filed following a Change of Control, and that the said offer would be declared admissible by the French Financial Markets Authority *Autorité des marchés financiers* (the "**AMF**") (or its successor), the Conversion/Exchange Ratio will be temporarily adjusted as determined by the Calculation Agent in accordance with the following formula (the result will be rounded pursuant to the method set out in Condition 15.7 (*Preservation of Bondholders' Rights*) above):

$$NCR = CR \times [1 + ICP \times (D1 / D2)]$$

where:

- **"NCR"** means the new Conversion/Exchange Ratio applicable during the Adjustment Period in case of a Public Offer (as defined below) calculated to three decimal places by rounding to the nearest one-thousandth (with 0.0005 being rounded up to the nearest thousandth, i.e. 0.001);
- **"CR"** means the previous Conversion/Exchange Ratio in effect prior to the Offer Opening Date (as defined below);
- **"ICP"** means the initial conversion premium, expressed as a percentage, showing the par value of the Bonds compared to the reference price of the Shares used at the time the final terms of the Bonds were determined, i.e. 30.0%;

- **"D1"** means the exact number of days left to run between the Offer Opening Date (inclusive) and 16 October 2025, the Maturity Date of the Bonds (exclusive); and
- **"D2"** means the exact number of days between the date of the Bondholders' general meeting authorising the amendment of the terms and conditions of the Bonds (25 January 2021) (inclusive), and 16 October 2025, the Maturity Date of the Bonds (exclusive), *i.e.* 1,725 days.

There will be no adjustment of the Conversion/Exchange Ratio if NCR would, by applying the above formula, result in an effective conversion price lower than the nominal amount of one Share.

The adjustment of the Conversion/Exchange Ratio indicated above will benefit only to those Bondholders who will exercise their Conversion/Exchange Right, between (and including):

(A) the first day on which the Shares may be tendered to the offer (the **"Offer Opening Date"**), and

(B) (1) if the offer is unconditional, the date that is fifteen Business Days after the date of publication by the AMF (or its successor) of the result of the offer or, if the offer is re-opened, the date that is fifteen Business Days after the date of publication by the AMF (or its successor) of the result of the re-opened offer;

(1) if the offer is conditional, (x) if the AMF (or its successor) declares that the offer is successful, the date that is fifteen Business Days after the date of publication by the AMF (or its successor) of the result of the offer or, if the offer is re-opened, the date that is fifteen Business Days after the date of publication by the AMF (or its successor) of the result of the re-opened offer or (y) if the AMF (or its successor) declares that the offer is unsuccessful, the date of publication by the AMF (or its successor) of the result of the offer; or

(2) if the bidder withdraws the offer, the date of publication by the AMF (or its successor) of the notice of such withdrawal.

This period will be referred to as the **"Adjustment Period in case of a Public Offer"**.

Delivery of shares resulting from an exercise of the Conversion/Exchange Right during the Public Offer Adjustment Period

Notwithstanding the provisions of paragraph 15.5.2, in the event of the exercise of the Conversion/Exchange Right during the Adjustment Period in case of a Public Offer, the Exercise Date will be deemed to be the Request Date and the corresponding Shares will be delivered within three Business Days of the Exercise Date.

15.8 **Calculation of adjustments of the Conversion/Exchange Ratio and notice to Bondholders in the event of adjustment**

The adjustments of the Conversation/Exchange Ratio will be calculated by the Calculation Agent.

In the event of an adjustment, the Company will inform the Bondholders through a notice published by the Company on its website (www.genfit.fr) no later than five Business Days following the new adjustment has taken effect.

In addition, the board of directors of the Company will report the calculations and results of all adjustments in the annual report following such adjustment.

15.9 **Aggregation, Treatment of fractional entitlements**

Each Bondholder exercising its Conversion/Exchange Right in relation to the Bonds may receive, as the case may be, a number of Shares calculated in accordance with Condition 15.3 (*Terms of allocation pursuant to the Conversion/Exchange Right*) based on the aggregate number of Bonds transferred to the Centralising Agent and for which the Conversion/Exchange Right has been exercised by such Bondholder.

If the number of Shares thus calculated is not a whole number, the Bondholder may request allocation of:

15.9.1 either the whole number of Shares immediately below such number; in this case, the Bondholder will receive an amount in cash determined by the Calculation Agent and equal to the product of the remaining fractional Share and the value of the Share, equal to the closing price of the Share traded on Euronext Paris (or, in the absence of listing on Euronext Paris, on any other Regulated Market or similar market on which the Share has its principal listing) on the Trading Day immediately preceding the Date of the Request;

15.9.2 or the whole number of Shares immediately above such number, on the condition that an amount in cash determined by the Calculation Agent and equal to the value of the additional fraction of a Share thus requested, valued on the basis provided for in the preceding paragraph, is paid to the Company.

In both cases, such amount in cash (if any) will be rounded to the nearest cent (with € 0.005 being rounded up to € 0.01).

In the event that the Bondholder would not specify its preferred option, such Bondholder will be given the whole number of Shares immediately below in addition to a cash supplement as described above.

15.10 **Calculation Agent, Independent Expert**

The Company reserves the right at any time to modify or terminate the appointment of the Calculation Agent or the Centralising Agent and/or appoint a substitute Calculation Agent or Centralising Agent or approve any change in the office through which such agent acts, provided that, so long as any Bond is outstanding, there will at all times be (i) a Calculation Agent, and (ii) a Centralising Agent having a specified office in a European city.

Any termination or appointment of the Centralising Agent shall only take effect (other than in the case of insolvency, when it shall be of immediate effect) after not less than 30

calendar days' notice thereof shall have been given to the Bondholders by the Company through a notice published on its Internet website (www.genfit.fr).

Adjustments, calculations and determinations performed by the Calculation Agent or, where applicable, an Independent Expert, pursuant to these Terms and Conditions shall be so made upon request by the Company and shall be final and binding (in the absence of bad faith or manifest error and subject to any determinations by an Independent Expert) on the Company, the Bondholders, the Centralising Agent and (in the case of adjustments, calculations and determinations performed by an Independent Expert) the Calculation Agent. The Calculation Agent may, subject to the provisions of the Calculation Agency Agreement, consult, at the expense of the Company, on any matter (including but not limited to, any legal matter), with any legal or other professional adviser and it shall be able to rely upon, and it shall not be liable and shall incur no liability as against the Bondholders and the Centralising Agent in respect of anything done, or omitted to be done, relating to that matter in good faith in accordance with that adviser's opinion.

The Calculation Agent is acting exclusively as an agent for and upon request from the Company. Neither the Calculation Agent (acting in such capacity) nor any Independent Expert appointed in connection with the Bonds (acting in such capacity), shall have any relationship of agency or trust with, and shall incur no liability as against, the Bondholders and the Centralising Agent.

If any doubt shall arise as to whether an adjustment falls to be made to the Conversion/Exchange Ratio or as to the appropriate adjustment to the Conversion/Exchange Ratio, and following consultation between the Company, the Calculation Agent and an Independent Expert, a written opinion of such Independent Expert in respect thereof shall be conclusive and binding on the Company, the Bondholders, the Centralising Agent and the Calculation Agent, save in the case of manifest error.

Exhibit 8.1

Subsidiaries of GENFIT S.A.

Name of Subsidiary	State/Jurisdiction of Incorporation
Genfit Corp.	Delaware (USA)
Verantis AG	Switzerland
Versantis Inc	Delaware (USA)

Exhibit 12.1

Certification by the Principal Executive Officer pursuant to

Securities Exchange Act Rules 13a-14(a) and 15d-14(a)

as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Pascal Prigent, certify that:

1. I have reviewed this annual report on Form 20-F of GENFIT S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 18, 2023
/s/ Pascal Prigent

Name:	Pascal Prigent
Title:	Chief Executive Officer
	(*Principal Executive Officer*)

Exhibit 12.2

Certification by the Principal Financial Officer pursuant to

Securities Exchange Act Rules 13a-14(a) and 15d-14(a)

as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas Baetz, certify that:

1. I have reviewed this annual report on Form 20-F of GENFIT S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 18, 2023

/s/ Thomas Baetz
Name: Thomas Baetz
Title: Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 13.1

Certification by the Principal Executive Officer pursuant to

18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of GENFIT S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Pascal Prigent, Chief Executive Officer of the Company, certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

a. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

b. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 18, 2023

/s/ Pascal Prigent

Name:	Pascal Prigent
Title:	Chief Executive Officer
	(*Principal Executive Officer*)

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of GENFIT S.A. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.

Exhibit 13.2

Certification by the Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to

Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of GENFIT S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Baetz, Chief Financial Officer of the Company, certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

a. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

b. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 18, 2023

/s/ Thomas Baetz

Name:	Thomas Baetz
Title:	Chief Financial Officer
	(*Principal Financial Officer*)

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of GENFIT S.A. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.