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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of report: September 20, 2023

Commission File Number: 001-38844

GENFIT S.A.
(Translation of registrant's name into English)

Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

☒ Form 20-F ☐ Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INCORPORATION BY REFERENCE

The contents of this report on Form 6-K (including Exhibit 99.1 and Exhibits 101) are hereby incorporated by reference into the registrant's registration statement on Form F-3 (File No. 333-271312) and registration statement on Form S-8 (File No. 333-271311) and related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Information contained on, or that can be accessed through, any website included in Exhibit 99.1 is expressly not incorporated by reference.

EXHIBIT LIST

Exhibit	Description
99.1	Half-Year Business and Financial Report for the period ended June 30, 2023.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Documen
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENFIT S.A.

Date: September 20, 2023

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer

Half-Year Business and Financial Report at June 30, 2023

Table of Contents

Disclaimer

This report contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about GENFIT's corporate strategy and objectives, our ability to meet milestones and receive payments from Ipsen, the potential of elafibranor to receive marketing authorization and successful launch and commercialization in PBC by Ipsen, anticipated timing for study enrollment and data readouts and development plans for our pipeline programs, expected timing for potential regulatory approvals and the impact of the development of our programs and our internal organization, our ability to qualify for and obtain specific regulatory pathways, as well as our financial outlook including cash flow and cash burn projections and business activity projections for 2023 and beyond. The use of certain words, including "believe, "potential", "expect", "target", "may" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among other things, the uncertainties inherent in research and development, including in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, which is available on the Company's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC") including the Company's 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023 and subsequent filings and reports filed with the AMF or SEC, including this Half-Year Business and Financial Report at June 30, 2023 or otherwise made public, by the Company.

In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods.

These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

1. OVERVIEW OF THE GROUP AND ITS MAIN R&D PROGRAMS

About GENFIT

GENFIT is a late-stage biopharmaceutical group (the "Group" or "GENFIT" or the "Company") dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs. The Group includes the parent company GENFIT SA incorporated under French law and two wholly owned subsidiaries: GENFIT Corp. (American subsidiary) and Versantis AG (Swiss subsidiary) whose accounts are consolidated with those of GENFIT SA.

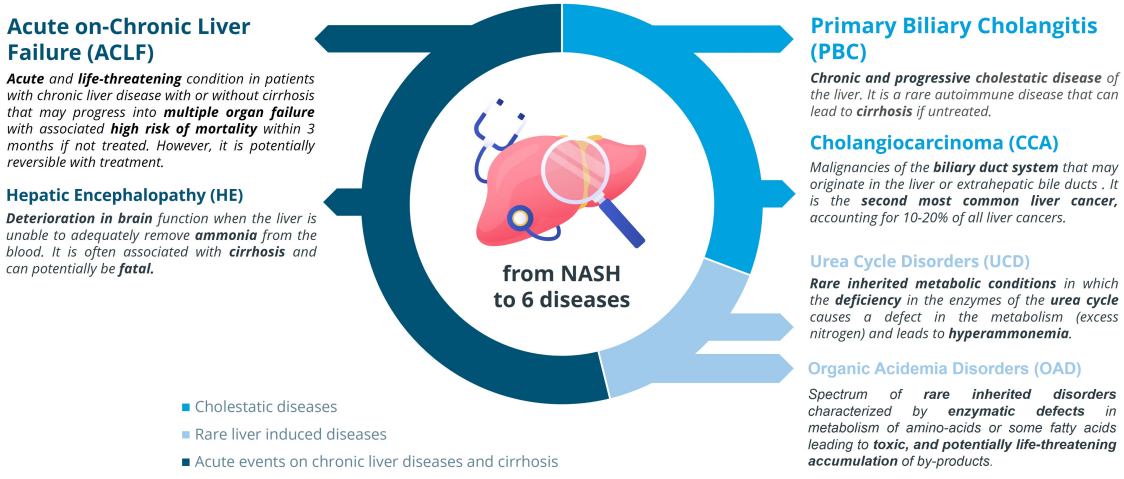
GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D pipeline covers six therapeutic areas via eight programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorders (UCD), organic acidemias (OA) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH[1] and ACLF.

GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital.

Overview of the main R&D programs of the Company

GENFIT remains faithful to its vocation and its specialization in hepatology, and is evolving towards having a portfolio that covers several serious and rare liver diseases that are characterized by largely unmet medical needs and their significant impact on patients' lives.



[1] At EASL Congress in June 2023, and after several years of discussion among the relevant stakeholders , it was announced that nonalcoholic steatohepatitis (NASH) would now be referred to as Metabolic dysfunction-associated steatohepatitis (MASH). In addition, Nonalcoholic fatty liver disease (NAFLD) will now be referred to as metabolic dysfunction-associated steatotic liver disease (MASLD). GENFIT is progressively transitioning its documentation over to this new nomenclature and both terms may appear in our documents during this period.

We are conducting eight therapeutic programs from early to late development stage with a frequent stream of clinical data expected in the coming years:

IND=Investigational New Drug
[1]All drugs under development are investigational compounds that have not been reviewed nor been approved by a regulatory authority in targeted indications
[2]Reflects management's anticipated timelines, which are subject to change | based on industry benchmark/average
[3]Out-licensed to Terns Pharmaceuticals and Ipsen
[4]In-licensed from Genoscience Pharma
[5]Repositioned molecule (Nitazoxanide)
[6]In-licensed from Seal Rock Therapeutics
[7]Potentially eligible for priority review voucher upon approval by the FDA
[8]In-licensed from Celloram

2. HALF-YEAR MANAGEMENT REPORT

2.1 Key Events of the First Half of 2023 and Main Events after the Reporting Period

PBC: Positive Results from Phase 3 ELATIVE® trial

On June 30, 2023 Ipsen and GENFIT announced positive interim topline data from the pivotal ELATIVE® Phase 3 trial. The first part of the trial assessed the efficacy and safety of elafibranor, an investigational dual α,δ PPAR agonist, in the treatment of patients with the rare cholestatic liver disease, primary biliary cholangitis (PBC), who have an inadequate response or intolerance to the current standard of care therapy, ursodeoxycholic acid (UDCA). Results position elafibranor as a potentially important new treatment option, where there is still high unmet need.

The trial met the primary endpoint with a statistically significant higher percentage of patients achieving a clinically meaningful reduction in cholestasis compared to patients who received placebo. 51% of patients on elafibranor 80mg achieved a cholestasis response compared with 4% on placebo ($p<0.0001$). Cholestasis response is defined in the trial as alkaline phosphatase (ALP) <1.67 x upper limit of normal (ULN), an ALP decrease ≥ 15 percent and total bilirubin (TB) ≤ ULN at 52 weeks. ALP and bilirubin are important predictors of disease progression. Reductions in levels of both can indicate reduced cholestatic injury and improved liver function.

The first key secondary endpoint, normalization of ALP at Week 52, was also met with statistically significant improvements for investigational elafibranor compared with placebo. For the other key secondary endpoint, a trend for pruritus improvement was observed with a greater decrease from baseline in the PBC Worst Itch NRS score for patients on elafibranor compared to placebo, which did not reach statistical significance.

In the study, elafibranor was generally well tolerated with a safety profile consistent with that observed in previously reported studies.

Ipsen will assume responsibility for all additional clinical development, including completion of the long-term extension period of the ELATIVE® trial, and global commercialization (outside of Greater China, where elafibranor is licensed to Terns).

Ipsen announced that it intends to submit regulatory applications for elafibranor following discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

ACLF franchise[1]: Strengthening the R&D portfolio and advancing ongoing programs

GENFIT's ACLF franchise[1] now comprises five assets (VS-01, NTZ, SRT-015, CLM-022, VS-02-HE) based on differentiated mechanisms of action leveraging complementary pathways.

VS-01-ACLF: First patient randomized in the Phase 2 trial

VS-01 is currently being evaluated in the international UNVEIL-IT™ Phase 2, open-label, randomized, controlled, multi-center, proof of concept study to assess its efficacy, safety, and tolerability in addition to standard of care (SOC), compared to SOC alone, in adult patients with ACLF grades 1 and 2 and ascites.

IND (Investigational New Drug) was in effect as of April 17, 2023, and the first patient was randomized in the Phase 2 trial in early July. The trial is expected to enroll approximately 60 adult patients with ACLF grades 1 and 2 Patients will be randomized in a 1:1 ratio to receive either daily intraperitoneal administration of VS-01 over 4 days on top of SOC (active treatment group) or SOC alone (control group).

The primary objective of the study is to measure efficacy using the Chronic Liver Failure Consortium (CLIF-C) ACLF score at day 7.

[1] Including HE as a therapeutic area closely associated with ACLF

Interim data are expected to be available in the first half of 2024 with the objective of supporting preparation of further testing of efficacy. Given the high unmet need in this indication and the Orphan Drug Designation obtained from the US Food and Drug Administration for VS-01, it is expected that the program may qualify for some of the expedited regulatory pathways provided by health authorities.

NTZ in ACLF: Phase 1 clinical data

In May 2023, GENFIT presented Phase 1 clinical data evaluating NTZ as part of its Acute-on-Chronic Liver Failure (ACLF) Program at Digestive Disease Week®.

The Phase 1, open-label clinical study was conducted to evaluate the safety, tolerability and pharmacokinetics (PK) of nitazoxanide (NTZ) in subjects with hepatic impairment (HI), as part of GENFIT's NTZ in ACLF program. For the study, subjects between 18 and 75 years of age with HI received repeated oral dose administration of NTZ 500 mg twice a day for 7 days. NTZ was generally well tolerated, with a favorable safety profile, in subjects with moderate and severe HI. Preliminary data from a similar Phase 1 study conducted in subjects with renal impairment also support a favorable safety and tolerability profile. Taken together, safety and pharmacokinetic results, as well as exploratory pharmacodynamic data, support further clinical development of NTZ in patients with ACLF.

In addition, at the European Association for the Study of the Liver (EASL) Congress 2023 GENFIT presented preclinical data showing beneficial effects of NTZ in ACLF disease model.

Following engagement with FDA, and on the basis of the preclinical work and Phase 1 data confirming the potential of NTZ in ACLF, GENFIT has decided to pursue the development of a new nitazoxanide formulation, which will permit greater dosing flexibility. As a result of this decision, and subject to successful development of a new formulation, we have revised the expected launch date of a Phase 2 clinical trial to the first half of 2025, which would cover both clinical study scenarios (healthy volunteers or patients with ACLF).

Exclusive worldwide rights licensed from Seal Rock Therapeutics for injectable formulation of ASK1 Inhibitor SRT-015 in acute liver disease

In May 2023, GENFIT licensed the exclusive worldwide rights of ASK1 Inhibitor SRT-015 (injectable formulation in acute liver disease) from Seal Rock Therapeutics, a Seattle, Washington (USA) based clinical stage company developing first-in-class and best-in-class kinase inhibitors.

Preclinical and clinical evidence support ASK1 inhibition as a relevant therapeutic strategy in multi-system disorders such as Acute-on-Chronic Liver Failure (ACLF). ASK1 inhibition has shown several potentially beneficial effects that may be relevant in ACLF, such as blocking LPS (lipopolysaccharide) associated hyperinflammatory response, reducing the ROS (Reactive Oxygen Species)-related immune response, reducing apoptosis, reducing release of the proinflammatory cytokines, reducing fibrosis, and protecting macrophage mitochondrial function. Multi-organ benefits have been observed in several animal models and clinical trials.

A First-in-Human study is planned in the second half of 2024 to support a Proof-of-Concept study in ACLF patients as early as 2025.

Under the terms of the agreement, Seal Rock Therapeutics is eligible for payments of up to 100 million euros, including regulatory, clinical and commercial milestones, as well as tiered royalties. This agreement does not have any material impact on our financial forecast included in section 2.2 of this report, insofar as virtually all of these payments would only begin to become due following positive Phase 2 results, which would not occur before 2026, according to our best estimates.

Exclusive worldwide rights licensed from Celloram Inc. for CLM-022 in liver disease

In July 2023, GENFIT licensed the exclusive worldwide rights to CLM-022, a first-in-class inflammasome inhibitor, from Celloram Inc., a Cleveland-based biotechnology company. GENFIT will leverage Celloram's acquired scientific insights on this molecule, to finalize IND enabling studies of this preclinical stage asset and secure an IND for future clinical trials. A preclinical proof-of-concept is targeted for 2024.

Under the terms of the agreement, Celloram is eligible for payments of up to 160 million euros, including regulatory, clinical and commercial milestones, as well as tiered royalties. This agreement does not have any material impact on our financial forecast included in section 2.2 of this report, insofar as virtually all of these payments would only begin to become due following positive Phase 2 results, which would not occur before 2028, according to our best estimates.

VS-02-HE preclinical program

VS-02-HE is in preclinical stages and is being developed in Hepatic Encephalopathy (HE).

HE 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.

VS-02-HE is a urease inhibitor designed to inhibit ureases by binding to nickel atoms in their active site.

IND enabling nonclinical studies are targeted to be completed in 2025.

CCA: First patient screening in a Phase 1b/2a study evaluating GNS561

The first patient is expected to be screened in the second half of 2023 in a Phase 1b/2a study evaluating GNS561 in patients with KRAS mutated cholangiocarcinoma (CCA).

In the Phase 1b, patients are 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 the Phase 2a study. First biomarker data are expected to be available as early as the first half of 2024 and should support preparation of further evaluation of efficacy with the optimal doses of GNS561 and a MEK inhibitor in Phase 2a of the study.

Given the high unmet need in this indication and the Orphan Drug Designation obtained from the FDA for GNS561, it is expected that the program may qualify for some of the expedited regulatory pathways provided by health authorities.

UCD and OA: preclinical programs

In addition to PBC, ACLF, HE and CCA, GENFIT is also pursuing the development of preclinical programs in other indications with high unmet needs through the development of VS-01-HAC.

VS-01-HAC is a potential first-line lifesaving treatment for acute hyperammonemic crisis associated with Inborn Errors of Metabolism in Urea Cycle Disorders (UCD) and Organic Acidemias (OA).

Investigational New Drug (IND) enabling nonclinical studies are targeted to be completed in 2024.

NASH Diagnostic: Publication of the Development and Validation of NIS2+™ in the Journal of Hepatology

In May 2023, GENFIT published on the development and validation of NIS2+™ in the Journal of Hepatology, which is one of the leading medical journals in the world.

NIS2+™ is a next-generation technology for the diagnosis of at-risk Non-Alcoholic Steatohepatitis (NASH)[2]. It is a non-invasive diagnostic technology designed as an optimization of NIS4® technology, a blood-based panel currently used to detect at-risk NASH. NIS2+™ is the only blood-based technology developed for the identification of at-risk NASH allowing it to be applied for large-scale use in clinical practice. There is currently a high unmet medical need for an In Vitro Diagnostic (IVD) in NASH.

NIS2+™ has demonstrated the robust and improved clinical performance of NIS2+™ allowing an efficient identification of at-risk NASH, irrespective of patient characteristics such as age, sex and type 2 diabetes. It was also demonstrated that NIS2+™ is 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.

GENFIT continues to explore the possibility of obtaining regulatory approval and CE Certificates of Conformity, with a development and commercial partner, to release an IVD test powered by NIS2+™ technology on the US and European markets.

[2] At EASL Congress in June 2023, and after several years of discussion among the relevant stakeholders , it was announced that nonalcoholic steatohepatitis (NASH) would now be referred to as Metabolic dysfunction-associated steatohepatitis (MASH). In addition, Nonalcoholic fatty liver disease (NAFLD) will now be referred to as metabolic dysfunction-associated steatotic liver disease (MASLD). GENFIT is progressively transitioning its documentation over to this new nomenclature and both NASH and MASH terms may appear in our documents during this period.

In addition, at the European Association for the Study of the Liver (EASL) Congress 2023 GENFIT presented NIS2+™ as an effective screening tool for optimizing patient selection in clinical trials targeting at-risk Non-Alcoholic Steatohepatitis (NASH) and NIS2+™ as the most adapted Non-Invasive Test (NIT) for an efficient identification of at-risk NASH that is not impacted by age.

Interactions with the financial community

During the first half of 2023, we had the opportunity to interact with many of our stakeholders, including members of the financial community.

For example, we participated in the following conferences:

- Corporate Access Events during the 41st JPMorgan Healthcare Conference in January
- Biotech Showcase: the investor conference for innovators in January
- 26th ODDO BHF Forum in January
- Invest Securities Biomed Forum in January
- Degroof Petercam's Virtual Healthcare Conference in January
- SVB Securities Global Biopharma Conference in February
- Kempen Lifesciences Conference in April

In addition, we held the following events for the financial community and shareholders:

- April: webcast and Q&A for the presentation of 2022 financial results
- May: in-person annual shareholders' meeting
- June: webcast and Q&A for the announcement of ELATIVE® trial interim topline data

Over the first part of the year, GENFIT also maintained regular contact with the financial community via non-deal roadshows and media interviews.

Main events related to Corporate Governance

At the Company's Annual Shareholders' Meeting held on May 24, 2023, all of the resolutions endorsed by the Board of Directors were adopted by a significant majority of the votes cast; this includes the renewal of financial authorizations that would allow the Company flexibility to seize relevant market opportunities.

In June 2023, Sandra Silvestri, M.D., Ph.D., replaced Steven Hildemann M.D., Ph.D., on the Board of Directors of the Company as representative of IPSEN, the legal entity that holds the board seat.

Sandra Silvestri, M.D., Ph.D., joined Ipsen in 2023 as Executive Vice President, Chief Medical Officer and Head of Global Medical Affairs, Patient Safety and Patient Affairs.

Prior to joining Ipsen, Ms. Silvestri held multiple leadership roles at Sanofi, where she was most recently SVP Chief Medical Officer for General Medicine GBU, leading a team of 1,600 medical employees worldwide. She also held several leadership positions at Eli Lilly in multiple disease areas including diabetology, endocrinology, neuroscience, immunology, dermatology, and oncology.

Sandra Silvestri is a medical doctor specialized in endocrinology and metabolic diseases. She has been an investigator in several clinical studies, published numerous book chapters as well as scientific articles in international journals, been a speaker in several national and international congresses, and from 2017 to 2023 she led the Gender Balance Board and Global Network at Sanofi. She stays active as a professor at the medical schools of the University of Florence, Italy, and Descartes University in Paris. She has lived in Italy, Denmark, USA, France, and speaks Italian, English and French.

Furthermore, in the first half of 2023, Sakina Sayah Jeanne and Tom Huijbers joined the Executive Committee, respectively as Executive Vice-President Research & Translational Science and Executive Vice-President Regulatory.

ESG commitment

In the first half of 2023, GENFIT's ESG commitment and performance were recognized by independent stakeholders:

- In July, GENFIT was awarded a gold medal by Ethifinance (compared to bronze in 2022) and ranked 2 out of 75 companies in the biopharmaceutical sector. This upgrade in the ratings is a testament to a company-wide effort in implementing our CSR initiatives and ensuring transparent communications in relation to our CSR approach.
- In June, GENFIT was classified by ODDO Research as "Best-in-Class" in its sector, based on two main criteria: activity impact and ESG maturity.

- In January 2023, GENFIT obtained a “Prime status” label by ISS ESG, upgrading its corporate rating from C to C+.

In the second half of 2023, GENFIT will continue to reaffirm its commitment to social/societal responsibility and sustainable development.

2.2 Strategy and Outlook

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. In order to distribute the risk across different programs, we target different but also complementary 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 initially developed by other companies (CCA: GNS561 from Genoscience Pharma; ACLF: VS-01-ACLF, SRT-015 and CLM-022 from respectively Versantis AG, Seal Rock Therapeutics and Celloram Inc.).

In addition, it is expected that most of the programs we pursue may qualify for some of the expedited regulatory pathways provided by health authorities, given the unmet medical needs that exist in the disease areas we target, as well as our candidates' profiles (e.g. Orphan Drug designation).

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, and progress to date

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:
  - PBC: with the successful outcome of the first phase of the ELATIVE® trial at the end of June, the responsibility of the pursuit of this program is progressively being transferred over, country to country, to Ipsen. Furthermore, Ipsen is responsible for NDA filing, long-term study, commercialization, lifecycle management, etc.
  - ACLF: with first patients now enrolled in our trials on VS-01, execution is on track.
  - CCA: the enrollment of the first patient is expected before the end of the year.
- to capitalize on the excellence of our research, continuing to rely on our pioneering work in ACLF:
  - With three additional assets added to our ACLF franchise[3] since the beginning of the year, our leadership in the field has further consolidated.
- to continue to strengthen our organization, both on the financial and human aspects:
  - We believe the success of the first phase of our Phase 3 ELATIVE® will considerably strengthen our cash position and financial visibility, if the product is approved, due to the potential revenue stream of milestone payments and royalties GENFIT is eligible for under the license agreement signed with Ipsen in December 2021;
  - We also believe that our ESG/extra-financial performance ("gold medal" by Ethifinance, "Best-in-Class" by ODDO Research and "Prime status" by ISS) demonstrates our strong commitment to a robust governance model that addresses material issues in business sustainability, social, societal and environmental challenges.

[3] Including HE as a therapeutic area closely associated with ACLF

Impact on financial outlook

We expect that our existing cash, cash equivalents and current financial assets will enable us to fund our operating expenses and capital expenditure requirements until approximately the fourth quarter of 2024. This is based on current assumptions and without taking exceptional events into account, as well as potential milestones and royalties that the Company may receive pursuant to the licensing agreement with Ipsen. In addition, 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 approximately €60 million in 2023.

2.3 Operating and Financial Review

2.3.1 Comments on the condensed statement of net income for the periods ended June 30, 2022 and June 30, 2023

Revenue and other income

The Company's revenue and other income mainly comprises revenue, the research tax credit, and other operating revenue.

Revenue and other income	Half-year ended	
(in € thousands)	**2022/06/30**	**2023/06/30**
Revenues	8,790	11,482
CIR tax credit	3,343	3,547
Government grants and subsidies	9	82
Other operating income	46	263
TOTAL	**12,188**	**15,374**

For the half-year ended June 30, 2023, total revenues and other income amounted to €15,374 (€12,188 for the same period in 2022).

Revenues

For the half-year ended June 30, 2023, Revenue amounted to €11,482 in 2023 (€8,790 for the same period in 2022).

Revenue is primarily composed of:

- 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").
  - During the first six months of 2023, €8.2 million was attributable to the partial recognition of deferred revenue as noted in Note 21 - "Deferred income and revenue".
  - During the first six months of 2022, €8.2 million was attributable to the partial recognition of deferred revenue as noted in Note 21 - "Deferred income and revenue".
- 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.
  - During the first six months of 2023, services provided under this contract generated €3.2 million in revenue.
  - During the first six months of 2022, services provided under this contract generated €0.6 million in revenue.

CIR tax credit

For the half-year ended June 30, 2023, the research tax credit (CIR) amounted to €3,547 in 2023 (€3,343 for the same period in 2022), due to an increase in research and development activity.

The research tax credit receivable from amounted to €14,847 as of June 30, 2023, €6,017 of which relates to 2022 and €5,282 of which relates to 2021. The balance for 2021 and 2022 has not yet been reimbursed in 2023 given the ongoing tax audit.

Other operating income

During the first six months of 2023, the Group recognized €263 in "Other operating income" (€46 for the same period in 2022), mainly comprised of exchange gains on trade receivables.

Operating Expenses by destination

The tables below break operating expenses down by destination, mainly into research and development expenses, general and administrative expenses, marketing and market access expenses, and restructuring and reorganization expenses.

Operating expenses and other operating income (expenses) *(in € thousands)*	Half-year ended 2022/06/30	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	(17,599)	(1,052)	(8,538)	(4,889)	(2,408)	(712)	—
General and administrative expenses	(8,229)	(133)	(38)	(3,230)	(4,580)	(248)	—
Marketing and market access expenses	(460)	(2)	—	(272)	(182)	(3)	—
Reorganization and restructuring income (expenses)	179	—	—	—	(1)	180	—
Other operating expenses	(423)	—	—	—	(422)	—	(1)
TOTAL	**(26,532)**	**(1,187)**	**(8,576)**	**(8,391)**	**(7,594)**	**(783)**	**(1)**

Operating expenses and other operating income (expenses) *(in € thousands)*	Half-year ended 2023/06/30	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 income (expenses)	(25,630)	(1,040)	(14,367)	(6,299)	(3,251)	(705)	33
General and administrative expenses	(9,105)	(162)	(96)	(3,919)	(4,645)	(283)	—
Marketing and market access expenses	(520)	(2)	(1)	(275)	(236)	(6)	—
Reorganization and restructuring income (expenses)	633	—	—	—	—	633	—
Other operating income (expenses)	(52)	—	—	—	(75)	3	20
TOTAL	**(34,673)**	**(1,204)**	**(14,464)**	**(10,492)**	**(8,207)**	**(358)**	**52**

For the half-year ended June 30, 2023 operating expenses amounted to €34,673 (€26,532 for the same period in 2022).

They include the following:

Research and development expenses

For the first six months of 2022, research and development expenses totaled €17.6 million, or 66.3% of our total operating expenses. These expenses were comprised of €8.5 million in contracted research and development conducted by third parties, €4.9 million in employee expenses, €2.4 million in other expenses, €0.7 million in depreciation, amortization and impairment charges and €1.1 million in raw materials and consumables.

For the first six months of 2023, research and development expenses totaled €25.6 million, or 72.8% of our total operating expenses. These expenses were comprised of €14.4 million in contracted research and development conducted by third parties, €6.3 million in employee expenses, €3.3 million in other expenses, €0.7 million in depreciation, amortization and impairment charges and €1.0 million in raw materials and consumables.

The increase of €5.8 million in contracted research and development conducted by third parties is mainly due to:

- Increasing costs related to the ELATIVE® product candidate of €2.8 million
- Increasing costs related to the VS-01 product candidate of €2.3 million,
- Increasing costs related to the GNS561 product candidate of €2.3 million,
- Increasing costs related to the NTZ product candidate €2.6 million, and
- The elafibranor project in NASH which recorded a final accrual reversal of €(1) million, which did not repeat in 2023.

The increase of €1.4 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 82 to 96 employees at June 30, 2022 and 2023, respectively), which includes a 7 person increase due to the Versantis acquisition.

The increase of €0.8 million in other expenses is mainly due to increasing costs related to consultants of €0.7 million, increasing costs related to patent applications of €0.1 million, decreasing costs related to recruiting fees of €0.1 million and increasing costs related to rent expenses of €0.1 million.

General and administrative expenses

For the first six months of 2022, general and administrative expenses totaled €8.2 million. These expenses were mainly comprised of €3.2 million in employee expenses and €4.6 million in other expenses.

For the first six months of 2023, general and administrative expenses totaled €9.1 million. These expenses were mainly comprised of €3.9 million in employee expenses and €4.6 million in other expenses.

The increase in general and administrative employee expenses was mainly due to the increase in workforce (from 50 to 56 employees at June 30, 2022 and 2023, respectively). Other expenses remained stable period over period.

Marketing and market access expenses

For the first six months of 2022, marketing and market access expenses totaled €0.5 million. These expenses were mainly comprised of €0.3 million in employee expenses and €0.2 million in other expenses.

For the first six months of 2023, marketing and market access expenses totaled €0.5 million. These expenses were mainly comprised of €0.3 million in employee expenses and €0.2 million in other expenses.

Marketing and market access expenses remained stable period over period.

Reorganization and restructuring income (expenses)

For the first half of 2022, reorganization and restructuring income amounted to €0.2 million.

For the first half of 2023, reorganization and restructuring income amounted to €0.6 million.

During the first half of 2023, the Group reversed the entire remaining RESOLVE-IT® provision consisting of un-used building space, which are now in use.

Financial income (expenses)

For the half-year ended June 30, 2023, financial income amounted to loss of €1.1 million, compared to a gain totaling €4.0 million for the same period in 2022.

For the first six months of 2022, the €4 million gain is a result of €6.0 million in realized and unrealized foreign exchange gains and €0.2 million in accrued and realized interest income, offset by interest expense of €2.2 million.

For the first six months of 2023, the €1.1 million loss is a result of €2.3 million in interest expense coupled with €0.6 million in foreign exchange losses, partially offset by €1.6 million in accrued and realized interest income.

Net income (loss)

The first half of 2023 resulted in net loss of €20,854 thousand compared with a net loss of €10,399 thousand in the first half of 2022.

2.3.2 Comments on the Group's Cash Flows for the periods ended June 30, 2022 and June 30, 2023

As of June 30, 2023, cash and cash equivalents amounted to €111,826 (€136,001 as of December 31, 2022).

Over the period, changes in cash flow by type of flow were as follows:

(in € thousands)	Half-year ended 2022/06/30	2023/06/30
Cash flows provided by (used in) operating activities	(47,499)	(25,074)
Cash flows provided by (used in) investment activities	(199)	2,682
Cash flows provided by (used in) financing activities	(1,943)	(1,764)
TOTAL	**(49,641)**	**(24,156)**

Cash flows provided by (used in) operating activities

Cash flow used in operating activities amounted to an outflow of €25,074 thousand for the half-year ended June 30, 2023 compared with an outflow of €47,499 thousand for the half-year ended June 30, 2022.

In the first half of 2023, this amount mainly stems from our net loss of €20,854 thousand, which is largely the result of our research and development efforts; notably for ELATIVE®, our Phase 3 clinical trial of elafibranor in PBC; UNVEIL-IT™, our Phase 2 clinical trial of VS-01 in ACLF; GNS561, as part of its cholangiocarcinoma program; and NTZ, as part of its ACLF program.

In the first half of 2022, these cash flows include the disbursement of €24,000 thousand corresponding to the VAT on the upfront payment received from Ipsen under the licensing agreement entered into in December 2021, as well as the disbursement of the legally required employee participation to the profits of GENFIT SA for a total of €628 thousand.

These cash flows reflect GENFIT's business, which requires significant research and development efforts, and generates expenses that change in line with progress on the Company's research programs, net of its operating revenues.

Cash flows provided by (used in) investing activities

Cash flow used in investing activities amounted to €2,682 thousand in the first half of 2023, compared with €(199) thousand in cash flow provided in the first half of 2022.

These cash flows include acquisitions, disposals and repayments of fixed assets and financial assets.

Cash flows provided by (used in) financing activities

Cash flow used in financing activities amounted to €1,764 thousand in the first half of 2023, compared with €1,943 thousand in the first half of 2022.

In the first half of 2023, these cash flows mainly reflect financial interest received and paid, the amount of which is stable compared with first half of 2022.

Currencies

GENFIT has expenses and owns bank accounts in multiple currencies, including the Euro (EUR), the US Dollar (USD) and the Swiss Franc (CHF) (given the Versantis acquisition in 2022). For further information please refer to Note 7.1 - "Foreign exchange risk" of section 3.6 - Notes to the consolidated financial statements.

2.4 Main Transactions with Related Parties

Investors are invited to refer to the information provided in Item 7.B - Related Party Transaction and note 28 to the Consolidated Annual Financial Statements for the year ended December 31, 2022 in the 2022 Annual Report on Form 20-F (the "2022 Form 20-F") for a summary of the Company's principal ongoing transactions with related parties. Transactions with related parties occurring during the first half of 2023 are described in Note 25 - "Related parties" of the half year condensed consolidated financial states for the period ended June 30, 2023 included in section 3 of this report.

2.5 Main Risks and Uncertainties

We encourage investors to take into consideration all of the information presented in our 2022 Form 20-F and in this Half-Year Business and Financial Report before deciding to invest in Company shares. This includes, in particular, the risk factors described in Item 3.D. “Risk Factors” of the 2022 Form 20-F (and the contents of this section), of which the realization may have (or has had in some cases) material adverse effect on the Group and its activity, financial situation, results, development or perspectives, and which are of importance in the investment decision-making process.

With the exception of the following risk factors, which are updated and replaced as below, our review of our risk factors has not prompted any modifications in the nature, quantity or categories of risk factors, nor in their ranking in terms of probability of occurrence or impact, in comparison with what was presented in Item 3.D “Risk Factors” of the 2022 Form-20-F. The risks faced by the Company and described in the 2022 Form 20-F remain essentially the same.

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. We announced the positive interim topline data for this trial at the end of June 2023. Pursuant to our agreement with Ipsen and in light of the ELATIVE® trial design, we began, over the course of summer 2023, transferring the conduct of the ELATIVE® study to Ipsen in certain countries, and we expect this transfer to be completed in other countries by the beginning of 2024.

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.

Although the topline data from the Phase 3 ELATIVE® clinical trial that we announced at the end of June 2023 were positive, 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 other development programs (VS-02-HE, SRT-015 and CLM-022) are at a much earlier stage of development, while others (VS-01-ACLF and GNS561) are in Phase 2 clinical trial (see section 2.1 - Key Events of the First Half of 2023 and Main Events after the Reporting Period). Clinical development of these product candidates faces similar risks and challenges as our development of elafibranor in PBC.

A failure of the clinical program 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, and because represents the most significant source of potential revenues for the Group in the short term. 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[4]. The results of earlier clinical trials and interim data are not necessarily predictive of future results and elafibranor in PBC or any other product candidate (NTZ or GNS561 or VS-01 or any other current or future drug candidates) 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, interim data or other data obtained from trials and studies are subject 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.

[4] At EASL Congress in June 2023, and after several years of discussion among the relevant stakeholders , it was announced that nonalcoholic steatohepatitis (NASH) would now be referred to as Metabolic dysfunction-associated steatohepatitis (MASH). In addition, Nonalcoholic fatty liver disease (NAFLD) will now be referred to as metabolic dysfunction-associated steatotic liver disease (MASLD). GENFIT is progressively transitioning its documentation over to this new nomenclature and both NASH and MASH terms may appear in our documents during this period.

Success in preclinical studies and early clinical trials or interim positive data cannot guarantee that the final results or subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate or confirm 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.

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 current partners for elafibranor and that of any future partners, to obtain regulatory approval for elafibranor and our other drug candidates.

We are currently conducting our Phase 3 ELATIVE® trial of elafibranor in PBC after having announced the topline positive interim results at the end of June 2023. In addition, we have two clinical studies that are currently underway, 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, be they final or interim, 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 made by the Group, its current partners or any future partners;
- 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 our other programs or clinical trials, 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 our trials, such as 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 the aforementioned complications that may negatively affect our plans or our development programs. The ELATIVE® trial was in particular 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 was 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 partners. 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 partners 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 potential successful commercialization of elafibranor in PBC. Our ability to generate short-term revenue derived from product sales will depend on the successful development and regulatory approval of elafibranor in PBC by our partners, 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 and data regarding the chemistry, manufacturing and controls for the drug.

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, including Phase 3 trials, we have conducted to date, or for ongoing trials, with our interim results. These regulators may also consider the data insufficient, in light of data produced by other drug candidates or already approved drugs and require future studies or data prior to approval.

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.

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 partners 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 partners 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.

Our future capital resources depend in large part on the successful continuation of development of elafibranor in PBC, as well as its potential regulatory approval and the success of future commercialization in this indication, if approved. 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 successful continuation of development of elafibranor in PBC, as well as its potential regulatory approval and the success of future commercialization in this indication, if approved. We expect Ipsen to file for conditional marketing authorization for elafibranor in PBC by end of 2023, although it is possible that this application will not be approved. 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.

Furthermore, any failure (or in certain cases a delay) of the development program, regulatory authorization or possible marketing of elafibranor in the PBC would result in the non-payment of milestones negotiated within the framework of our partnership agreements concluded with Ipsen and Terns Pharmaceuticals.

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.

We have also entered into licensing agreements with Genoscience to develop and use GNS561 in CCA, with Seal Rock Therapeutics to develop and use an injectable formulation of SRT-015 in acute liver diseases and with Celloram to develop and use CLM-022 in the treatment of liver diseases.

Should we seek to collaborate with additional third parties with respect to our development programs or to market or co-market our product candidates, those that we in-license or our NIS4® technology and its updates, we may not be able to locate a suitable partner 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 indications 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.

In addition, in-licensing agreements such as those we have signed with Genoscience, Seal Rock Therapeutics and Celloram, which contain obligations to pay milestones in the event the partner meets clinical, regulatory and commercial milestones and royalties in the event of commercialization, could also impact our ability to generate profits if we are unable to obtain commercial benefit from these drug candidates.

Finally, 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.

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.

In May 2023, the European Commission proposed the creation of a unitary Supplementary Protection Certificate (SPC) that is valid in all EU countries. If this project is accepted in the future, it would allow third parties to only bring one legal proceeding in an attempt to obtain an invalidity decision by SPC that is valid in all EU countries.

The European Commission also proposed revisions to pharmaceutical legislation which aim to reduce the duration of regulatory data protection and the duration of market exclusivity granted to orphan drugs.

If these proposals are accepted, the duration of the regulatory protection of our products could be reduced.

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.

Finally, in May 2023, we announced the licensing deal made with Seal Rock Therapeutics for the exclusive worldwide rights for the ASK-1 inhibitor SRT-015 to develop an injectable formulation for use in the treatment of acute liver diseases, particularly in ACLF. In July 2023, we entered into a licensing agreement with Celloram for the exclusive worldwide rights to develop and use CLM-022, an inflammasome inhibitor, in the treatment of liver diseases, particularly in ACLF. In return, these two companies are eligible for clinical, regulatory and commercial milestone payments and royalties if the products are commercialized. Given that ACLF is a new therapeutic area for the Company, it is possible that, despite prior audits and evaluation procedures being carried out, or if the partnership with both companies is less effective than expected, we may not be able to achieve the full potential of these two programs.

We may 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 considering 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 partners also 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 if the revenue that we plan on receiving as part of our licensing-out contracts is less substantial than expected or we do not receive this revenue at all, and/or to further expand our pipeline, and to continue our clinical development and pre-commercialization activities.

However, 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.

As we operate in multiple currencies including the US Dollar, the Swiss Franc and the Euro, we invite investors to read Note 7.1 - "Foreign Exchange Risk" of the notes to the 2023 half year condensed consolidated financial statements and its sensitivity tables included herein.

3. HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AT JUNE 30, 2023

3.1 Consolidated statements of financial position

ASSETS	Notes	As of	
(in € thousands)		2022/12/31	2023/06/30
Current assets			
Cash and cash equivalents	13	136,001	111,826
Current trade and others receivables	15	15,906	20,184
Other current financial assets	16	4,550	—
Other current assets	17	1,998	2,578
Inventories	—	4	4
Total - Current assets		***158,459***	***134,592***
Non-current assets			
Intangible assets	14	43,957	46,182
Property, plant and equipment	—	8,210	8,144
Other non-current financial assets	16	4,914	4,986
Deferred tax assets	11	—	—
Total - Non-current assets		***57,081***	***59,313***
Total - Assets		**215,540**	**193,905**

SHAREHOLDERS' EQUITY AND LIABILITIES	Notes	As of	
(in € thousands)		2022/12/31	2023/06/30
Current liabilities			
Current convertible loans	18	415	415
Other current loans and borrowings	18	4,665	7,333
Current trade and other payables	20	14,845	21,705
Current deferred income and revenue	21	14,479	11,244
Current provisions	22	61	56
Other current tax liabilities	11	4,906	4,906
Total - Current liabilities		***39,370***	***45,660***
Non-current liabilities			
Non-current convertible loans	18	49,861	51,009
Other non-current loans and borrowings	18	20,334	16,665
Non-current trade and other payables	20	448	—
Non-current deferred income and revenue	21	9,706	4,746
Non-current employee benefits	—	782	813
Deferred tax liabilities	11	510	491
Total - Non-current liabilities		***81,641***	***73,725***
Shareholders' equity			
Share capital	23	12,459	12,459
Share premium	—	444,683	444,957
Retained earnings (accumulated deficit)	—	(337,550)	(360,902)
Currency translation adjustment	—	(1,344)	(1,139)
Net profit (loss)	—	(23,719)	(20,854)
Total - Shareholders' equity		***94,528***	***74,520***
Total - Shareholders' equity & liabilities		**215,540**	**193,905**

The accompanying notes form an integral part of these consolidated financial statements.

3.2 Consolidated statements of operations

(in € thousands, except earnings per share data)	Notes	Half-year ended 2022/06/30	2023/06/30
Revenues and other income			
Revenue	8	8,790	11,482
Other income	8	3,398	3,893
Revenues and other income		***12,188***	***15,374***
Operating expenses and other operating income (expenses)			
Research and development expenses	9	(17,599)	(25,630)
General and administrative expenses	9	(8,229)	(9,105)
Marketing and market access expenses	9	(460)	(520)
Reorganization and restructuring income (expenses)	9	179	633
Other operating expenses	9	(423)	(52)
Operating income (loss)		***(14,344)***	***(19,299)***
Financial income	10	6,182	1,748
Financial expenses	10	(2,197)	(2,890)
Financial profit (loss)		***3,985***	***(1,141)***
Net profit (loss) before tax		***(10,359)***	***(20,440)***
Income tax benefit (expense)	11	(40)	(414)
Net profit (loss)		**(10,399)**	**(20,854)**
Basic and diluted earnings (loss) per share			
Basic earnings (loss) per share (€/share)	12	(0.21)	(0.42)
Diluted earnings (loss) per share (€/share)	12	(0.21)	(0.42)

The accompanying notes form an integral part of these consolidated financial statements.

3.3 Consolidated statements of other comprehensive income (loss)

(in € thousands)	Notes	Half-year ended 2022/06/30	2023/06/30
Net profit (loss)		**(10,399)**	**(20,854)**
Actuarial gains and losses net of tax	0	238	50
Other comprehensive income (loss) that will never be reclassified to profit or loss		***238***	***50***
Exchange differences on translation of foreign operations		159	205
Other comprehensive income (loss) that are or may be reclassified to profit or loss		***159***	***205***
Total comprehensive income (loss)		**(10,002)**	**(20,599)**
Attributable to owners of the Company		(10,002)	(20,599)

The accompanying notes form an integral part of these consolidated financial statements.

3.4 Consolidated statements of cash flows

(in € thousands)	Notes	Half-year ended 2022/06/30	Half-year ended 2023/06/30
Cash flows from operating activities			
+ Net profit (loss)		(10,399)	(20,854)
Reconciliation of net loss to net cash used in operating activities			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets		944	835
+ Impairment and provision for litigation	22	(74)	(396)
+ Expenses related to share-based compensation	—	148	274
- Gain on disposal of property, plant and equipment		1	(52)
+ Net finance expenses (revenue)		1,057	763
+ Income tax expense (benefit)	11	40	414
+ Other non-cash items	10	1,095	1,199
Operating cash flows before change in working capital		***(7,188)***	***(17,817)***
Decrease (increase) in trade receivables and other assets	15	(5,071)	(4,858)
(Decrease) increase in trade payables and other liabilities	20	(35,241)	(2,398)
Change in working capital		***(40,311)***	***(7,256)***
Income tax paid		—	—
Net cash flows provided by (used in) in operating activities		***(47,499)***	***(25,074)***
Cash flows from investment activities			
- Acquisition of intangible assets	14	(14)	(2,000)
- Acquisition of property, plant and equipment	—	265	61
+ Proceeds from disposal of / reimbursement of property, plant and equipment	14	—	62
- Acquisition of financial instruments	16	(449)	9
+ Proceeds from disposal of financial instruments	16	—	4,550
Net cash flows provided by (used in) investment activities		***(199)***	***2,682***
Cash flows from financing activities			
- Repayments of loans and borrowings	18	(310)	(464)
- Payments on lease debts	18	(593)	(530)
- Financial interests paid (including finance lease)		(1,057)	(1,106)
+ Financial interests received		17	337
Net cash flows provided by (used in) financing activities		***(1,943)***	***(1,764)***
Increase (decrease) in cash and cash equivalents		**(49,641)**	**(24,155)**
Cash and cash equivalents at the beginning of the period	13	258,756	136,001
Effects of exchange rate changes on cash		—	(20)
Cash and cash equivalents at the end of the period		**209,115**	**111,826**

The accompanying notes form an integral part of these consolidated financial statements.

3.5 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, 2022	**49,815,489**	**12,454**	**444,438**	**(986)**	**(404,090)**	**22**	**67,259**	**119,097**
Net profit (loss)							(10,399)	(10,399)
Other comprehensive income (loss)					238	159		397
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**238**	**159**	**(10,399)**	**(10,002)**
Allocation of prior period profit (loss)					67,259		(67,259)	—
Share-based compensation			148					148
Treasury shares				(65)				(65)
Other movements			—		(12)			(12)
As of June 30, 2022	**49,815,489**	**12,454**	**444,586**	**(1,051)**	**(336,605)**	**181**	**(10,399)**	**109,166**
Net profit (loss)							(13,320)	(13,320)
Other comprehensive income (loss)					20	(1,525)		(1,505)
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**20**	**(1,525)**	**(13,320)**	**(14,825)**
Allocation of prior period profit (loss)					—		—	—
Capital increase	19,494	5	—		(5)			—
Share-based compensation			97					97
Treasury shares				73				73
Other movements			—		17			17
As of December 31, 2022	**49,834,983**	**12,459**	**444,683**	**(978)**	**(336,573)**	**(1,344)**	**(23,719)**	**94,528**
Net profit (loss)							(20,854)	(20,854)
Other comprehensive income (loss)					50	205		255
Total comprehensive income (loss)	**—**	**—**	**—**	**—**	**50**	**205**	**(20,854)**	**(20,599)**
Allocation of prior period profit (loss)					(23,719)		23,719	—
Share-based compensation			274					274
Treasury shares				94				94
Other movements					223			223
As of June 30, 2023	**49,834,983**	**12,459**	**444,957**	**(884)**	**(360,019)**	**(1,139)**	**(20,854)**	**74,520**

The accompanying notes form an integral part of these consolidated financial statements.

3.6 Notes to the 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), and Versantis, Inc. (U.S. Subsidiary, dissolved before June 30, 2023) (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. Major events in the period

2.1.1 Seal Rock license agreement

On May 31, 2023, GENFIT announced the signing of a licensing agreement for the exclusive worldwide rights to the ASK1 inhibitor SRT-015 with Seal Rock Therapeutics, a clinical-stage company based in Seattle, USA developing “best-in-class” and “first-in-class” kinase inhibitors.

SRT-015 is an injectable therapy intended for use in acute liver conditions, and GENFIT has acquired the rights to SRT-015 for use in liver conditions for which an injectable therapy is intended to be administered over a period of 21 consecutive days or less, including Acute on Chronic Liver Failure (ACLF) support during this period. Preclinical and clinical evidence support ASK1 inhibition as a relevant therapeutic strategy in multi-system disorders such as ACLF.

Under the terms of the agreement, Seal Rock is eligible for payments of up to €100 million, including regulatory, clinical and commercial milestone payments, as well as tiered royalties. For further information related to the accounting treatment of the licensing rights, refer to Note 14 - "Goodwill and Intangible Assets".

2.1.2 Positive Results from Phase 3 ELATIVE® trial

On June 30, 2023, GENFIT announced positive topline data from the pivotal ELATIVE® Phase 3 trial. In the trial, the efficacy and safety of elafibranor, an investigational dual α,δ PPAR agonist, is being assessed for the treatment of patients with the rare cholestatic liver disease, primary biliary cholangitis (PBC), who have an inadequate response or intolerance to the current standard of care therapy, ursodeoxycholic acid (UDCA).

The trial met its primary composite endpoint, with 51% of patients on elafibranor 80mg achieving a cholestasis response compared with 4% on placebo ($p<0.0001$). Cholestasis response is defined in the trial as alkaline phosphatase (ALP) <1.67 x upper limit of normal (ULN), an ALP decrease ≥ 15 percent and total bilirubin (TB) ≤ ULN at 52 weeks. ALP and bilirubin are important predictors of disease progression. Reductions in levels of both can indicate reduced cholestatic injury and improved liver function.

The first secondary endpoint, normalization of ALP at Week 52, was also met with statistically significant improvements for investigational elafibranor compared with placebo. For the other secondary endpoint, a trend for pruritus improvement was observed with a greater decrease from baseline in the PBC Worst Itch NRS score for patients on elafibranor compared to placebo, which did not reach statistical significance. In the study, elafibranor was generally well tolerated with a safety profile consistent with that observed in previously reported studies.

2.2. Event after the period

2.2.1 Celloram Inc. licence agreement

On July 28, 2023, GENFIT licensed the exclusive worldwide rights to CLM-022, a first-in-class inflammasome inhibitor, from Celloram Inc., a Cleveland-based biotechnology company. GENFIT will leverage Celloram’s acquired scientific insights on this molecule, to finalize IND enabling studies of this preclinical stage asset and secure an IND for future clinical trials. A preclinical proof-of-concept is targeted for 2024.

Under the terms of the agreement, Celloram is eligible for payments of up to €160 million, including regulatory, clinical and commercial milestones, as well as tiered royalties.

3. BASIS OF PRESENTATION

The half year consolidated financial statements of GENFIT have been prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”) and as adopted by the European Union at June 30, 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"). Comparative information is presented for the year ended December 31, 2022 and for the half year ended June 30, 2023.

In accordance with European Commission Regulation 1606/2002, these consolidated interim financial statements for the six-month period ended June 30, 2023 have been prepared in accordance with IAS 34 – Interim Financial Reporting, and should be read in conjunction with the Group’s most recent annual consolidated financial statements for the year ended December 31, 2022. They do not include all the information required for a complete set of financial statements in accordance with IFRS, but a selection of notes explaining significant events and transactions with a view to understanding the changes in the Group’s financial position and performance since the most recent annual consolidated financial statements.

These consolidated half year financial statements have been prepared using the historical cost measurement basis, except for certain assets and liabilities that are measured at fair value, on a going concern basis, using consistent methods, fair presentation, and the cut-off concept.

These consolidated half year financial statements for the period ended June 30, 2023 were prepared under the responsibility of the Board of Directors that approved such statements on September 19, 2023.

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 half-year financial statements are the same as those applied to the most recent consolidated annual financial statements.

The following new standards are applicable from January 1, 2023, but do not have any material effect on the Group’s financial statements for the period ended June 30, 2023.

- IFRS 17 Insurance Contracts,
- Amendments to IFRS 17 - First application of IFRS 17 and IFRS 9 - Comparative Information,
- Amendments to IAS 1 and Practice Statement 2 - Disclosure of Accounting Policies,
- Amendments to IAS 8 Definition of Accounting Estimates,
- Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction, and
- Amendments to IAS 1 Classification of Liabilities as Current or Non-current.

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

The amendments and modifications to the standards below are applicable for financial years beginning after January 1, 2024, as specified below. GENFIT is in the process of assessing whether the adoption of these amendments and modifications to the standards will have a material impact on the financial statements.

- Amendments to IAS 7 and IFRS 7 Supplier Finance Arrangements, effective in 2024
- Amendments to IFRS 16 Lease Liability in a Sale and Leaseback, effective in 2024
- Amendments to IAS 1 Non-current Liabilities with Covenants, effective in 2024, and
- Amendments to IAS 21 Lack of Exchangeability, effective in 2025.

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 the following:

- Allocation of revenue to performance obligations provided for in the agreement with Ipsen, see Note 8 - "Revenues and other income"
- Research tax credits, see Note 8 - "Revenues and other income"
- Accruals related to clinical trials, see Note 20 - "Trade and other payables"
- Valuation of our investments in Genoscience, see Note 14 - "Goodwill and intangible assets"
- Valuation of our VS-01 assets related to the Versantis acquisition, see Note 14 - "Goodwill and intangible assets"
- Valuation of our license rights acquired, see Note 14 - "Goodwill and intangible assets"
- Convertible loans, see Note 18 - "Loans and borrowings"

4.2. Consolidation

Going concern

When assessing going concern, the Group's Board of Directors mainly considers 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

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.

Versantis Inc was dissolved on June 2, 2023. All assets and liabilities of the company were transferred to Versantis AG. The impact to the financial statements was not material.

Accounting policies

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

4.3. Foreign currency

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.

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:

Ratio : 1 US dollars (USD) = x euros (EUR)	Half-year ended	
	2022/06/30	2023/06/30
Exchange rate at period end	0.96274	0.92030
Average exchange rate for the period	0.91494	0.92515

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)	Half-year ended	
	2022/06/30	2023/06/30
Exchange rate at period end	N/A	1.02166
Average exchange rate for the period	N/A	1.01462

5. ACQUISITIONS

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.

See Note 2.1 "Acquisition of the Clinical-stage Biopharmaceutical Company Versantis" in the Notes to the Consolidated Financial Statements in the Company's 2022 20-F filing for a detailed description.

6. 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	Half-year ended	
(in € thousands)	2022/06/30	2023/06/30
Revenue from France	100 %	100 %
Revenue from other countries	— %	— %
TOTAL	100 %	100 %

For the six month period ended June 30, 2022 and 2023, revenue was generated entirely in France. Substantially all revenue was generated from Ipsen.

Non-current assets by geographical area

Non-current assets break down by geographical area as follows:

NON-CURRENT ASSETS	As of December 31, 2022			As of June 30, 2023		
(thousands of euros)	France	Switzerland	Total	France	Switzerland	Total
TOTAL	12,923	44,158	57,081	15,719	43,589	59,308

7. 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.

7.1. 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 as of and for the periods stated below.

Sensitivity of the Group's cash and cash equivalents to a variation of +/- 10% of the US dollar against the euro	**As of**	
(in € thousands or in US dollar thousands, as applicable)	**2022/12/31**	**2023/06/30**
Cash and cash equivalents denominated in US dollars	34,192	25,853
Equivalent in euros, on the basis of the exchange rate described below	32,057	23,793
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	35,619	26,436
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	29,143	21,630

Sensitivity of the Group's expenses to a variation of +/- 10% of the US dollar against the euro	**Half-year ended**	
(in € thousands or in US dollar thousands, as applicable)	**2022/06/30**	**2023/06/30**
Expenses denominated in US dollars	7,562	9,045
Equivalent in euros, on the basis of the exchange rate described below	7,280	8,324
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	8,089	9,249
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	6,618	7,567

2023/06/30: Equivalent in euros, on the basis of 1 euro = 1.0866 dollars US.

2022/06/30: Equivalent in euros, on the basis of 1 euro = 1.0387 dollars US.

2022/12/31: Equivalent in euros, on the basis of 1 euro = 1.0666 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 2023.

Sensitivity of the Group's cash and cash equivalents to a variation of +/- 10% of the CH franc against the euro	As of	
(in € thousands or in CH franc thousands, as applicable)	2022/12/31	2023/06/30
Cash and cash equivalents denominated in CH franc	2,321	453
Equivalent in euros, on the basis of the exchange rate described below	2,357	463
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	2,618	514
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	2,142	421
Sensitivity of the Group's expenses to a variation of +/- 10% of the CH franc against the euro	**Half-year ended**	
(in € thousands or in CH franc thousands, as applicable)	**2022/06/30**	**2023/06/30**
Expenses denominated in CH franc	N/A	3,045
Equivalent in euros, on the basis of the exchange rate described below	N/A	3,111
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	N/A	3,457
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	N/A	2,828

2023/06/30: Equivalent in euros, on the basis of a 1 euro = 0.9788 CHF.

2022/12/31: Equivalent in euros, on the basis of 1 euro = 0.9847 CHF.

Cash, cash equivalents and financial assets	As of	
(in € thousands)	2022/12/31	2023/06/30
At origin, denominated in EUR		
Cash and cash equivalents	101,536	87,547
Current and non current financial assets	9,456	4,958
Total	***110,993***	***92,504***
At origin, denominated in USD		
Cash and cash equivalents	32,057	23,793
Current and non current financial assets	7	15
Total	***32,064***	***23,808***
At origin, denominated in CHF		
Cash and cash equivalents	2,358	463
Current and non current financial assets	—	13
Total	***2,358***	***476***
Total, in EUR		
Cash and cash equivalents	136,001	111,826
Current and non current financial assets	9,464	4,986
Total	**145,464**	**116,812**

7.2. Interest rate risk

As of June 30, 2023, 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, 2022 and June 30, 2023, the Group's financial liabilities totaled €75.3 million and €75.4 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.

7.3. Liquidity risk

The Group's 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 18 - "Loans and borrowings"), 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 18 - "Loans and borrowings").

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, 2022 and June 30, 2023, the Group had €145,464 and €116,812 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 were 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.

7.4. 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.

8. REVENUES AND OTHER INCOME

8.1. Revenues from contracts with customers

Financial statement line item detail

Revenue and other income	**Half-year ended**	
(in € thousands)	**2022/06/30**	**2023/06/30**
Revenues	8,790	11,482
CIR tax credit	3,343	3,547
Government grants and subsidies	9	82
Other operating income	46	263
TOTAL	**12,188**	**15,374**

For the half-year ended June 30, 2023, the total revenues and other income amounted to €15,374 (€12,188 for the same period in 2022).

For the half-year ended June 30, 2023, Revenue amounted to €11,482 in 2023 (€8,790 for the same period in 2022).

Revenue is primarily composed of:

- 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").
  - During the first six months of 2023, €8.2 million was attributable to the partial recognition of deferred revenue as noted in Note 21 - "Deferred income and revenue".
  - During the first six months of 2022, €8.2 million was attributable to the partial recognition of deferred revenue as noted in Note 21 - "Deferred income and revenue".
- 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. This agreement was subsequently amended following the unblinding of the study to specify costs to be borne by the parties in the agreement. This position is reflected in the financial statements.
  - During the first six months of 2023, services provided under this contract generated €3.2 million in revenue.
  - During the first six months of 2022, services provided under this contract generated €0.6 million in revenue.

8.2. Other income

8.2.1. 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 15 - "Trade and other receivables" and the table below).

8.2.2. 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	**Half-year ended**	
(in € thousands)	**2022/06/30**	**2023/06/30**
CIR tax credit	3,343	3,547
Other operating income	46	263
Government grants and subsidies	9	82
TOTAL	**3,398**	**3,893**

During the first six months of 2023, the research tax credit (CIR) amounted to €3,547 in 2023 (€3,343 for the same period in 2022), due to an increase in research and development activity.

The research tax credit receivable amounted to €14,847 as of June 30, 2023, €6,017 of which relates to 2022 and €5,282 of which relates to 2021. The balance for 2021 and 2022 has not yet been reimbursed in 2023 given the ongoing tax audit.

During the first six months of 2023, the Group recognized €263 in “Other operating income” (€46 for the same period in 2022), mainly comprised of exchange gains on trade receivables.

9. OPERATING EXPENSES

Financial statement line item detail

Operating expenses and other operating income (expenses)	Half-year ended	Of which :					
(in € thousands)	2022/06/30	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	(17,599)	(1,052)	(8,538)	(4,889)	(2,408)	(712)	—
General and administrative expenses	(8,229)	(133)	(38)	(3,230)	(4,580)	(248)	—
Marketing and market access expenses	(460)	(2)	—	(272)	(182)	(3)	—
Reorganization and restructuring income (expenses)	179	—	—	—	(1)	180	—
Other operating expenses	(423)	—	—	—	(422)	—	(1)
TOTAL	**(26,532)**	**(1,187)**	**(8,576)**	**(8,391)**	**(7,594)**	**(783)**	**(1)**

Operating expenses and other operating income (expenses)	Half-year ended	Of which :					
(in € thousands)	2023/06/30	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 income (expenses)	(25,630)	(1,040)	(14,367)	(6,299)	(3,251)	(705)	33
General and administrative expenses	(9,105)	(162)	(96)	(3,919)	(4,645)	(283)	—
Marketing and market access expenses	(520)	(2)	(1)	(275)	(236)	(6)	—
Reorganization and restructuring income (expenses)	633	—	—	—	—	633	—
Other operating income (expenses)	(52)	—	—	—	(75)	3	20
TOTAL	**(34,673)**	**(1,204)**	**(14,464)**	**(10,492)**	**(8,207)**	**(358)**	**52**

2023 Activity

Research and Development Expenses

The increase in research and development expenses is mainly due to increasing costs related to the ELATIVE® product candidate, the VS-01 product candidate, the GNS561 product candidate, the NTZ product candidate, as well as increased staffing levels.

General and administrative expenses

The increase in general and administrative employee expenses was mainly due to the increase in workforce (from 50 to 56 employees at June 30, 2022 and 2023, respectively).

Marketing and market access expenses

Marketing and market access expenses remained stable period over period.

Reorganization and restructuring income (expenses)

During the first half of 2023, the Group reversed the entire remaining RESOLVE-IT provision consisting of un-used building space, which are now in use.

Other operating income (expenses)

For the six months ended June 30, 2023, other operating expenses were not material.

Employee expenses

Employee expenses and number of employees were as follows:

Employee expenses	Half-year ended	
(in € thousands)	**2022/06/30**	**2023/06/30**
Wages and salaries	(5,842)	(7,413)
Social security costs	(2,317)	(2,737)
Changes in pension provision	(84)	(69)
Employee profit-sharing	—	—
Share-based compensation	(148)	(274)
TOTAL	**(8,391)**	**(10,492)**

Number of employees at year-end	Half-year ended	
	2022/06/30	**2023/06/30**
Average number of employees	127	152
Number of employees		
Research and development	65	77
Services related to research and development	17	19
Administration and management	50	56
Marketing and commercial	2	2
TOTAL	**134**	**154**

The increase in employee expenses resulted mainly from an increase in workforce, with an average headcount from 127 in 2022 to 152 in 2023.

10. FINANCIAL INCOME AND EXPENSES

Financial income and expenses	Half-year ended	
(in € thousands)	**2022/06/30**	**2023/06/30**
Financial income		
Interest income	17	337
Foreign exchange gain	6,032	71
Other financial income	132	1,341
TOTAL - Financial income	***6,182***	***1,748***
Financial expenses		
Interest expenses	(2,160)	(2,253)
Interest expenses for leases	(33)	(36)
Foreign exchange losses	0	(586)
Other financial expenses	(4)	(14)
TOTAL - Financial expenses	***(2,197)***	***(2,890)***
FINANCIAL GAIN (LOSS)	**3,985**	**(1,141)**

11. INCOME TAX

Tax Inspection

We are subject to a tax audit by the French tax authorities 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 amounted to €14,847 as of June 30, 2023, €6,017 of which relates to 2022 and €5,282 of which relates to 2021. The balance for 2021 has not yet been reimbursed in 2022 given the ongoing tax audit.

Change in Legislation

In 2017, the United States Congress passed the Tax Cuts and Jobs Act of 2017, which included a tax law change on Section 174 of the Internal Revenue Code. Research and development costs specified under Section 174 of the Code must be capitalized and amortized pro rata over 5 years for domestic expenditures and 15 years for foreign expenditures. Said provision came into effect for tax years commencing after December 31, 2021.

The group concluded that income taxes (and likewise other current tax liabilities) for the period ended December 31, 2022 were underestimated by €196 in the 2022 financial statements. The Group concluded that this error was not material individually or in the aggregate for any of the relevant periods and recognized this expense entirely in the first half of 2023.

The tax expense for the period ended June 30, 2023 relates to the 2022 and 2023 taxes of Genfit Corp.

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**	
	2022/06/30	**2023/06/30**
Profit (loss) for the period (in € thousands)	**(10,399)**	**(20,854)**
Weighted average number of ordinary shares used to calculate basic earnings (loss) per share	49,668,718	49,701,858
Basic earnings (loss) per share (€/share)	**(0.21)**	**(0.42)**
Diluted earnings (loss) per share (€/share)	**(0.21)**	**(0.42)**

The weighted average numbers of ordinary shares as noted above exclude treasury 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	**Half-year ended**
	2023/06/30
BSA	35,070
STOCK OPTIONS	995,381
AGA	124,391
OCEANES	10,580,141

13. CASH AND CASH EQUIVALENTS

The main components of cash equivalents were:

- UCITS and interest-bearing current accounts, available immediately;
- Term accounts, available within the contractual maturities or by the way of early exit with no penalty; and
- Negotiable medium-term notes, available with a quarterly maturity or by the way of early exit with no penalty.

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

Cash and cash equivalents	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Short-term deposits	119,090	98,042
Cash on hand and bank accounts	16,910	13,784
TOTAL	**136,001**	**111,826**

Short-term deposits	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
TERM ACCOUNTS	119,090	98,042
TOTAL	**119,090**	**98,042**

14. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The company does not have any goodwill.

Intangible assets

Seal Rock license agreement (2023)

As previously noted in Note 2 - "Major events in the period and events after the period", on May 31, 2023, GENFIT announced the signing of a licensing agreement for the exclusive worldwide rights to the injectable formulation of ASK1 inhibitor SRT-015 in acute liver disease with Seal Rock Therapeutics, a clinical-stage company based in Seattle, USA.

Under the terms of the agreement, GENFIT made an upfront payment in the amount of €2 million to Seal Rock in exchange for acquiring the know-how and rights of use to SRT-015 as described above. (That amount is noted in the table below under line item "Other intangibles.") In accordance with IAS 38 - Intangible assets this amount was capitalized and allocated to Intangible assets. Further, given the nature of the intangible asset, it was determined to have a definite useful life of 20 years, consistent with patent 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. As future milestones for this agreement are paid, they will be analyzed and be either i) capitalized and subject to the same annual impairment test or ii) expensed as incurred.

Acquisition of Versantis (2022)

As previously noted in Note 5 - "Acquisitions", 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. During the period, there was no indication of loss of value. The value of the asset as of June 30, 2023 is €43.6 million (after CHF/EUR currency translation adjustments).

The following tables show the variations in intangible assets for the year ended December 31, 2022 and the half-year ended June 30, 2023:

(in € thousands)	As of 2021/12/31	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**

(in € thousands)	As of 2022/12/31	Increase	Decrease	Translation adjustments	Reclassification	As of 2023/06/30
Gross						
Software	977	—	(13)	—	—	964
Patents	351	—	—	—	2	352
Other intangibles	43,569	2,000	—	248	—	45,817
TOTAL—Gross	***44,897***	***2,000***	***(13)***	***248***	***2***	***47,134***
Accumulated depreciation and impairment						
Software	(940)	(30)	19	—	—	(951)
Patents	—	—	—	—	—	—
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	***(940)***	***(30)***	***19***	***—***	***—***	***(951)***
TOTAL - Net	**43,957**	**1,970**	**6**	**248**	**2**	**46,182**

15. TRADE AND OTHER RECEIVABLES

Trade and other receivables consisted of the following:

Trade and other receivables - Total	As of	
(in € thousands)	**2022/12/31**	**2023/06/30**
Trade receivables, net	3,188	2,787
Research tax credit	11,299	14,847
VAT receivables	1,288	2,473
Grants receivables	4	8
Other receivables	126	69
TOTAL	**15,906**	**20,184**
Of which : Current	15,906	20,184
Of which : Non-current	—	—

Trade receivables, net

Trade receivables amounted to €2,787 as of June 30, 2023 and €3,188 as of December 31, 2022. The balance mainly corresponds to revenue related to the Transition Services Agreement with Ipsen.

Research tax credit

The research tax credit receivable for the year 2022 amounted to €11,299.

The research tax credit receivable for the as of June 30, 2023 amounts to €14,847. This balance includes the 2021 and 2022 balance as there is currently a tax inspection taking carried out by the French tax authorities.

VAT receivables

The VAT receivable amounted to €2,473 at June 30, 2023. (€1,288 at December 31, 2022).

Other receivables

The line item “other receivables” primarily consists of credit notes from suppliers as of June 30, 2023 and December 31, 2022.

16. OTHER FINANCIAL ASSETS

Other financial assets consisted of the following:

Financial assets - Total	As of	
(in € thousands)	2022/12/31	2023/06/30
Non consolidated equity investments	3,133	3,133
Other investments	483	483
Financial investments	4,550	—
Loans	428	452
Deposits and guarantees	335	302
Liquidity contract	534	616
TOTAL	**9,464**	**4,986**
Of which : Current	4,550	—
Of which : Non-current	4,914	4,986

Financial assets - Variations	As of	Increase	Decrease	As of
(in € thousands)	2022/12/31			2023/06/30
Non consolidated equity investments	3,133	—	—	3,133
Other investments	483	—	—	483
Financial investments	4,550	—	(4,550)	—
Loans	428	24	—	452
Deposits and guarantees	335	35	(68)	302
Liquidity contract	534	—	82	616
TOTAL	**9,464**	**58**	**(4,536)**	**4,986**

The total amount of financial assets of the Company was €9,464 at December 31, 2022, and €4,986 at June 30, 2023. This change is mainly due to the short term financial asset with a term of 180 days.

Non-consolidated equity investments

As of June 30, 2023, 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. During the period, there was no indication of loss of value.

Other investments

As of June 30, 2023, the value of "Other investments" totaled €483. The balance relates solely relates to our investment in CAPTECH SANTE.

Financial investments

As of June 30, 2023, the value of "Financial investments" totaled €0. This related solely to a short term investment whose term was 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 June 30, 2023, the liquidity account had a cash balance of €616, and as of December 31, 2022 a cash balance of €534.

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	
	2022/12/31	2023/06/30
Number of shares (recorded as a deduction from equity)	**138,691**	**123,140**

17. OTHER ASSETS

Other assets amount to €2,578 at June 30, 2023 and €1,998 at December 31, 2022, respectively, and consisted of prepaid expenses related to current operating expenses.

18. LOANS AND BORROWINGS

18.1. Breakdown of convertible loan

On October 16, 2017, the Company issued 6,081,081 OCEANEs at par with a nominal unit value of €29.60 per bond for an aggregate nominal amount of €180 million. This debt was renegotiated in January 2021, and share conversions were executed during said period.

See Note 20.1 "Breakdown of convertible loan" in the Notes to the Consolidated Financial Statements in the Company's 2022 20-F filing for a detailed description of the OCEANEs repurchase and amendment of terms, the accounting impacts of the debt renegotiation, and conversions into shares executed in 2021 following this renegotiation.

Updated balances after renegotiation

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 31/12/2022 :	
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%
As of 30/06/2023 :	
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 21.2% of the share capital of the Company at June 30, 2023 (representing a 17.5% dilution if all OCEANEs were converted).

Conversion Ratio

The conversion ration is 5.5 shares per OCEANE.

Conversion terms

There are no specific terms that need to be met for a holder of OCEANEs to convert their debt into GENFIT shares.

Conversions

There were no conversions for the six month period ended June 30, 2023.

Current and non current balances

Convertible loans - Total	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Convertible loans	50,276	51,424
TOTAL	**50,276**	**51,424**

Convertible loans - Current	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Convertible loans	415	415
TOTAL	**415**	**415**

Convertible loans - Non current	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Convertible loans	49,861	51,009
TOTAL	**49,861**	**51,009**

18.2. Breakdown of other loans and borrowings

Other loans and borrowings consisted of the following:

Other loans and borrowings - Total	As of	
(in € thousands)	2022/12/31	2023/06/30
Refundable and conditional advances	3,229	3,229
Bank loans	15,196	14,732
Obligations under leases	6,559	6,030
Accrued interests	14	8
TOTAL	**24,999**	**23,998**

Other loans and borrowings - Current	As of	
(in € thousands)	2022/12/31	2023/06/30
Refundable and conditional advances	—	—
Bank loans	3,619	6,321
Obligations under leases	1,032	1,005
Accrued interests	14	8
TOTAL	**4,665**	**7,333**

Other loans and borrowings - Non current	As of	
(in € thousands)	2022/12/31	2023/06/30
Refundable and conditional advances	3,229	3,229
Bank loans	11,578	8,411
Obligations under leases	5,527	5,025
Accrued interests	—	—
TOTAL	**20,334**	**16,665**

18.2.1. Refundable and conditional advances

Refundable and conditional advances—general overview *(in € thousands)*	Grant date	Total amount allocated	Receipts	Repayments	Effects of discounting	Net book value As of 2023/06/30
BPI FRANCE - IT-DIAB Development of a global strategy for the prevention and management of type 2 diabetes	2008/12/23	3,229	3,229	—	—	3,229
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 2022/12/31
BPI FRANCE - IT-DIAB Development of a global strategy for the prevention and management of type 2 diabetes	2008/12/23	3,229	3,229	—	—	3,229
TOTAL		3,229	3,229	—	—	3,229

18.2.2. Bank loans

See Note 20.2.2 "Bank loans" in the Notes to the Consolidated Financial Statements in the Company's 2022 20-F filing for a detailed description of the Group's bank loans and related accounting treatment.

Balances by loan

Bank loans consisted of the following as of December 31, 2022 and June 30, 2023:

Bank loans *(in € thousands)*	Loan date	Facility size	Interest rate	Available As of 2023/06/30	Installments	Outstanding As of 2022/12/31	Outstanding As of 2023/06/30
BNP 4	April 2017	800	0.87 %	—	60 monthly	54	—
AUTRES	-	—	— %	—	—	17	15
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	1,900	1,700
BPI PRÊT TAUX BONIFIE	November 2021	2,250	2.25 %	—	20 quarterly	2,250	2,036
TOTAL		20,465		—		**15,221**	**14,751**

18.3 Maturities of financial liabilities

Maturity of financial liabilities *(in € thousands)*	As of 2023/06/30	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	57,356	415	—	56,940	—	—	—
Bank loans	14,732	6,321	6,343	863	868	336	—
Leases	6,030	1,005	1,017	1,029	1,040	1,053	886
Accrued interests	8	8	—	—	—	—	—
TOTAL - Other loans and borrowings	***78,125***	***7,748***	***7,360***	***58,832***	***1,909***	***1,389***	***886***
TOTAL	81,354	7,748	7,360	58,832	1,909	1,389	4,116

The values in the table above are nominal (contractual) values according to IFRS 7.39(a).

19. FAIR VALUE OF FINANCIAL INSTRUMENTS

Financial detail

The following tables provide the financial assets and liabilities carrying values by category and fair values as of June 30, 2023 and December 31, 2022:

	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**

	As of 30/06/2023							
		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	—							
Loans	452			452			452	
Deposits and guarantees	302			302			302	
Trade receivables	2,787			2,787			2,787	
Cash and cash equivalents	111,826	111,826				111,826		
TOTAL - Assets	***118,983***	***112,309***	***3,133***	***3,541***	**—**	***111,826***	***3,541***	***3,617***
Liabilities								
Conditional advances	3,229				3,229			3,229
Convertible loans	51,424				51,424		50,208	
Bank loans	14,732				14,732		14,732	
Obligations under finance leases	6,030				6,030		6,030	
Accrued interests	8				8		8	
Trade payables	15,883				15,883		15,883	
Other payables	1,207				1,207		1,207	
TOTAL - Liabilities	**92,513**	**—**	**—**	**—**	**92,513**	**—**	**88,067**	**3,229**

20. TRADE AND OTHER PAYABLES

Financial detail

Trade and other payables consisted of the following:

Trade and other payables - Total	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Trade payables	8,613	15,883
Social security costs payables	4,838	3,537
VAT payables	200	880
Taxes payables	316	198
Other payables	1,325	1,207
TOTAL	**15,293**	**21,705**

Trade and other payables - Current	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Trade payables	8,613	15,883
Social security costs payables	4,838	3,537
VAT payables	200	880
Taxes payables	316	198
Other payables	877	1,207
TOTAL	**14,845**	**21,705**

Trade and other payables - Non current	**As of**	
(in € thousands)	**2022/12/31**	**2023/06/30**
Trade payables	—	—
Social security costs payables	—	—
VAT payables	—	—
Taxes payables	—	—
Other payables	448	—
TOTAL	**448**	**—**

At June 30, 2023, trade payables amounted to €15,883 (€8,613 at December 31, 2022). 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 (€9,163 and €3,924 at June 30, 2023 and December 31, 2022 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.

21. 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 June 30, 2023, the Company considers that this initial budget is still appropriate based on progress performed.

During the first six months of 2022,€8.2 million of said balance was recognized as revenue.

During the first six months of 2023, €8.2 million of said balance was recognized as revenue.

As of June 30, 2023, €15.9 million of Deferred income remains, €11.1 million of which relates to Current deferred income and €4.8 million of which relates to Noncurrent deferred income, which was determined based on the original budget.

See Note 8 - "Revenues and Other income".

22. PROVISIONS

Financial detail

At June 30, 2023 and at December 31, 2022, this line item amounted to €56 and €61, respectively.

Change in provisions	**As of**	Increase	Decrease	Decrease	**As of**
(in € thousands)	**2022/12/31**		(used)	(unused)	**2023/06/30**
Provision for charges	61	—	(21)	16	56
TOTAL	**61**	**—**	**(21)**	**16**	**56**

23. EQUITY

Detailed breakdown

Share capital

Number of shares	**As of**	
	2022/12/31	**2023/06/30**
Ordinary shares issued (€0.25 par value per share)	49,834,983	49,834,983
Convertible preferred shares registered	—	—
Total shares issued	**49,834,983**	**49,834,983**
Less treasury shares	—	—
Outstanding shares	**49,834,983**	**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 2023

None.

24. LITIGATION AND CONTINGENT LIABILITIES

Class Action

In May 2020, following the Group announcement on the interim results of our RESOLVE-IT® Phase 3 clinical trial in which elafibranor had not achieved the primary or key secondary endpoints, a purported shareholder class action complaint was filed in state court in the Commonwealth of Massachusetts, naming the Group, the board of directors and certain members of the senior management as defendants, alleging that defendants made materially misleading statements about the development of elafibranor in connection with our U.S. initial public offering in violation of U.S. federal securities laws.

In October 2020, the plaintiff voluntarily dismissed the Commonwealth of Massachusetts action, but in December 2020, the same plaintiff filed a purported shareholder class action complaint in state court in the State of New York, alleging claims substantially similar to those in the previous complaint against the same defendants, as well as the underwriters of our U.S. initial public offering.

In March 2021, the Company and the other defendants filed a motion to dismiss. 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. As of June 30, 2023, the time to appeal the decision of the Appellate Division has expired.

25. RELATED PARTIES

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 June 30, 2023, 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 2023 or 2022, 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.

The Transition Services Agreement (the TSA) signed between the Company and Ipsen Pharma on April 6, 2022, which governs the conditions under which a certain number of transition services are carried out by the Company in the interest of smoothly running the phase clinical trial 3 ELATIVE®, was supplemented by a “Part B Transition Services Agreement” (the “Part B Agreement”). It will be signed signed between the parties following approval by the Company's Board of Directors on September 19, 2023 in accordance with the policy relating to transactions between Related Parties and the Company.

The Part B Agreement governs the conditions under which a certain number of transition services have been and continue to be carried out by the Company in the same interest mentioned above, until the total transfer of responsibility for the trial is turned over to IPSEN, and in particular the terms of remuneration of these services during the specific period when some patients had completed the treatment corresponding to the first part of the clinical trial and initiated the treatment of the second part and others had not.

These services are independent of those provided for by the TSA and the license contract.

26. 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 agreement with Seal Rock

The Group has entered into a licensing agreement with Seal Rock under which we are obligated to pay royalties and contingent payments based on future events. Under the terms of the agreement, Seal Rock is eligible for payments of up to €98 million, including regulatory, clinical and commercial milestone payments, as well as tiered royalties. As of June 30, 2023, it should be noted that in accordance with the rules defined by IAS 37, GENFIT's obligations under the terms of the contract constitute contingent liabilities not recognized in the consolidated accounts.

Obligations under the terms of license and collaboration agreement with Genoscience

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, 2022 or June 30, 2023.

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 5 - "Acquisitions".

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 June 30, 2023.

Contingent assets

Terns

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 June 30, 2023. 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 .

Ipsen

Under the Collaboration and License Agreement with Ipsen, GENFIT is eligible for milestone payments up to €360 million. All such milestone payments are classified as contingent assets not recognized in the Company's consolidated financial statements for the period ending June 30, 2023.

27. SUPPLEMENTAL CASH FLOW INFORMATION

Supplemental cash flow information

Disclosure of non-cash financing and investing activities

- Accrued property, plant and equipment, at June 30, 2022: €27
- Accrued property, plant and equipment, at June 30, 2022: €35

4. STATUTORY AUDITORS' LIMITED REVIEW REPORT ON 2023 HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GRANT THORNTON
Membre français de Grant Thornton International
29, rue du Pont 92200 Neuilly-sur-Seine S.A.S. au capital
de € 2 297 184 632 013 843 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles et du Centre

ERNST & YOUNG et Autres
14, rue du Vieux Faubourg 59042 Lille cedex S.A.S.
à capital variable 438 476 913 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles et du Centre

GENFIT

For the period from 1 January to 30 June 2023

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

To the Shareholders,

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

- the review of the accompanying condensed half-yearly consolidated financial statements of GENFIT, for the period from 1 January to 30 June 2023;
- the verification of the information presented in the half-yearly management report.

These condensed half-yearly consolidated financial statements were drawn up under the responsibility of the Board of Directors. Our role is to express a conclusion on these financial statements based on our review

1. Conclusion on the financial statements

We conducted our review in accordance with the professional standards applicable in France.

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

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

2. Specific verification

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

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

Neuilly-sur-Seine and Lille, 20 September 2023
The Statutory Auditors
(French original signed by)

GRANT THORNTON
Membre français de Grant Thornton International
Samuel Clochard

ERNST & YOUNG et Autres
Sandrine Ledez

5. DECLARATION BY THE PERSON RESPONSIBLE FOR THE INFORMATION

“I hereby declare, to the best of my knowledge, that the financial statements for the most recent half year have been prepared in accordance with the applicable accounting standards and give a true and fair view of the assets and liabilities, the financial position and the results of the Company and all the other companies included in the scope of consolidation, and that the half-year management report gives a fair description of the important events of the first six months of the fiscal year and their impact on the half year financial statements, the main related party transactions as well as a description of the main risks and uncertainties for the six months to come.”

Pascal Prigent

Chief Executive Officer

Loos, September 20, 2023


GENFIT
TOWARDS BETTER MEDICINE