

Half-Year Business and Financial Report

at June 30, 2024

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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 Iqirvo®/elafibranor to receive marketing authorization and successful launch and commercialization in PBC by Ipsen outside the United States, the Iqirvo®/elafibranor competitive landscape, anticipated timing for study enrollment and data readouts and development plans for our pipeline programs, in particular in VS-01 in ACLF and GNS561 in CCA, 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 and R&D activity projections for 2024 and beyond. The use of certain words, including "believe", "potential", "expect", "target", "may", "should" 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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed with the AMF on April 5, 2024, 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 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024 and subsequent filings and reports filed with the AMF or SEC, including this Half-Year Business and Financial Report at June 30, 2024 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") committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. 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 a solid scientific heritage spanning more than two decades. Today, GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target other serious diseases, such as Cholangiocarcinoma (CCA), Urea Cycle Disorder (UCD) and Organic Acidemia (OA). GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated in the FDA's accelerated approval of Iqirvo®/elafibranor for Primary Biliary Cholangitis (PBC) in June 2024. Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-Associated Steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels.

GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

Overview of the main R&D programs of the Company

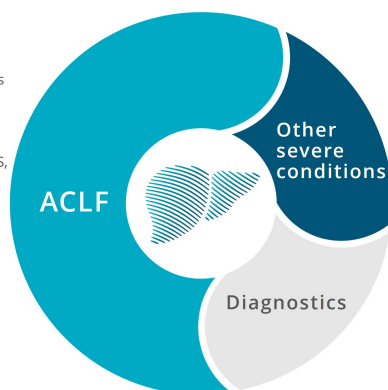
GENFIT remains faithful to its vocation and its specialization in hepatology, and is evolving towards having a portfolio that covers several serious and rare liver diseases that are characterized by largely unmet medical needs and their significant impact on patients' lives.

Acute-on-Chronic Liver Failure (ACLF)

- **Hepatic and extrahepatic** organ dysfunctions and failures
- **High short-term mortality** (23% to 74% mortality at 28 days¹)
- **No specific therapies approved** for patients with ACLF
- Estimated prevalence of ~**300,000 patients by 2036**² for US, EU4 and UK
- **High unmet medical need** and a **significant economic burden** for healthcare systems

Hepatic Encephalopathy (HE)

- one of the most common **complications of ACLF**
- It is a **central nervous system disorder**
- As many as **45% of patients with cirrhosis** will experience at least one episode of HE³
- Patients with ACLF and HE have **higher mortality rates** compared to patients who have ACLF only⁴
- HE is largely **underdiagnosed and undertreated**



Cholangiocarcinoma (CCA)

- **Rare type of biliary tract cancer**, it's the second most common primary liver malignancy
- **Highly aggressive** and is often refractory to chemotherapy - **Poor prognosis and high mortality**
- **Limited therapeutic options**, and survival benefit remains limited

Urea Cycle Disorders & Organic Acidemias (UCD/OA)

- 2 groups of **metabolic diseases** with deficiency of an enzyme involved in the urea cycle
- **Ultra-rare conditions** but a **very high mortality**
- As many as **45%⁵ of UCD patients remain untreated**

"At-Risk" MASH

- Identification of **"At-Risk" MASH - Non-invasive diagnostic program** based on the identification of specific biomarkers

Ammonia

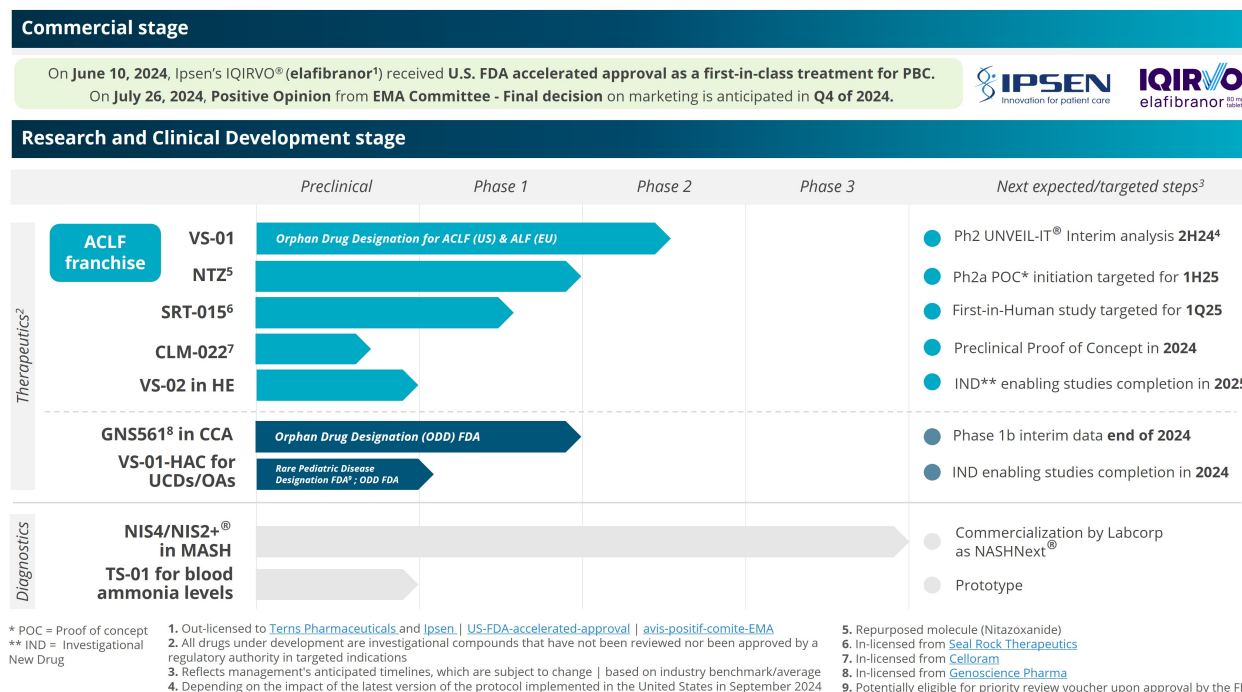
- Prototype stage of development for point-of-care, including **at-home measurement of ammonia in blood**

1. Arroyo V et al., Nat. Rev. Dis. Primers 2 (2016) / 2. IQVIA market research / 3. Vilstrup et al., Hepatology 2014; Poordad et al., Aliment Pharmacol Ther 2007 - 4. Maggi DC, et al. Ann Hep 2019 / 5. The EASL-CLIF Consortium is a network of more than a hundred of European University Hospitals which carry out clinical investigations of the EASL-CLIF Chair aimed at performing large observational, pathophysiological and therapeutic studies to increase our understanding of Chronic Liver Failure and to improve the management of patients with cirrhosis

Over the past few years, GENFIT has made a strategic pivot towards Acute-On-Chronic Liver Failure (ACLF) and other life-threatening liver conditions, broadening its research pipeline to include promising drug candidates that aim to meet the urgent and unmet needs of this challenging condition.

Our R&D pipeline now includes two therapeutic franchises: one focused on ACLF with five proprietary or in-licensed assets, and one focused on other life threatening diseases with two proprietary assets. We also have developed two programs in a diagnostic franchise.

In December 2021, Ipsen and GENFIT entered into an exclusive licensing agreement¹ for the rights to elafibranor, a compound that at that time was being evaluated in Phase 3 by GENFIT for the treatment of Primary Biliary Cholangitis (PBC). Following positive interim Phase 3 results and subsequent regulatory approvals by the U.S. Food and Drug Administration (FDA) in June 2024, elafibranor is now marketed in the United States by Ipsen (as Iqirvo[®] 80 mg tablets) as a first-in-class treatment for PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. GENFIT has received and continues to receive revenue from this agreement in the form of milestone payments and royalties on sales.



¹ Except for China, Hong Kong, Taiwan, and Macau, where Terns Pharmaceuticals holds the exclusive license to develop and market elafibranor

2. HALF-YEAR MANAGEMENT REPORT

2.1 Key Events of the First Half of 2024 and Main Events after the Reporting Period

PBC: Accelerated Approval of Ipsen's Iqirvo® (elafibranor) by the U.S. Food and Drug Administration involving new payments to GENFIT under the license agreement with Ipsen

On June 10, 2024, GENFIT announced the achievement of a historic corporate milestone: the U.S. Food and Drug Administration (FDA) accelerated approval of Iqirvo®/elafibranor 80 mg tablets as a first-in-class treatment for PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

Elafibranor is now marketed and commercialized in the U.S. by Ipsen under the trademark Iqirvo®.

This indication was approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Iqirvo®/elafibranor is not recommended for people who have or who develop decompensated cirrhosis (e.g., ascites, variceal bleeding, Hepatic Encephalopathy).

On June 5, 2024, Ipsen announced new late-breaking data at the European Association for the Study of the Liver (EASL) Congress demonstrating the enduring efficacy of elafibranor in managing disease progression after 78 weeks of treatment. New data from the ELATIVE® Phase 3 trial showed 70% of patients treated with elafibranor achieved composite endpoint of slowing disease progression measured by biochemical response after 78-weeks. Data from the itch domain of the PBC-40 and 5-D Itch questionnaires shows the potential of elafibranor to improve itch-related quality of life in patients with moderate-to-severe pruritus.

Upon first commercial sale of Iqirvo®/elafibranor in the U.S., GENFIT received a milestone of €48.7 million from Ipsen. For more information regarding milestone payments received in 2024, see [Note 2.1.1 - "Historic Milestone Achieved with U.S. FDA Accelerated Approval of Ipsen's Iqirvo® for Primary Biliary Cholangitis"](#) to our consolidated financial statements included in this half-year report.

In Europe, on July 26, 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) announced that it had issued a positive opinion for Ipsen's Iqirvo®/elafibranor for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. A decision on whether or not Iqirvo®/elafibranor should be granted marketing authorization by the European Commission is expected early in the last quarter of 2024.

The period was also marked by the following changes in the Iqirvo®/elafibranor competitive landscape:

- On September 3, 2024, the European Commission (EC) made the decision to revoke the conditional marketing authorisation of Ocaliva® (obeticholic acid) in Europe for second-line treatment of patients with PBC. The EC decision was taken following a recommendation of June 28, 2024, from the EMA's Committee for Medicinal Products for Human Use (CHMP). According to the CHMP, study 747-302 (COBALT), a Phase 3 confirmatory study of Ocaliva in patients with PBC, did not confirm the clinical benefit of Ocaliva. Consequently, the CHMP considered that the benefit/risk balance of Ocaliva is no longer favorable. The EMA has referenced the ability for Advanz Pharma to continue – subject to local laws and regulations – to supply Ocaliva® in the EU only on a compassionate access or named patient program basis for existing patients. On September 5, 2024, Advanz Pharma announced that this EC decision has been suspended with immediate effect by the European Court of Justice. Consequently, Ocaliva® conditional marketing authorization remains valid in Europe until further notice from the Court. On September 13, 2024, the Gastrointestinal Drugs Advisory Committee of the FDA also concluded that the benefit-risk profile of Ocaliva is not favourable for the treatment of PBC. Ocaliva might be withdrawn from the U.S. market if the FDA follows the decision of its advisory committee. The final decision of the FDA is expected by October 15, 2024.
- On August 14, 2024, Gilead announced that the FDA had granted accelerated approval to Livdelzi® (seladelpar) for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The use of Livdelzi® is not recommended for people who have or develop decompensated cirrhosis. The accelerated approval was based primarily on data from the pivotal placebo-controlled Phase 3 RESPONSE study. Improved survival or prevention of liver decompensation events were not assessed in this study and have therefore not been demonstrated. Definitive approval in this indication is dependent on verification and description of the clinical benefit demonstrated in the confirmatory study(s) for which Gilead is now responsible.

ACLF franchise: Progress on UNVEIL-IT[®] and highlights of the EASL Congress[™] 2024

The UNVEIL-IT[®] Phase 2 trial for VS-01 progressed, with the opening of several new clinical investigation sites and geographic expansion into the U.S. However, the initial uptake of recruitment was below our expectations, and we have been working closely with investigators to address this. As a result, we have modified our protocol to better account for the logistics of the care for these patients, as well as their many comorbidities. We feel that the latest version of the protocol addresses the initial challenges and should allow us to maintain our timeline of having preliminary results before the end of the year. We will monitor the impact of the implementation of the new protocol and will update this guidance as appropriate.

During the EASL Congress 2024, GENFIT co-hosted an event with the European Foundation for the Study of Chronic Liver Failure (EF CLIF) to mark the beginning of a research collaboration aimed at advancing the understanding of ACLF. EF CLIF has conducted several large prospective observational studies in large numbers of patients admitted to hospital in Europe and Latin America for acute decompensation of cirrhosis, helping to better understand the onset and progression of ACLF. Both EF CLIF and GENFIT are committed to working towards achieving a patient-centered healthcare system and are pleased to be associated with the Global Liver Institute (GLI) and the European Liver Patients' Association (ELPA) for the launch of this initiative.

During the congress, GENFIT also presented data from its two lead programs in ACLF:

- Poster #1: blood and peritoneal metabolomics suggest VS-01 actively captures metabolites associated with ACLF
- Poster #2: Nitazoxanide directly protects from stress-induced cell death to alleviate liver damage in preclinical models of ACLF

GENFIT also presented its commitment to patient advocacy and its ACLF programs at the European Liver Patients' Association (ELPA) educational training event, which aims to raise patient awareness on drug innovations and medical advances.

MASH Diagnostics: New European Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease including NIS2+[®] as key tool for detecting at-risk MASH

The new Clinical Practice Guidelines for metabolic dysfunction-associated steatotic liver disease (MASLD) published in June 2024 in the Journal of Hepatology have included our NIS2+[®] Diagnostic technology as a key tool for detecting at-risk MASH. These guidelines were developed as a joint effort by the European Association for the Study of the Liver (EASL), the European Association for the Study of Diabetes (EASD), and the European Association for the Study of Obesity (EASO), and provide healthcare providers an update on prevention, screening, diagnosis, follow-up and treatment for MASLD. The new guidelines were presented during the EASL Congress 2024.

NIS2+[®] is included for the first time in these guidelines as a non-invasive tool to detect at-risk MASH, and is the only blood-based panel mentioned for this condition. With the recent U.S. Food and Drug Administration approval of resmetirom in the US, and given that liver biopsy will be used sparingly in routine clinical practice due to its invasiveness and procedure-related limitations, alternative non-invasive panels with high predictive value validated for the detection of at-risk MASH such as NIS2+[®], could play an important role in selecting individuals able to benefit from pharmacotherapy.

During the first half of 2024, NIS2+[®] was also recognized by the scientific community through an article published in JHep Reports in January 2024. This article provided a global analysis of the impact of age on different non-invasive tests concluding that, unlike other usual non-invasive tests such as FIB-4 or ELF, NIS2+[®] was not impacted by this factor, allowing physicians to use and interpret NIS2+[®] results irrespective of patients' age.

Main events related to Corporate Governance and ESG commitment

Following the death of Mr. Xavier Guille des Buttes in April 2024, Vice-Chairman of the Board of Directors, the composition of the Board of Directors of the Company changed. In accordance with the succession plan, Mr. Éric Baclet became Vice-Chairman of the Board of Directors. He was also appointed Chairman of the Nominations and Compensation Committee. Mr. Jean-François Tiné joined the Audit Committee. In May, the Board of Directors appointed Ms. Katherine Kalin as member of the ESG Committee.

GENFIT's Board of Directors and its committees are henceforth composed as follows at the date of this report:

	Audit Committee	Nomination and Compensation Committee	Strategy and Alliances Committee	ESG Committee
Jean-François Mouney Chairman of the Board		Member	Chairman	Member
Éric Baclet Vice-Chairman of the Board	Member	Chairman		
Florence Séjourné (representative of Biotech Avenir SAS) Director				
Sandra Silvestri (representative of IPSEN) Director				
Katherine Kalin Director			Member	Member
Catherine Larue Director		Member		Chairman
Anne-Hélène Monsellato Director	Chairman			
Jean-François Tiné Director	Member		Member	

At the Company's Annual Shareholders' Meeting held on May 22, 2024, all of the resolutions 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.

At this meeting and in order to clarify the ambition of the Company's Corporate Social Responsibility approach, as well as the role played by the Board of Directors in this goal, the Company's shareholders were asked to approve an addition to the Company's corporate purpose as set out in its bylaws. The corporate purpose has been modified as follows: "The Company aims to generate a positive and significant social, societal and environmental impact in the course of its activities. As part of this approach, the Board of Directors undertake to take into consideration (i) the social, societal, environmental consequences of its decisions on all of the company's stakeholders, and (ii) the consequences of its decision on the environment".

In July 2024, GENFIT was recognized as a forerunner in ESG within its sector and as such invited by France Biotech to join its new taskforce aiming to mobilize French healthtech entrepreneurs on ESG-related issues. The goal is to work collaboratively to identify pioneering approaches and promote them to develop a more protective, sustainable, and resilient healthcare system.

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 life-threatening liver diseases - for greater operational efficiency, and to distribute the risk across different programs with different mechanisms of action, with the goal to improve our chances of success.

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

- Repurposing of molecules approved in other indications (e.g. NTZ, an antiparasitic drug, in ACLF); and
- In-licensing and/or acquisition of molecules developed by other companies (e.g. GNS561, from Genoscience Pharma, in CCA, and in ACLF, VS-01-ACLF from Versantis AG, SRT-015 from Seal Rock Therapeutics and CLM-022 from Celloram Inc.).

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 our 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 for 2024

In 2024, GENFIT prioritizes the execution of its clinical development programs (VS-01, NTZ, GNS561), as well as research programs (SRT-015, CLM-022, VS-02-HE) focused on pre-clinical/non-clinical development.

The Company also intends to strengthen its scientific leadership in ACLF in the field through various collaborations, including academic partnerships and patient-related initiatives.

Additionally, it maintains a continuous effort aiming to enhance operational excellence to the highest standards.

Impact on financial outlook

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until at least the start of the fourth quarter of 2025. This is based on current assumptions and programs and does not include exceptional events. This estimation includes our expectations to receive future milestone revenue, subject to approval by applicable regulatory authorities and European commercial launches of elafibranor in PBC by Ipsen, representing a total of approximately €26.5 million (in addition to the €13.3 million milestone already received in February 2024 and the €48.7 million milestone already received in August 2024).

2.3 Operating and Financial Review

2.3.1 Comments on the condensed statement of net income for the periods ended June 30, 2023 and June 30, 2024

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 (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Revenues	11,482	58,973
CIR tax credit	3,547	2,108
Government grants and subsidies	82	21
Other operating income	263	97
TOTAL	15,374	61,199

For the half-year ended June 30, 2024, total revenues and other income amounted to €61,199 (€15,374 for the same period in 2023).

Revenues

For the half-year ended June 30, 2024, Revenue amounted to €58,973 in 2024 (€11,482 for the same period in 2023).

Revenue is primarily composed of:

- Licensing Agreement (Ipsen). In December 2021, GENFIT and Ipsen entered into an exclusive licensing agreement for elafibranor (marketed as Iqirvo®/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 2024:
 - €48.7 million was attributable to a milestone invoiced to Ipsen in June 2024 following the first commercial sale of Iqirvo®/elafibranor in the U.S.
 - €9.3 million was attributable to the partial recognition of deferred revenue as noted in [Note 20 - "Deferred income and revenue"](#).
 - €0.2 million was attributable to royalty revenue from U.S. sales of Iqirvo®/elafibranor.
 - During the first six months of 2023:
 - €8.2 million was attributable to the partial recognition of deferred revenue as noted in [Note 20 - "Deferred income and revenue"](#).
- Transition Services Agreement (Ipsen). GENFIT and Ipsen entered into the Transition Services Agreement and Part B Transition Services Agreement, signed in April 2022 and September 2023 respectively, in order to facilitate the transition of certain services related to the Phase 3 ELATIVE® clinical trial until the complete transfer of the responsibility of the trial to Ipsen.
 - During the first six months of 2024, services provided under this contract generated €0.8 million in revenue.
 - During the first six months of 2023, services provided under this contract generated €3.2 million in revenue.

CIR tax credit

During the first six months of 2024, the research tax credit (CIR) amounted to €2,108 in 2024 including €177 of legally required related interest, (€3,547 for the same period in 2023), due to a reduction in eligible research and development expenses.

The research tax credit receivable amounted to €7,738 as of June 30, 2024, which comprises balances from 2023 onward.

- €1,931 relating to 2024
- €5,807 relating to 2023

Previously withheld balances from 2021 and 2022 totaling €6,570 have since been reimbursed on May 8, 2024, inclusive of legally required related interest of €177.

Other operating income

During the first six months of 2024, the Group recognized €97 in "Other operating income" (€263 for the same period in 2023), 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)	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
<i>(in € thousands)</i>							
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

Operating expenses and other operating income (expenses)	Half-year ended 2024/06/30	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
<i>(in € thousands)</i>							
Research and development expenses	(18,984)	(1,056)	(7,838)	(6,610)	(2,806)	(675)	—
General and administrative expenses	(10,564)	(152)	(69)	(4,380)	(5,778)	(185)	—
Marketing and market access expenses	(390)	(2)	—	(295)	(89)	(3)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income (expenses)	(39)	—	—	—	(102)	—	62
TOTAL	(29,977)	(1,210)	(7,907)	(11,284)	(8,774)	(863)	62

For the half-year ended June 30, 2024 operating expenses amounted to €29,977 (€34,673 for the same period in 2023).

They include the following:

Research and development expenses

For the first six months of 2023, research and development expenses totaled €25.6 million. 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.

For the first six months of 2024, research and development expenses totaled €19.0 million. These expenses were comprised of €7.8 million in contracted research and development conducted by third parties, €6.6 million in employee expenses, €2.8 million in other expenses, €0.7 million in depreciation, amortization and impairment charges and €1.1 million in raw materials and consumables.

The decrease of €6.6 million in contracted research and development conducted by third parties is mainly due to:

- Decreasing costs related to the ELATIVE® product candidate (approved by the FDA in the US in June 2024 and marketed under the name Iqirvo®/elafibranor) of €7.4 million
- Increasing costs related to the SRT-015 product candidate of €0.5 million, and
- Increasing costs related to the VS-01 product candidate of €0.3 million.

The increase of €0.3 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 96 to 106 employees at June 30, 2023 and 2024, respectively).

The decrease of €0.5 million in other expenses is mainly due to decreasing costs related to maintenance costs of €0.3 million and decreasing costs related to consultants of €0.2 million.

General and administrative 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.

For the first six months of 2024, general and administrative expenses totaled €10.6 million. These expenses were mainly comprised of €4.4 million in employee expenses and €5.8 million in other expenses.

The increase of €0.5 million in employee expenses in the general and administrative function was mainly due to the increase in workforce (from 56 to 61 employees at June 30, 2023 and 2024, respectively).

The increase of €1.2 million in other expenses in the general and administrative function was mainly due to increases in i) maintenance costs of €0.7 million, ii) consulting costs of €0.2 million, iii) donations of €0.2 million, et iv) recruiting fees of €0.1 million.

Marketing and market access 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.

For the first six months of 2024, marketing and market access expenses totaled €0.4 million. These expenses were mainly comprised of €0.3 million in employee expenses and €0.1 million in other 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 unused building space, which are now in use. There was no reorganization and restructuring expense in 2024.

Financial income (expenses)

For the half-year ended June 30, 2024, financial income amounted to loss of €0.9 million, compared to a loss of €1.1 million for the same period in 2023.

For the first six months of 2024, this is primarily the result of interest expense of €2.3 million, realized and unrealized foreign exchange loss of €0.6 million, and €1.7 million in accrued and realized interest income.

For the first six months of 2024, this is primarily the result of interest expense of €2.3 million, realized and unrealized foreign exchange loss of €42 thousand, and €1.3 million in accrued and realized interest income.

Net income (loss)

The first half of 2024 resulted in net profit of €30,311 thousand compared with a net loss of €20,854 thousand in the first half of 2023.

2.3.2 Comments on the Group's Cash Flows for the periods ended June 30, 2023 and June 30, 2024

As of June 30, 2024, cash and cash equivalents amounted to €61,645 (€77,789 as of December 31, 2023).

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

(in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Cash flows provided by (used in) operating activities	(25,074)	(11,187)
Cash flows provided by (used in) investment activities	2,682	(687)
Cash flows provided by (used in) financing activities	(1,764)	(4,225)

Cash flows provided by (used in) operating activities

Cash flow used in operating activities amounted to an outflow of €11,187 thousand for the half-year ended June 30, 2024 compared with an outflow of €25,074 thousand for the half-year ended June 30, 2023.

In the first half of 2024, this amount mainly stems from our research and development efforts; notably for ELATIVE®, our Phase 3 clinical trial of elafibranor in PBC (approved by the FDA in June 2024); 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 2023, this amount mainly stems from our net loss of €20.9 million, 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.

The change between the first half of 2024 and 2023 is further explained by the receipt of a milestone of €13.3 million from IPSEN in 2024 (incurred and recorded in 2023, upon the acceptance of the NDA filing with the FDA and the filing of the marketing authorization application with the EMA for the accelerated approval of elafibranor).

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 €-687 thousand in the first half of 2024, compared with €2,682 thousand in cash flow provided in the first half of 2023.

In the first half of 2024, 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 €-4,225 thousand in the first half of 2024, compared with €-1,764 thousand in the first half of 2023.

In the first half of 2024, these cash flows mainly reflect financial interest received and paid. The decrease is mainly explained by loan repayments for the period.

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 6.1 - "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, 2023 in the 2023 Annual Report on Form 20-F (the "2023 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 2024 are described in [Note 24 - "Related parties"](#) of the half year condensed consolidated financial states for the period ended June 30, 2024 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 2023 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 2023 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 2023 Form-20-F. The risks faced by the Company and described in the 2023 Form 20-F remain essentially the same.

Drug development is subject to a number of risks and the Group is highly exposed to the occurrence of any one of these inherent risks. Our activities in this area are all the more risky as many of our drug candidates are being evaluated in ACLF, a new therapeutic area characterized by short-term life-threatening prognosis, are at an early development stage and, for some of them, we were not involved in the initial research and discovery work, and may be less familiar with their mechanisms of action.

Drug development is a long, costly and uncertain process, aimed at demonstrating the therapeutic benefit of a drug candidate that competes with existing products and standards of care or other drug candidates in development.

In June 2023, we announced positive interim results from the Phase 3 ELATIVE® trial for our drug candidate elafibranor in PBC following clinical development carried out under the licensing agreements we signed with Terns Pharmaceuticals in 2019 in Greater China, and Ipsen in 2021 in other major pharmaceutical markets. Following these results, our product pipeline now composed of drug candidates whose development is much less advanced and therefore inherently more risky. These drug candidates, even if they have demonstrated promising initial preclinical or clinical results, have yet to obtain their preclinical and/or clinical proof-of-concept in the indications for which they are intended.

For example, in the second half of 2023, our drug candidates VS-01 in ACLF and GNS561 in CCA entered Phase 2 and Phase 1b/2 respectively, in order to provide clinical proof-of-concept.

Our other drug candidates are at an even earlier stage, since they have, either obtained initial Phase 1 clinical trial results (NTZ), or have never been administered in humans (SRT-015, VS-01 in UCD/OAs, VS-02 in HE and CLM-022), in the therapeutic areas in which we are developing them.

Many of these drug candidates are being developed to treat ACLF (VS-01, NTZ, SRT-015, CLM-022), a condition for which we have little experience, for which no treatment has yet been approved and characterized by an unfavorable short-term life-threatening prognosis which can complicate patient recruitment for trials. CCA also faces this challenge. As a result, we are more exposed to the risks associated with the preclinical and clinical development of our drug candidates than companies operating in better-explored therapeutic areas and with patients facing diseases which are less life-threatening in the short-term, while being, like them, still exposed to the risk of not being able to demonstrate that our drug candidates provide sufficient therapeutic benefit. Some of these product candidates are also intended to treat diseases for which we have limited experience with drug development, which creates further risks in their development.

Finally, the recent addition to our portfolio of some of the programs we are developing (GNS561, VS-01 and VS-02, SRT-015 and CLM-022) results either from the recent acquisition of licensing rights from other companies (Genoscience, Seal Rock Therapeutics and Celloram), or from our Group's acquisition of Versantis AG. Despite due diligence and evaluation procedures, we have carried out on the quality of previous results obtained by these companies, the development of these programs is riskier than if we had developed them ourselves from the outset.

Development failure can occur at any stage of preclinical or clinical development. The results of earlier preclinical studies or clinical trials are not necessarily predictive of future results of product candidates that we or our collaborators advance through preclinical studies or clinical trials. We may not have favorable results in later clinical trials, which may delay, limit or prevent our ability to receive regulatory approval or marketing authorization.

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

Success in preclinical studies and early clinical trials, or positive interim clinical results, does not ensure that final clinical results or subsequent clinical trials will generate the same or similar results, or otherwise, provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us or our current and potential future collaborators, have suffered significant setbacks in later-stage trials, including Phase 3 clinical trials and at other stages of preclinical and clinical development, for example in MASH, 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 Metabolic dysfunction-Associated Steatohepatitis or MASH. Elafibranor did not demonstrate a statistically significant effect on the primary surrogate efficacy endpoint of MASH resolution without worsening of fibrosis or on the key secondary endpoints. These results led us to stop development of elafibranor in MASH due to lack of efficacy but not due to safety reasons.

In addition, the design of a preclinical study or 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 preclinical study or 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 Iqirvo[®]/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. Such instances undermine the readability and acceptability of the results, both for the clinical trial sponsor and regulatory authorities, and our ability to create long-term shareholder value, and could lead to halting the development of the product candidate.

Delays in the commencement and completion of preclinical studies and clinical trials, and in enrollment of patients for clinical trials, including our ongoing clinical trials, may be due to various reasons, in particular those inherent to the therapeutic area and to the technical characteristics of the protocols, administration of study drug and could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our drug candidates. Such delays and costs could impair our financing capacity, and these events may limit or compromise our ability to continue development and to eventually commercialize our drug candidates.

Our pipeline includes several drug candidates at different stages of preclinical and clinical development (see [Item 1.2 - "Overview of the main R&D programs of the Company"](#)).

Preclinical and clinical development of a drug candidate is a long, costly and uncertain process, aimed at demonstrating the therapeutic benefit of a drug candidate that competes with existing products and standards of care or those currently under development.

At the preclinical stage, we may not be able to generate and complete the preclinical, toxicological, in vivo or in vitro data needed to support the launch of clinical trials with regulatory authorities, or such data may be obtained later than anticipated, which in the latter case could increase our product development costs, delay the subsequent phase of clinical development, and potentially limit our ability to obtain regulatory approval of our drug candidates.

The results from these trials may not be available when we expect, or we, or our collaborators, may be required to conduct additional clinical trials or preclinical studies not currently planned in order to receive approval for our product candidates. In addition, our clinical programs and those of our partners Ipsen and Terns Pharmaceuticals are subject to a number of variables and contingencies.

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 and funding required for conducting and completing clinical trials due to unforeseen costs or changes in the strategy of the Group, or its current or future partners;
- 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 (EC) and similar foreign regulatory authorities;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- 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;
- 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;
- 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 (for example ACLF and CCA), the rarity of the characteristics of the population being studied (as is the case for the profile of patients enrolled in our Phase 1b/2 trial evaluating GNS561 and our Phase 2 trial evaluating VS-01), the unfavorable short-term life-threatening prognosis for the patient suffering from the disease and/or the severe deterioration of their health status following the diagnosis, the nature of the protocol, the risks or technological difficulties related to procedures that may be required as part of the trial (related to, for example, to the intravenous administration of some of our drug candidates such as VS-01 or SRT-015), the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial, insufficient human resources or organizational difficulties within clinical investigation centers, and competition from other clinical trial programs for the same indications or with products with the same mechanism of action as our product candidates;
- natural disasters or pandemics; and
- inability to retain enrolled patients after a clinical trial is underway.

For example, our RESOLVE-IT® trial was a clinical trial in a disease without any approved therapies at the time 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.

Delays in the commencement, enrollment and completion of our clinical trials could significantly increase our product development costs, which could impair our financing capacity or limit our ability to obtain regulatory approvals required for the continued development of other drug candidates and future commercialization, or have a material impact on our financial position, commercial prospects and ability to generate revenues.

We cannot be certain that Iqirvo®/elafibranor (Iqirvo® is the elafibranor trade name selected by our partner Ipsen) or any of our other current or future product candidates, even if they meet preclinical, clinical and regulatory requirements if needed, will receive regulatory approval or certification, as applicable, and without regulatory approval or certification, we or our collaborators will not be able to market our product candidates, to continue to market them or to market them in all the territories or indications where we or our current or future partners would like to market them. There is no guarantee that obtaining authorization to market a drug candidate in a given territory will lead to similar authorization to market it in another territory.

In June 2024, the U.S. FDA granted an accelerated approval to Iqirvo®/elafibranor (Iqirvo® is the elafibranor trade name selected by our partner Ipsen) to be commercialized in the U.S for treatment of PBC. Iqirvo®/elafibranor is not currently approved for commercialization in any other territory or indication and we currently have no other products approved for sale and we cannot guarantee that we or any of our current or future collaborators will ever have other marketable products.

Our business and financial situation in the short term, including future revenues and financing capacity, mainly depends on the commercialization of Iqirvo®/elafibranor in PBC in U.S. and potentially in the E.U. States, where our partner Ipsen received a positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA), although must be confirmed by the European Commission (EC) in order to be marketed in the E.U.. Our ability to generate additional long-term revenue derived from product sales will also depend on Ipsen's ability to obtain regulatory approval of Iqirvo®/elafibranor in PBC or in other indication in other countries, as well as successful commercialization in these other territories or indications. In the long-term and also to a lesser extent, we may be able to generate indirect revenues if clinical development and subsequent commercialization by our partner Terns Pharmaceuticals in Greater China is successful.

There is no guarantee that the approval of Iqirvo®/elafibranor in PBC in the U.S. will lead to similar approval in the E.U. or other countries, or in another indication.

More generally, 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 EC (based on the positive opinion of the EMA), as applicable. The same is true for other countries, including the United Kingdom since Brexit. NDAs, marketing authorization applications or MAAs and MAs in other countries must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. These marketing applications must also include significant information regarding the chemistry, manufacturing and controls for the drug.

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

Obtaining marketing authorization is therefore a long and costly process, with an uncertain outcome, and these applications may fail.

Even if a drug is approved (whether conditional approval or final approval), the FDA, EMA, or competent authorities in other countries may limit the indications for which the drug can be marketed, require a comprehensive warning to appear on the drug's label, packaging and/or package insert, or make approval conditional on additional clinical trials or costly and/or time-consuming reports, or post-marketing studies (as is the case for FDA accelerated approval and for the potential conditional approval to be received by the EC for Iqirvo®/elafibranor in PBC). In some cases, authorization may be withdrawn after it has been granted. In some cases, regulatory approval or certification for any of our product candidates may be withdrawn.

Finally, obtaining regulatory approval or certification for marketing of a drug candidate or diagnostic in one country or indication does not ensure that we will be able to obtain regulatory approval or certification in any other country or indication.

To accelerate the development, approval or future commercialization of some of our other drug candidates, we, or our current or future collaborators, may seek to use certain regulatory pathways, but such mechanisms may not actually lead to a faster development or regulatory review or approval process, and may not increase the likelihood that our drug candidates will receive marketing approval.

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

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

In addition, even if one or more drug candidates qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may also seek various other designation mechanisms (such as Fast Track designation from the FDA, or orphan drug designation) for our product candidates in the future, and even if granted, these designations may not lead to accelerated regulatory approval, or approval at all.

For the commercialization of Iqirvo®/elafibranor in PBC, we and our current partner in the territories concerned (Ipsen) have been or may also be able to benefit from two other regulatory approval procedures. These are accelerated approval by the FDA and conditional marketing authorization by the EMEA.

The advantage of these procedures is that it is possible to obtain marketing authorization on the basis of surrogate endpoints (a marker, laboratory measurement, physical sign or other measure, which is thought to predict clinical benefit but which is not itself a measure of clinical benefit).

As is customary, the benefit of these procedures for the marketing of Iqirvo®/elafibranor in PBC has been subject to our partner Ipsen's commitment to diligently conduct post-authorization studies to verify, describe and confirm the clinical benefit of the drug. Iqirvo®/elafibranor is therefore subject in the U.S., and would be subject in E.U. if also approved, to strict compliance requirements during its marketing, such as the performance of Phase 4 trials or post-authorization clinical trials by our partner Ipsen in order to confirm the effect on the clinical endpoint. In the absence of post-marketing studies or confirmation of clinical benefit by such post-marketing studies, the FDA and the EMA or regulatory authorities in other countries may initiate proceedings to withdraw approval of the drug in question.

More generally, accelerated FDA approval is possible if the drug candidate (1) represents a treatment for a serious disease, (2) offers a real benefit compared to other existing therapies, and (3) demonstrates an effect on an endpoint that provides reasonable assurance of clinical benefit. Conditional marketing authorization by the EMA is possible if (1) the benefit/risk ratio of the drug candidate is positive, (2) it is likely that the applicant will be able to provide the required comprehensive clinical trial data, (3) the drug candidate corresponds to an unmet medical need, and (4) the public health interest in the immediate availability of the drug candidate on the market outweighs the risks associated with the fact that additional data still need to be provided.

Given these eligibility criteria, we are also studying the possibility of benefiting from the two regulatory approval procedures described above for the development of GNS561 in Cholangiocarcinoma and VS-01 in ACLF. In view of the significant unmet medical needs in these indications, the Orphan Drug Designation granted by the FDA for GNS561 and VS-01 could make these programs eligible for the various accelerated regulatory pathways proposed by the health authorities. However, the processes described above entail decisions which are at the discretion of the EMA, the FDA or any other competent authority, and no guarantee can be given that they will be obtained.

Our near and medium-term future capital resources depend in large part on the successful commercialization of Iqirvo®/elafibranor in PBC in the United States by our partner Ipsen, its ability to obtain regulatory approval(s) for marketing in countries other than the United States and the success of its commercialization in these other potential territories, and the confirmation of its therapeutic benefit in confirmatory clinical studies following these market launches. Because our access to alternative financing is limited, failure or relative success in any of these aspects 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 near and mid-term future capital resources depend in large part on the successful commercialization of Iqirvo®/elafibranor in PBC in the U.S. by our partner Ipsen, its ability to obtain marketing authorization in other territories and the success of its eventual commercialization in these territories, and the confirmation of its therapeutic benefit in confirmatory clinical studies.

Because we have limited access to capital to fund our operations, a delay or the refusal of marketing authorization, unsuccessful post-marketing studies or limited commercial success in these territories 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, failure in the successful commercialization of Iqirvo®/elafibranor in PBC could result in the non-payment of milestones and/or lower royalties negotiated under our partnership agreement with Ipsen. To a lesser extent, development failure of elafibranor in Greater China through Terns Pharmaceuticals could result in similar outcomes.

Developing the full medical and commercial potential of NIS4® and its derivatives, and of diagnostic tests using these technologies, remains subject to the risks associated with diagnostic product development, requires regulatory approval which may not be obtained. Its commercial potential will also depend on the distribution of the first approved therapeutic treatments for MASH.

In order to reach the largest number of MASH patients possible, we, or our future partners, need to develop an IVD powered by NIS4® technology or its improvements to identify patients with MASH and fibrosis who may be eligible for therapeutic intervention.

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

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

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

The NIS4® technology and its improvements have been developed in a field where no MASH-specific non-invasive test has been approved or CE marked nor commercialized for clinical care to date, and in an area where clinical experience is currently limited. Our development approach relies therefore on new methodologies. It is thus possible that, in this context, our diagnostic development does not meet a favorable outcome or that, despite a favorable outcome, regulatory authorities determine that the results of our clinical trials or those of our collaborators are insufficient to grant market approval or CE Certificates of Conformity for an IVD test using the NIS4® technology for clinical care of MASH patients.

Each regulatory authority may indeed refuse to issue approval or certification, impose conditions to such issuance, or require additional data prior to issuance, even when such approval or certification would have been already granted by regulatory authorities in other jurisdictions. Regulatory authorities may also modify their approval or certification policies, particularly by adding new or additional conditions to grant approval or certification. As an example, Regulation (EU) 2017/746 (IVDR) governing IVDs in the EEA entered into application on May 26, 2022 includes stricter requirements for manufacturers of IVDs to obtain the CE Certificate of Conformity and commercialize IVDs in the EEA. We are also required to provide clinical data in the form of a performance evaluation report as part of the conformity assessment process prior to CE marking and in post marketing clinical follow-up activities. Fulfillment of the obligations imposed by the IVDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the IVDR.

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

Once these authorizations have been obtained, the deployment of the IVD test will also depend to a large extent on the spread of the first approved treatment solutions for MASH, such as the recently approved treatment of Madrigal Pharmaceuticals. At the date of this report, Rezdiffra from Madrigal Pharmaceuticals is the sole approved treatment in MASH and many other companies have failed in the clinical development stage in this indication.

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

It is possible, in particular, that an LDT or IVD powered by NIS4® or its variations, at the time of its launch on the market for clinical care, will not replace the current tests and medical examinations. In that case, the place of a test powered by NIS4® or its variations, initially or as a complement or substitute of certain examinations would have to be assessed through additional clinical studies that would allow evaluating its medico-economic benefit often required to obtain reimbursement. The results of these studies may not meet the needs of clinical practitioners or demonstrates a favorable economic outcome. With such results, a test powered by NIS4® or its variations may not obtain reimbursement, especially in European countries, which could materially affect product sales.

Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, in particular due to competition from other therapeutic or diagnostic solutions, and as a result our revenues generated from their sales may be limited.

The commercial success of Iqirvo®/elafibranor as a treatment for PBC or in other indications, our other drug candidates or an LDT or IVD powered by NIS4® or its improvements, if approved or cleared, will depend upon their acceptance among the medical community, including physicians, healthcare payors and patients. Given that there are a limited number of products approved for the treatment of PBC, and no products approved for treatment of ACLF, we do not know the degree to which Iqirvo®/elafibranor or our other product candidates would be accepted as a therapy, if approved. Additionally, we cannot be assured that NASHNext®, or IVD powered by NIS4® or its improvements will continue to be accepted by the medical community as a means of identifying patients with MASH or fibrosis who may be appropriate candidates for therapeutic intervention, and even if an LDT or IVD powered by NIS4® or its improvements is used, a physician may still require additional testing (e.g. liver biopsy) to confirm diagnosis using a test based on our technologies. The competitive intensity represented by current competitors' treatments (such as Livdelzi® /seladelpar from Gilead for the treatment of PBC, which has received accelerated approval in the U.S. by the FDA in August 2024) or future ones could very significantly influence the adoption of our products or product candidates.

The degree of market acceptance of Iqirvo®/elafibranor or any of our other drug candidates, or NASHNext® or IVD using our diagnostic technologies, if and when they would be approved will depend on a number of factors, including:

- changes in the standard of care or availability of alternative therapies at similar or lower costs (including generics) or with better reimbursement rates for the targeted indications for any of our product candidates, such as competitors' product candidates that are in development for the treatment of PBC, or other cholestatic diseases like ACLF or CCA, or an alternative to liver biopsy for the diagnosis of MASH and fibrosis;
- limitations in the approved clinical indications or patient populations for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- limitations or warnings, including boxed warnings, contained in our drug candidates' FDA - or EC - approved packaging, if and when approved;
- lack of significant adverse side effects;
- sales, marketing and distribution support for our products and those of our competitors or competitors of our partners;
- availability of coverage and adequate reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug or diagnostic candidates are designated under physician diagnostic and treatment guidelines for the treatment of the indications for which we, our partners Ipsen and Terns Pharmaceuticals or a potential future partner have received regulatory approval;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

The following could also have a negative impact on sales:

- if they were subject to intellectual property rights held by third parties;
- if we or our current or future partners had no stock, or if we or our current or future partners were unable to have stock of our authorized products manufactured; and
- if we or our current or future partners fail to obtain regulatory approval for the manufacture of our products.

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

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

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

In addition, the nature of the policies adopted by future governments in countries where the largest commercial outlets for healthcare products are concentrated could affect the reimbursement of our products and product candidates, and therefore their commercialization.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, as well as other healthcare reform and cost-containment measures that may be adopted in the future, at both the federal and state levels in the United States, as well as internationally, may result in more rigorous coverage criteria and lower reimbursement from both government funded programs as well as private payors, and in additional downward pressure on the price that we or our partners receive for any approved product candidate.

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

Under our supervision or the supervision of our partners, substantial portions of operations related to the clinical development and the commercialization of drugs or drug candidates are outsourced to third-party service providers, including preclinical studies and clinical trials, collection and analysis of data and manufacturing of drugs or drug candidates and the realization of certain analyses performed under our agreements with Labcorp and Q2 pertaining to an LDT or IVD powered by NIS4® technology or its variations for use in the clinical research and clinical diagnostics markets. In particular, we subcontract certain elements of the design and/or conduct of preclinical studies and clinical trials to CROs, as well as the manufacturing of active ingredients and therapeutic units to CMOs.

We also contract with external investigators and other specialized services providers, for example with respect to certain statistical analyses, to perform services such as carrying out and supervising, and collecting, analyzing and formatting of data for trials.

Although we or our partners are involved in the design of the protocols for these trials and in monitoring them, we do not control all the stages of test performance and cannot guarantee that the third parties will fulfil their contractual and regulatory obligations; for example, our partner Ipsen relies on CROs for trials confirming the therapeutic benefit of Iqirvo®/elafibranor in PBC. In particular, a contractor's failure to comply with protocols or regulatory constraints, or repeated delays by a contractor, could compromise the development of our products or result in liability for us, including our contractual liability resulting from provisions in agreements we have signed with Ipsen and Terns Pharmaceuticals for the development of elafibranor. Such events could also inflate the product development costs borne by us.

Finally, we depend on CROs for the implementation of a substantial number of preclinical studies and all the clinical trials that will enable us to evaluate all our drug candidates.

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

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

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

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

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

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

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

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

Furthermore, an increase in the cost of raw materials, energy, or other direct or indirect costs, or more generally a general rise in the prices of goods and services, or a shortage of the raw materials used to manufacture our product candidates, could increase the cost of manufacturing and developing our product candidates, or necessitate the cessation of manufacturing, and increase logistics costs; and this particularly in a difficult geopolitical context such as that induced by the current conflict in Ukraine or the conflict in the Middle East, for example.

For example, our partner Ipsen depends on a supplier of active ingredient and a supplier of therapeutic units (CMO) for trials confirming the therapeutic benefit of Iqirvo®/elafibranor in PBC as well as for the supply of commercial batches.

With regard to VS-01, we are also dependent on several CMOs to cover the supply of therapeutic units and other materials required for the ongoing Phase 2 trial in ACLF.

Concerning NTZ, we use the already commercialized formulation in our clinical trials, which is available to purchase from pharmaceutical wholesalers and are until we are able to finalize our reformulation process are therefore subject to market fluctuations in availability and price. We depend on CMO for the development and supply of this formulation.

Regarding the supply of GNS561, we depend on our partner Genoscience Pharma with whom we have signed a supply agreement to cover the needs of the Phase 1b/2 trial evaluating GNS561 in Cholangiocarcinoma. We also depend on our partners Seal Rock Therapeutics and Celloram to cover the supply needs linked to the first preclinical developments of SRT-015 and CLM-022, and we depend on CMO for the development and supply of new injectable formulations.

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

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

We have not generated any significant recurring revenue from product sales until now. Indirect revenues resulting from our licensing agreements depend or will depend, among other things, on the successful development and/or commercialization by our partners of the product candidates or products for which we have granted or will grant the marketing rights. As a result, our ability to sustainably reduce our losses, reach lasting profitability, as a result of such types of revenue, and maintain our shareholders equity on our own is unproven, and we may never achieve or sustain profitability.

We recorded a net loss of €28,894 thousand for the year ended December 31, 2023 and €23,719 thousand for the year ended December 31, 2022. Other than the year ended December 31, 2021, we have a history of recorded losses during prior years.

We have never generated any direct profits from the sale of our products and we do not expect to become profitable from such profits in the foreseeable future. Although the collaboration and license agreement entered into with Ipsen in 2021 in particular has enabled us to receive very significant milestone payments linked to the development and commercialization in the U.S. of Iqirvo®/elafibranor in PBC, and includes the potential to receive further milestone payments and royalties on sales of the drug in the U.S. and possibly other territories, there is no assurance that this will occur on the timelines we expect or ever.

In recent years, our most significant revenue has resulted from one-time upfront payments received in 2019 under our license agreement with Terns Pharmaceuticals and in 2021, 2023 and 2024 under our license agreement and our transition service agreements with Ipsen. To these are added, to a lesser extent, the reimbursements of our research tax credit or CIR, which alone have the character of significant recurring operating income, although our ability to continue to benefit from the CIR depends on our ability to continue to meet the criteria and decisions of French policy makers with respect to the scope or rate of the CIR benefit (see Note 10 - "Income Tax" to the financial statements for the year ended December 31, 2023).

Revenues from our agreements with Labcorp/Covance and Q2 for the use of our NIS4[®] diagnostic technology and its improvements have so far been insignificant. Their eventual growth will depend on many external factors, including the commercialization of the first treatments approved for MASH. However, these revenues will never be of the same order as those that could result from the commercialization or eventual commercialization of our drug candidates, and will never enable us to be profitable on their own.

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

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

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

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

Our ability to achieve sustainable profitability in the future will mainly depend on our ability and also that of our current or future partners to obtain marketing approval for and successfully commercialize our products and product candidates in the major pharmaceutical markets, particularly our lead product candidate, Iqirvo[®]/elafibranor.

Our ability to achieve sustainable profitability in the future will mainly depend on our ability and also that of our current or future partners to obtain marketing approval for and successfully commercialize our products and product candidates in the major pharmaceutical markets, particularly our lead product candidate, Iqirvo[®]/elafibranor. The success of NASHNext[®] LDT commercialized by Labcorp powered by NIS4[®] technology, or by Q2, or a future IVD powered by NIS4[®] or its improvements for clinical care will not on their own enable us to be profitable. We, or our partners, may not be successful in our or their efforts to obtain such approval and to commercialize the products.

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

- obtaining positive results in preclinical studies and clinical trials;
- regulatory bodies determining that clinical data are sufficient, without further clinical data, to support an application for approval, whether or not conditional or accelerated;
- obtaining approval to market Iqirvo[®]/elafibranor in other major territories and obtaining approval to market our other product candidates in key pharmaceutical markets;
- obtaining additional positive results in our or our partners' formal validation studies required to commercialize a test powered by NIS4[®] or its improvements for clinical care that would allow an IVD test to be developed and approved for diagnosing MASH patients;
- expanding manufacturing of commercial supply for our licensed product candidates;
- establishing sales, marketing and distribution capabilities to effectively market and sell our drug candidates;
- market acceptance by patients and the medical community of Iqirvo[®]/elafibranor and our other product candidates;
- market acceptance by patients and the medical community of an LDT or IVD powered by NIS4[®] as a diagnostic complement to liver biopsy for clinical care; and

- negotiating and securing coverage and adequate reimbursement from third-party payors for Iqirvo®/elafibranor and an LDT or IVD powered by NIS4® or its improvements and our other product candidates.

We may also have to carry out preparatory activities for the future commercialization of some of our product candidates, in order to gain a better understanding of how doctors treat and diagnose their patients, without deriving any benefit from them, particularly in the absence of subsequent approval. Furthermore, as most of the therapeutic areas for which we are targeting our product candidates are characterized by medical needs that remain largely unsatisfied, there is considerable uncertainty as to the level of adoption of future treatments and diagnostic tools by patients and healthcare professionals, as well as third-party payers.

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

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

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

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

On January 29, 2021, we amended the terms and conditions of our convertible bonds (called OCEANEs in French law) initially issued in October 2017, mainly to extend the maturity by an additional three years, from October 16, 2022 to October 16, 2025, and increase the conversion ratio from one (1) share per bond to 5.5 shares for one bond, i.e., an implicit conversion price of €5.38 per share instead of €29.60. In addition, we carried out a partial repurchase of 2,895,260 convertible bonds, representing 48% of the outstanding bonds, resulting in €94.3 million nominal amount of bonds remaining outstanding on January 29, 2021 (compared to €180 million nominal amount initially). Following the closing of the transaction, we received conversion requests covering 1,262,159 convertible bonds. As of the date of this report, 1,909,742 convertible bonds are outstanding, representing a nominal amount of €56,528 thousand (versus €180,000 thousand initially) and potentially the issuance of 10,503,581 new shares, giving potential dilution of approximately 17.4 %. We cannot guarantee that additional conversion will take place, or that only part of the remaining bonds will be converted, before the maturity of this loan. As of the date of this Report, our stock price remains below €5.38, which is the theoretical conversion price of the OCEANEs. It is possible that if our stock price does not reach a price at which the bondholders will deem conversion economically viable, we will be required to repay the nominal amount at maturity in October 2025.

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

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

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

Finally, the conversion of some or all of our currently outstanding convertible bonds into ordinary shares would dilute the ownership interests of existing shareholders, including holders of our ADSs. Any sales in the public market of the ordinary shares issuable upon such conversion or any anticipated conversion of our convertible bonds into ordinary shares could adversely affect prevailing market prices of our ordinary shares or ADS and limit our ability to raise funds through capital raises. In addition, since 2016, we have set up several stock option plans, free allocation of free shares and stock warrants, many of which are still outstanding, giving a potential dilution of approximately 2.7 % (potentially the issuance of 363,581 new shares). We may in the future allocate or issue new equity-linked instruments, including convertible bonds or equity-linked compensation, the vesting and/or exercise of which could further dilute the ownership interests of shareholders, including holders of ADSs.

We have carried out a specific review of our liquidity risk and consider that we will be able to meet our maturities for the next 12 months. As of June 30, 2024, we had €61.6 million, in cash and cash equivalents (€77.8 million as of December 31, 2023). In view of these amounts as of June 30, 2024, and in light of the renegotiation of the convertible bonds in January 2021, including the extension of their maturity, we believe that the amount of cash, cash equivalents and other current financial assets and future revenues we may receive from our licensing agreements is sufficient to ensure our financing, in view of its projects and current obligations, over the next twelve months.

3. HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AT JUNE 30, 2024

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3.1 Consolidated Statements of Financial Position

ASSETS (in € thousands)	Notes	As of	
		2023/12/31	2024/06/30
Current assets			
Cash and cash equivalents	12	77,789	61,645
Current trade and others receivables	14	32,707	71,044
Other current assets	16	2,615	3,690
Inventories	—	4	4
Total - Current assets		113,115	136,384
Non-current assets			
Intangible assets	13	48,761	46,946
Property, plant and equipment	—	7,872	8,059
Other non-current financial assets	15	4,125	3,388
Deferred tax assets	—	—	—
Total - Non-current assets		60,758	58,393
Total - Assets		173,872	194,777

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	Notes	As of	
		2023/12/31	2024/06/30
Current liabilities			
Current convertible loans	17	415	413
Other current loans and borrowings	17	7,510	7,605
Current trade and other payables	19	18,799	22,159
Current deferred income and revenue	20	11,692	6,095
Current provisions	21	40	40
Other current tax liabilities	—	23	118
Total - Current liabilities		38,480	36,430
Non-current liabilities			
Non-current convertible loans	17	52,206	53,233
Other non-current loans and borrowings	17	10,047	6,553
Non-current deferred income and revenue	20	3,755	—
Non-current employee benefits	—	978	1,026
Deferred tax liabilities	—	455	171
Total - Non-current liabilities		67,441	60,983
Shareholders' equity			
Share capital	22	12,459	12,477
Share premium	—	445,261	446,490
Retained earnings (accumulated deficit)	—	(361,870)	(391,461)
Currency translation adjustment	—	996	(452)
Net profit (loss)	—	(28,894)	30,311
Total - Shareholders' equity		67,951	97,363
Total - Shareholders' equity & liabilities		173,872	194,777

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	
		2023/06/30	2024/06/30
Revenues and other income			
Revenue	7	11,482	58,973
Other income	7	3,893	2,226
Revenues and other income		15,374	61,199
Operating expenses and other operating income (expenses)			
Research and development expenses	8	(25,630)	(18,984)
General and administrative expenses	8	(9,105)	(10,564)
Marketing and market access expenses	8	(520)	(390)
Reorganization and restructuring income (expenses)	8	633	—
Other operating expenses	8	(52)	(39)
Operating income (loss)		(19,299)	31,222
Financial income	9	1,748	1,546
Financial expenses	9	(2,890)	(2,419)
Financial profit (loss)		(1,141)	(873)
Net profit (loss) before tax		(20,440)	30,349
Income tax benefit (expense)	10	(414)	(39)
Net profit (loss)		(20,854)	30,311
Basic and diluted earnings (loss) per share			
Basic earnings (loss) per share (€/share)	11	(0.42)	0.61
Diluted earnings (loss) per share (€/share)	11	(0.42)	0.53

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	
		2023/06/30	2024/06/30
Net profit (loss)		(20,854)	30,311
Actuarial gains and losses net of tax	—	50	46
Change in fair value of equity instruments included in financial assets and financial liabilities	15	—	(923)
Other comprehensive income (loss) that will never be reclassified to profit or loss		50	(877)
Exchange differences on translation of foreign operations		205	(1,448)
Other comprehensive income (loss) that are or may be reclassified to profit or loss		205	(1,448)
Total comprehensive income (loss)		(20,599)	27,986

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

3.4 Consolidated Statements of Cash Flows

<i>(in € thousands)</i>	Notes	Half-year ended 2023/06/30	Half-year ended 2024/06/30
Cash flows from operating activities			
+ Net profit (loss)		(20,854)	30,311
Reconciliation of net loss to net cash used in operating activities			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets		835	854
+ Impairment and provisions	21	(396)	105
+ Expenses related to share-based compensation	—	274	334
- Loss (gain) on disposal of property, plant and equipment		(52)	(62)
+ Net finance expenses (revenue)		763	542
+ Income tax expense (benefit)	10	414	39
+ Other non-cash items	—	1,199	1,687
Operating cash flows before change in working capital		(17,817)	33,809
Decrease (increase) in trade receivables and other assets	14	(4,858)	(39,413)
(Decrease) increase in trade payables and other liabilities	19	(2,398)	(5,572)
Change in working capital		(7,256)	(44,984)
Income tax paid		—	(12)
Net cash flows provided by (used in) in operating activities		(25,074)	(11,187)
Cash flows from investment activities			
- Acquisition net of cash acquired (Versantis intangible)	—	—	—
- Acquisition of other intangible assets	13	(2,000)	—
- Acquisition of property, plant and equipment	—	61	(737)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	—	62	78
- Acquisition of financial instruments	15	9	(28)
+ Proceeds from disposal of financial instruments	15	4,550	—
Net cash flows provided by (used in) investment activities		2,682	(687)
Cash flows from financing activities			
+ Proceeds from issue of share capital (net)	22	—	—
+ Proceeds from new loans and borrowings net of issue costs	17	—	—
- Repayments of loans and borrowings	17	(464)	(3,143)
- Payments on lease debts	17	(530)	(545)
- Financial interests paid (including finance lease)		(1,106)	(1,073)
+ Financial interests received		337	535
Net cash flows provided by (used in) financing activities		(1,764)	(4,225)
Increase (decrease) in cash and cash equivalents		(24,155)	(16,100)
Cash and cash equivalents at the beginning of the period	12	136,001	77,789
Effects of exchange rate changes on cash		(20)	(43)
Cash and cash equivalents at the end of the period		111,826	61,645

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)

	Share capital		Share premium	Treasury shares	Retained earnings (accumulated deficit)	Currency translation adjustment	Net profit (loss)	Total shareholders' equity
	Number of shares	Share capital						
<i>(in € thousands)</i>								
As of January 01, 2023	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
Net profit (loss)							(8,040)	(8,040)
Other comprehensive income (loss)					(886)	2,135		1,249
Total comprehensive income (loss)	—	—	—	—	(886)	2,135	(8,040)	(6,791)
Allocation of prior period profit (loss)					—		—	—
Share-based compensation			304					304
Treasury shares				(86)				(86)
Other movements					4			4
As of December 31, 2023	49,834,983	12,459	445,261	(970)	(360,901)	996	(28,894)	67,951
Net profit (loss)							30,311	30,311
Other comprehensive income (loss)					(877)	(1,448)		(2,325)
Total comprehensive income (loss)	—	—	—	—	(877)	(1,448)	30,311	27,986
Allocation of prior period profit (loss)					(28,894)		28,894	—
Capital increase	71,500	18	662		(7)			673
Equity component of OCEANE net of deferred taxes			232					232
Share-based compensation			334					334
Treasury shares				171				171
Other movements					16			16
As of June 30, 2024	49,906,483	12,477	446,490	(799)	(390,663)	(452)	30,311	97,363

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) and Versantis AG (Swiss subsidiary) (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 Historic Milestone Achieved with U.S. FDA Accelerated Approval of Ipsen's Iqirvo® for Primary Biliary Cholangitis

FDA Approval

On June 10, 2024, GENFIT announced the achievement of a historic corporate milestone: the U.S. Food and Drug Administration (FDA) accelerated approval of Iqirvo®/elafibranor 80 mg tablets, as a first-in-class treatment for PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

Elafibranor is marketed and commercialized by Ipsen under the trademark Iqirvo® and can be prescribed in the U.S. for eligible patients.

This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Iqirvo®/elafibranor is not recommended for people who have or who develop decompensated cirrhosis (e.g., ascites, variceal bleeding, Hepatic Encephalopathy).

License and Collaboration Agreement with Ipsen, and milestone payments

As previously communicated, in December 2021, Ipsen acquired global rights to develop and commercialize the molecule (except for China, Hong Kong, Taiwan, and Macau, where Terns Pharmaceuticals holds the exclusive license to develop and market elafibranor).

Under the terms of the agreement, GENFIT is eligible to receive a €48.7 million milestone payment upon the first commercial sale of Iqirvo®/elafibranor in the U.S. This event occurred on June 17, 2024, and as such this amount was invoiced to Ipsen and was recorded as revenue on the consolidated statement of operations for the half year ended June 30, 2024.

GENFIT expects to receive an additional €26.5 million milestone payment, subject to approval by applicable European regulatory authorities. GENFIT is also eligible for tiered double-digit royalties of up to 20%, applied to the annual sales of licensed products realized by Ipsen. See [Note 25 - Commitments, contingent liabilities and contingent assets](#). Related royalty revenues for the first half of 2024 totaled €154 thousand.

2.2. Events after the period

Milestone received

GENFIT collected the €48.7 million milestone payment from Ipsen in August of 2024 (recognized in June 2024 upon the first commercial sale of Iqirvo®/elafibranor in the U.S.).

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, 2024. Comparative information is presented for the year ended December 31, 2023 and for the half year ended 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").

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 in accordance with the IFRS general principles of fair presentation), going concern, accrual basis of accounting, consistency of presentation, materiality and aggregation.

These consolidated half year financial statements for the period ended June 30, 2024 were prepared under the responsibility of the Board of Directors that approved such statements on September 18, 2024.

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 (€).

In accordance with European Commission Regulation 1606/2002, these consolidated interim financial statements for the six-month period ended June 30, 2024 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, 2023. 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.

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, 2024, but do not have any material effect on the Group's financial statements for the period ended June 30, 2024.

- Amendments to IAS 7 and IFRS 7 Supplier Finance Arrangements,
- Amendments to IFRS 16 Lease Liability in a Sale and Leaseback,
- Amendments to IAS 1 Non-current Liabilities with Covenants, 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, 2025, 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 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 7 - "Revenues and other income"](#)
- Research tax credits, see [Note 7 - "Revenues and other income"](#)
- Accruals related to clinical trials, see [Note 19 - "Trade and other payables"](#)
- Valuation of our VS-01 assets related to the Versantis acquisition, see [Note 13 - "Goodwill and intangible assets"](#)

- Valuation of our license rights acquired, see [Note 13 - "Goodwill and intangible assets"](#)
- Valuation of our investments in Genoscience, see [Note 15 - "Other financial assets"](#)
- Convertible loans, see [Note 17 - "Loans and borrowings"](#)
- Average tax rate for the annual period (see [Note 10 - "Income tax"](#))

4.2. Consolidation

Going concern

The consolidated financial statements were prepared on a going concern basis. The Group believes it has sufficient resources to continue operating for at least twelve months following the consolidated financial statements' publication.

When assessing going concern, the Group's Board of Directors considers the liquidity available at the statement of financial position date, milestones whose collection is considered highly probable (subject to approval by applicable regulatory authorities and European commercial launches of elafibranor in PBC), the cash spend projections for the next 12-month period as from the date of the financial statements are issued, and the availability of other funding.

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.

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 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	
	2023/06/30	2024/06/30
Exchange rate at period end	0.92030	0.93414
Average exchange rate for the period	0.92515	0.92490

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	
	2023/06/30	2024/06/30
Exchange rate at period end	1.02166	1.03799
Average exchange rate for the period	1.01462	1.04035

5. SEGMENT INFORMATION

The Board of Directors and Chief Executive Officer are the chief operating decision makers.

The Board of Directors and the Chief Executive Officer oversee the operations and manage the business as one segment with a single activity; namely, the research and development of innovative medicines and diagnostic solutions, the marketing of which depends on the success of the clinical development phase.

The assets, liabilities and operating income (loss) are mainly located in France and in Switzerland (the latter as a result of the acquisition of Versantis in September 2022).

Revenue breakdown by geographical area

Revenue by destination (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Revenue from France	100 %	100 %
Revenue from other countries	— %	— %
TOTAL	100 %	100 %

For the six month period ended June 30, 2023 and 2024, substantially all revenue was generated 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 (thousands of euros)	As of December 31, 2023			As of June 30, 2024		
	France	Switzerland	Total	France	Switzerland	Total
TOTAL	13,869	46,889	60,758	13,351	45,042	58,393

6. FINANCIAL RISKS MANAGEMENT

The Group may be exposed to the following risks arising from financial instruments: foreign exchange risk, interest rate risk, liquidity risk and credit risk.

6.1. Foreign exchange risk

The Group's overall exposure to the foreign exchange risk depends, in particular, on:

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

Given the significant portion of its operations denominated in US dollars, the Group decided to limit the conversions into euros of its US dollar denominated cash, issued notably from its March 2019 Nasdaq IPO in US dollars, and not to use any specific hedging arrangements, in order to cover expenses denominated in US dollars over the coming years.

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

	2023/12/31	2024/06/30
Cash and cash equivalents denominated in US dollars	22,023	15,811
Equivalent in euros, on the basis of the exchange rate described below	19,930	14,769
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	22,145	16,410
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	18,119	13,427

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)

	2023/06/30	2024/06/30
Expenses denominated in US dollars	9,045	6,991
Equivalent in euros, on the basis of the exchange rate described below	8,324	6,531
Equivalent in euros, in the event of an increase of 10% of US dollar vs euro	9,249	7,256
Equivalent in euros, in the event of a decrease of 10% of US dollar vs euro	7,567	5,937

2024/06/30 : Equivalent in euros, on the basis of 1 euro = 0,93414 dollars US

2023/06/30 : Equivalent in euros, on the basis of 1 euro = 0,9203 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 per the periods stated below.

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)

	2023/12/31	2024/06/30
Cash and cash equivalents denominated in CH franc	1,111	944
Equivalent in euros, on the basis of the exchange rate described below	1,200	980
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	1,333	1,088
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	1,091	890

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)

	2023/06/30	2024/06/30
Expenses denominated in CH franc	3,045	1,064
Equivalent in euros, on the basis of the exchange rate described below	3,111	1,104
Equivalent in euros, in the event of an increase of 10% of CH franc vs euro	3,457	1,227
Equivalent in euros, in the event of a decrease of 10% of CH franc vs euro	2,828	1,004

2024/06/30 : Equivalent in euros, on the basis of 1 euro = 1,03799 CH franc

2023/06/30 : Equivalent in euros, on the basis of 1 euro = 1,0217 CH franc

Cash, cash equivalents and financial assets (in € thousands)	As of	
	2023/12/31	2024/06/30
At origin, denominated in EUR		
Cash and cash equivalents	56,593	45,888
Current and non current financial assets	4,095	3,359
Total	60,689	49,247
At origin, denominated in USD		
Cash and cash equivalents	19,931	14,769
Current and non current financial assets	15	15
Total	19,946	14,785
At origin, denominated in CHF		
Cash and cash equivalents	1,200	980
Current and non current financial assets	14	14
Total	1,214	993
Total, in EUR		
Cash and cash equivalents	77,789	61,645
Current and non current financial assets	4,125	3,388
Total	81,913	65,033

6.2. Interest rate risk

As of June 30, 2024, 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, 2023 and June 30, 2024, the Group's financial liabilities totaled €70.2 million and €67.8 million respectively (net of the equity component of the convertible loan and debt issue costs). Current borrowings are at a fixed rate. The Group's exposure to interest rate risk through its financial assets is also insignificant since these assets are mainly euro-denominated Undertakings for the Collective Investment of Transferable Securities (UCITs), medium-term negotiable notes or term deposits with progressive rates denominated in euros or US dollars.

6.3. Liquidity risk

The Group's loans and borrowings mainly consist of bonds convertible or exchangeable into new or existing shares (OCEANES), repayable for a nominal amount of €56.7 million on October 16, 2025 (see [Note 17 - "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, 2023 and June 30, 2024, the Group had €77,789 and €61,645 respectively in cash and cash equivalents. 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.

6.4. Credit risk

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

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

7. REVENUES AND OTHER INCOME

7.1. Revenues from contracts with customers

Financial statement line item detail

Revenue and other income (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Revenues	11,482	58,973
CIR tax credit	3,547	2,108
Government grants and subsidies	82	21
Other operating income	263	97
TOTAL	15,374	61,199

For the half-year ended June 30, 2024, the total revenues and other income amounted to €61,199 (€15,374 for the same period in 2023).

For the half-year ended June 30, 2024, Revenue amounted to €58,973 in 2024 (€11,482 for the same period in 2023).

Revenue is primarily composed of:

- Licensing Agreement (Ipsen). In December 2021, GENFIT and Ipsen entered into an exclusive licensing agreement for elafibranor (marketed as Iqirvo®), 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 2024:
 - €48.7 million was attributable to a milestone invoiced to Ipsen in June 2024 following the first commercial sale of Iqirvo®/elafibranor in the U.S.
 - €9.3 million was attributable to the partial recognition of deferred revenue as noted in [Note 20 - "Deferred income and revenue"](#).
 - €0.2 million was attributable to royalty revenue from U.S. sales of Iqirvo®/elafibranor.
 - During the first six months of 2023:
 - €8.2 million was attributable to the partial recognition of deferred revenue as noted in [Note 20 - "Deferred income and revenue"](#).
- Transition Services Agreement (Ipsen). GENFIT and Ipsen entered into the Transition Services Agreement and Part B Transition Services Agreement, signed in April 2022 and September 2023 respectively, in order to facilitate the transition of certain services related to the Phase 3 ELATIVE® clinical trial until the complete transfer of the responsibility of the trial to Ipsen.
 - During the first six months of 2024, services provided under this contract generated €0.8 million in revenue.
 - During the first six months of 2023, services provided under this contract generated €3.2 million in revenue.

7.2. Other income

7.2.1. Research tax credit

The Research Tax Credit ("Crédit d'Impôt Recherche," or "CIR") is granted to entities by the French tax authorities in order to encourage them to conduct technical and scientific research. Entities that demonstrate that their research expenditures meet the required CIR criteria receive a tax credit that may be used for the payment of their income tax due for the fiscal year in which the expenditures were incurred, as well as in the next three years. If taxes due are not sufficient to cover the full amount of tax credit at the end of the three-year period, the difference is paid in cash to the entity by the tax authorities. If a company meets certain criteria in terms of sales, headcount or assets to be considered a small/mid-size company, immediate payment of the Research Tax Credit can be requested. The Group meets such criteria.

The Group applies for CIR for research expenditures incurred in each fiscal year and recognizes the amount claimed in the line item "Other income" in the statements of operations in the same fiscal year. In the notes to the financial statements, the amount claimed is recognized under the heading "Research tax credit" (see [Note 14 - "Trade and other receivables"](#) and the table below).

The breakdown of Other income is as follows:

Other income (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
CIR tax credit	3,547	2,108
Other operating income	263	97
Government grants and subsidies	82	21
TOTAL	3,893	2,226

During the first six months of 2024, the research tax credit (CIR) amounted to €2,108 in 2024 including €177 of legally required related interest, (€3,547 for the same period in 2023), due to a reduction in eligible research and development expenses.

Note that there is a tax inspection currently taking place as noted in [Note 10 - "Income tax"](#).

During the first six months of 2024, the Group recognized €97 in "Other operating income" (€263 for the same period in 2023), mainly comprised of exchange gains on trade receivables.

8. OPERATING EXPENSES

Financial statement line item detail

Operating expenses and other operating income (expenses)	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
<i>(in € thousands)</i>							
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

Operating expenses and other operating income (expenses)	Half-year ended 2024/06/30	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
<i>(in € thousands)</i>							
Research and development expenses	(18,984)	(1,056)	(7,838)	(6,610)	(2,806)	(675)	—
General and administrative expenses	(10,564)	(152)	(69)	(4,380)	(5,778)	(185)	—
Marketing and market access expenses	(390)	(2)	—	(295)	(89)	(3)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income (expenses)	(39)	—	—	—	(102)	—	62
TOTAL	(29,977)	(1,210)	(7,907)	(11,284)	(8,774)	(863)	62

2023 Activity

- *Research and Development Expenses*

The decrease in research and development expenses is mainly explained by the decrease in costs related to our ELATIVE® program (following FDA approval in June 2024), partly offset by i) increase in costs related to our product candidates, in particular VS-01 and SRT-015 as well as ii) increased staffing levels.

- *General and administrative expenses*

The increase in general and administrative employee expenses was mainly due to an increase in workforce and other expenses.

- *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 2024, there were no reorganization and restructuring expenses.

- *Other operating income (expenses)*

For the six months ended June 30, 2024, other operating expenses were not material.

Employee expenses

Employee expenses and number of employees were as follows:

Employee expenses (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Wages and salaries	(7,413)	(7,848)
Social security costs	(2,737)	(3,025)
Changes in pension provision	(69)	(77)
Share-based compensation	(274)	(334)
TOTAL	(10,492)	(11,284)

Number of employees at year-end	Half-year ended	
	2023/06/30	2024/06/30
Average number of employees	152	164
Number of employees		
Research and development	77	86
Services related to research and development	19	20
Administration and management	56	61
Marketing and commercial	2	2
TOTAL	154	169

The increase in employee expenses resulted mainly from an increase in workforce, with an average headcount from 152 in 2023 to 164 in 2024.

9. FINANCIAL INCOME AND EXPENSES

Financial income and expenses (in € thousands)	Half-year ended	
	2023/06/30	2024/06/30
Financial income		
Interest income	337	535
Foreign exchange gain	71	271
Other financial income	1,341	740
TOTAL - Financial income	1,748	1,546
Financial expenses		
Interest expenses	(2,253)	(2,327)
Interest expenses for leases	(36)	(33)
Foreign exchange losses	(586)	(42)
Other financial expenses	(14)	(18)
TOTAL - Financial expenses	(2,890)	(2,419)
FINANCIAL GAIN (LOSS)	(1,141)	(873)

10. 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.

Research tax credit receivable

The research tax credit receivable amounted to €7,738 as of June 30, 2024, which comprises balances from 2023 onward.

- €1,931 relating to 2024
- €5,807 relating to 2023

Previously withheld balances from 2021 and 2022 have since been reimbursed on May 28, 2024 in the amount of €6,570 which includes legally required related interest of €177.

Tax expense

The income tax expense for the interim period is determined by applying management's best estimate of the weighted average tax rate for the annual period, adjusted for certain items fully applicable to the interim period if necessary to profit or loss before tax. The Group has made this assessment based on currently available information regarding the activities of the Group's entities, as well as the effective tax rates applicable in each relevant jurisdiction and historical data.

11. 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	Half-year ended	
	2023/06/30	2024/06/30
Profit (loss) for the period (in € thousands)	(20,854)	30,311
Basic earnings (loss) per share (€/share)	(0.42)	0.61
Weighted average number of ordinary shares used to calculate diluted earnings (loss) per share	49,701,858	60,363,017
Diluted earnings (loss) per share (€/share)	(0.42)	0.53

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	
	06/30/2023	06/30/2024
BSA	35,070	0
STOCK OPTIONS	995,381	0
AGA	124,391	0
OCEANES	10,580,141	0

12. 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 (in € thousands)	As of	
	2023/12/31	2024/06/30
Short-term deposits	67,530	53,803
Cash on hand and bank accounts	10,258	7,842
TOTAL	77,789	61,645

Short-term deposits (in € thousands)	As of	
	2023/12/31	2024/06/30
TERM ACCOUNTS	67,530	53,803
TOTAL	67,530	53,803

13. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The company does not have any goodwill.

Intangible assets

Seal Rock license agreement (2023)

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. See Note 14 "Goodwill and intangible assets" in the Notes to the Consolidated Financial Statements in the Company's 2023 20-F filing for a detailed description.

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. This addition 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. The annual impairment test will be based on a valuation methodology including an income approach using discounted cash flow techniques for the injectable formulation of ASK1 inhibitor SRT-015 in acute liver disease.

Indicators of impairment considered by the Group are as follows:

- Failure of or unfavorable data from our clinical trials
- Competition from other clinical trial programs covering the same indications as our drug candidates
- Availability of necessary financing

The value of the asset is €2 million at June 30, 2024. In 2024, there has been no indication of impairment.

Acquisition of Versantis (2022)

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. See Note 30 "Acquisitions" in the Notes to the Consolidated Financial Statements in the Company's 2023 20-F filing for a detailed description.

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 and IAS 36 - Impairment of 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.

Indicators of impairment considered by the Group are as follows:

- Failure of or unfavorable data from our clinical trials
- Competition from other clinical trial programs covering the same indications as our drug candidates
- Availability of necessary financing

The value of the asset is €44.5 million (after CHF/EUR currency translation adjustments) at June 30, 2024. In 2024, there has been no indication of impairment.

Other intangible assets

Intangible assets (apart from Celloram, Seal Rock and Versantis) is comprised primarily of office and scientific software. The following tables show the variations in intangible assets for the year ended December 31, 2023 and the half-year ended June 30, 2024:

(in € thousands)	As of 2022/12/31	Increase	Decrease	Translation adjustments	Reclassification	As of 2023/12/31
Gross						
Software	977	24	(45)	—	—	955
Patents	351	—	—	—	18	369
Other intangibles	43,569	2,050	—	2,746	—	48,366
TOTAL—Gross	44,897	2,074	(45)	2,747	18	49,690
Accumulated depreciation and impairment						
Software	(940)	(63)	75	—	—	(928)
Patents	—	—	—	—	—	—
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	(940)	(64)	75	—	—	(928)
TOTAL - Net	43,957	2,010	29	2,747	18	48,761

(in € thousands)	As of 2023/12/31	Increase	Decrease	Translation adjustments	Reclassification	As of 2024/06/30
Gross						
Software	955	—	(91)	—	—	864
Patents	369	—	—	—	(12)	357
Other intangibles	48,366	—	—	(1,798)	—	46,568
TOTAL—Gross	49,690	—	(91)	(1,798)	(12)	47,789
Accumulated depreciation and impairment						
Software	(928)	(6)	91	—	—	(843)
Patents	—	—	—	—	—	—
Other intangibles	—	—	—	—	—	—
TOTAL - Accumulated depreciation and impairment	(928)	(6)	91	—	—	(843)
TOTAL - Net	48,761	(6)	—	(1,798)	(12)	46,946

14. TRADE AND OTHER RECEIVABLES

Trade and other receivables consisted of the following:

Trade and other receivables - Total (in € thousands)	As of	
	2023/12/31	2024/06/30
Trade receivables, net	18,526	61,464
Research tax credit	12,200	7,738
Social security costs receivables	—	8
VAT receivables	1,476	1,773
Grants receivables	7	9
Other receivables	498	51
TOTAL	32,707	71,044
Of which : Current	32,707	71,044
Of which : Non-current	—	—

Trade receivables, net

Trade receivables amounted to €61,464 as of June 30, 2024 and €18,526 as of December 31, 2023. The balance mainly corresponds to revenue related to the Licence and Collaboration Agreement and Transition Services Agreement with Ipsen.

Research tax credit

The research tax credit receivable as of June 30, 2024 amounts to €7,738 and €12,200 as of December 31, 2023. These balances as well as the tax inspection currently taking place are described further in [Note 10 - "Income tax"](#).

VAT receivables

The VAT receivable amounted to €1,773 at June 30, 2024 (€1,476 at December 31, 2023).

Other receivables

The line item "other receivables" primarily consists of credit notes from suppliers as of June 30, 2024 and December 31, 2023.

15. OTHER FINANCIAL ASSETS

Other financial assets consisted of the following:

Financial assets - Total <i>(in € thousands)</i>	As of	
	2023/12/31	2024/06/30
Non consolidated equity investments	2,348	1,425
Other investments	471	459
Loans	472	500
Deposits and guarantees	303	302
Liquidity contract	531	701
TOTAL	4,125	3,388
Of which : Current	—	—
Of which : Non-current	4,125	3,388

Financial assets - Variations <i>(in € thousands)</i>	As of	Increase	Decrease	As of
	2023/12/31			2024/06/30
Non consolidated equity investments	2,348	—	(923)	1,425
Other investments	471	—	(12)	459
Loans	472	28	—	500
Deposits and guarantees	303	29	(29)	302
Liquidity contract	531	170	—	701
TOTAL	4,125	228	(964)	3,388

The total amount of financial assets of the Company was €4,125 at December 31, 2023, and €3,388 at June 30, 2024.

Non-consolidated equity investments

As of June 30, 2024, the value of "Non-consolidated equity investments" relates solely to our equity purchase in Genoscience Pharma. Since the transaction occurred, no shares have been sold. The gross value of the investment (and the initial transaction amount from 2021) totals €3,133. The net value of the investment (net of impairments) totals €1,425 as of June 30, 2024.

We did not complete the equity purchase in Genoscience Pharma for trading purposes. Therefore, pursuant to IFRS 9 and IAS 36, we elected to classify the equity in Genoscience Pharma we acquired in December 2021 as equity instruments recognized at fair value through other comprehensive income (OCI).

During the period, there was indication of loss of value based on Genoscience Pharma's progress in clinical trials and financing. As such, in accordance with IFRS 13, we updated our estimated of the fair value of our equity stake in Genoscience Pharma, which was based on a valuation methodology including a royalty based income approach using discounted cash flow techniques for the company's main scientific research programs. The aforementioned income method utilizes management's estimates of future operating results, cash flows discounted using a weighted-average cost of capital that reflects market participant assumptions, and the expected success rate of each program. Based on our analysis performed as of June 30, 2024, an impairment loss of €923 was recognized in OCI.

The period over which management has projected its cash flows spans through 2038. The drug price growth rate used to extrapolate cash flow projections is 1%. Furthermore, we have performed the following sensitivity analyses in order to determine the change in value of the asset by modifying certain key assumptions.

Values assigned to each key assumption

- Discount rate: 12.5%

The amount by which the asset would decrease if the weighted average cost of capital increased by 1%: €113

- Overall expected success rate: 14.5%

The amount by which the asset would decrease if the estimated overall success rate decreased by 1%: €118

Indicators of impairment considered by the Group as part of the impairment test above are as follows:

- Failure of or unfavorable data from our clinical trials, as well as delays
- Competition from other clinical trial programs covering the same indications as our drug candidates
- Availability of necessary financing

Other investments

As of June 30, 2024, the value of "Other investments" totaled €459. The balance relates solely to our investment in CAPTECH SANTE.

Liquidity contract

Consistent with customary practice in the French securities market, we entered into a liquidity agreement (Contrat de Liquidité) with Crédit Industriel et Commercial S.A. ("CIC") in August 2013. The liquidity agreement was entered into in accordance with applicable laws and regulations in France. The liquidity agreement authorizes CIC to carry out market purchases and sales of our shares on Euronext Paris.

As of June 30, 2024, the liquidity account had a cash balance of €701, and as of December 31, 2023 a cash balance of €531.

CIC holds the following number of GENFIT shares on behalf of the Company, recorded as a deduction in equity:

Financial assets - Current	As of	
	2023/12/31	2024/06/30
Number of shares (recorded as a deduction from equity)	147,812	131,000

16. OTHER ASSETS

Other assets amount to €3,690 at June 30, 2024 and €2,615 at December 31, 2023, respectively, and consisted of prepaid expenses related to current operating expenses.

17. LOANS AND BORROWINGS

17.1. 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.

Updated balances

As of 31/12/2023 :

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%

As of 30/06/2024 :

Number of bonds	1,915,662
Nominal amount of the loan	56,703,595.20€
Nominal unit value of the bonds	29.60€
Effective interest rate	8.8%

Nominal annual interest rate

The nominal annual interest rate is 3.5%, payable semi-annually in arrears

Repayment terms

Final reimbursement is scheduled for October 16, 2025.

Redemption prior to maturity at the option of the Company is possible if the arithmetic volume-weighted average price of GENFIT's listed share price and the then prevailing conversion ratio over a 20 day trading period exceeds 1.5 times the nominal value of the OCEANEs.

Conversion ratio and terms

The conversion ratio is 5.5 ordinary shares per bond.

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

8,000 bonds were converted to 44,000 GENFIT shares during the six month period ended June 30, 2024.

Conversion / exchange premium

The conversion / exchange premium is 30% relative to GENFIT's reference share price (22.77€).

Maximum dilution

The potential issuance of new shares upon conversion requests of the outstanding OCEANEs would represent 21.1% of the share capital of the Company at June 30, 2024 (representing a 17.4% dilution if all OCEANEs were converted).

Current and non current balances

Convertible loans - Total (in € thousands)	As of	
	2023/12/31	2024/06/30
Convertible loans	52,622	53,646
TOTAL	52,622	53,646

Convertible loans - Current (in € thousands)	As of	
	2023/12/31	2024/06/30
Convertible loans	415	413
TOTAL	415	413

Convertible loans - Non current (in € thousands)	As of	
	2023/12/31	2024/06/30
Convertible loans	52,206	53,233
TOTAL	52,206	53,233

17.2. Breakdown of other loans and borrowings

Other loans and borrowings consisted of the following:

Other loans and borrowings - Total <i>(in € thousands)</i>	As of	
	2023/12/31	2024/06/30
Bank loans	11,578	8,524
Obligations under leases	5,884	5,623
Accrued interests	7	11
Bank overdrafts	89	—
TOTAL	17,557	14,158

Other loans and borrowings - Current <i>(in € thousands)</i>	As of	
	2023/12/31	2024/06/30
Bank loans	6,339	6,456
Obligations under leases	1,076	1,138
Accrued interests	7	11
Bank overdrafts	89	—
TOTAL	7,510	7,605

Other loans and borrowings - Non current <i>(in € thousands)</i>	As of	
	2023/12/31	2024/06/30
Bank loans	5,239	2,068
Obligations under leases	4,808	4,485
Accrued interests	—	—
Bank overdrafts	—	—
TOTAL	10,047	6,553

17.2.1. Refundable and conditional advances

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

As of December 31, 2023, the balance of the conditional advance was €0. There has been no additional activity in 2024.

17.2.2. Bank loans

See Note 20.2.2 "Bank loans" in the Notes to the Consolidated Financial Statements in the Company's 2023 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, 2023 and June 30, 2024:

Bank loans <i>(in € thousands)</i>	Loan date	Facility size	Interest rate	Available As of 2024/06/30	Installments	Outstanding As of 2023/12/31	Outstanding As of 2024/06/30
BNP 4	April 2017	800	0.87 %	—	60 monthly	—	—
AUTRES	-	—	— %	—	—	13	11
CDN PGE	June 2021	900	1.36 %	—	8 quarterly	675	563
CIC PGE	June 2021	2,200	0.75 %	—	8 quarterly	1,650	1,100
BNP PGE	June 2021	4,900	0.45 %	—	8 quarterly	3,675	2,450
NATIXIS PGE	June 2021	3,000	0.40 %	—	8 quarterly	2,250	1,500
BPI PGE	July 2021	2,000	2.25 %	—	16 quarterly	1,500	1,300
BPI PRÊT TAUX BONIFIE	November 2021	2,250	2.25 %	—	20 quarterly	1,820	1,601
TOTAL						11,583	8,525

17.3 Maturities of financial liabilities

Maturity of financial liabilities <i>(in € thousands)</i>	As of 2024/06/30	Less than 1 year	Less than 2 years	Less than 3 years	Less than 4 years	Less than 5 years	More than 5 years
TOTAL - Refundable and conditional advances	—	—	—	—	—	—	—
Convertible loans	57,117	413	56,704	—	—	—	—
Bank loans	8,524	6,456	863	868	336	—	—
Leases	5,623	1,138	1,151	1,164	1,178	992	—
Accrued interests	11	11	—	—	—	—	—
TOTAL - Other loans and borrowings	71,275	8,018	58,717	2,033	1,514	992	—
TOTAL	71,275	8,018	58,717	2,033	1,514	992	—

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

18. 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, 2024 and December 31, 2023:

	As of 31/12/2023							
	Carrying value					Fair value		
	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
<i>(in € thousands)</i>								
Assets								
Equity investments	2,348		2,348					2,348
Other investments	471	471						471
Loans	472			472			472	
Deposits and guarantees	303			303			303	
Liquidity contracts	531	531				531		
Trade receivables	18,526			18,526			18,526	
Cash and cash equivalents	77,789	77,789				77,789		
TOTAL - Assets	100,439	78,790	2,348	19,300	—	78,319	19,300	2,819
Liabilities								
Convertible loans	52,622				52,622		51,939	
Bank loans	11,578				11,578		11,578	
Obligations under finance leases	5,884				5,884		5,884	
Accrued interests	7				7		7	
Bank overdrafts	89				89		89	
Trade payables	10,448				10,448		10,448	
Other payables	914				914		914	
TOTAL - Liabilities	81,541	—	—	—	81,541	—	80,858	—

As of 30/06/2024

	Carrying value					Fair value		
	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
<i>(in € thousands)</i>								
Assets								
Equity investments	1,425		1,425					1,425
Other investments	459	459						459
Loans	500			500			500	
Deposits and guarantees	302			302			302	
Liquidity contracts	701	701				701		
Trade receivables	61,464			61,464			61,464	
Cash and cash equivalents	61,645	61,645				61,645		
TOTAL - Assets	126,498	62,805	1,425	62,267	—	62,346	62,267	1,885
Liabilities								
Convertible loans	53,646				53,646		57,470	
Bank loans	8,524				8,524		8,524	
Obligations under finance leases	5,623				5,623		5,623	
Accrued interests	11				11		11	
Trade payables	8,039				8,039		8,039	
Other payables	395				395		395	
TOTAL - Liabilities	76,238	—	—	—	76,238	—	80,061	—

19. TRADE AND OTHER PAYABLES

Financial detail

Trade and other payables consisted of the following:

Trade and other payables - Total	As of	
	2023/12/31	2024/06/30
<i>(in € thousands)</i>		
Trade payables	10,448	8,039
Social security costs payables	4,188	3,159
VAT payables	3,139	10,352
Taxes payables	110	214
Other payables	914	395
TOTAL	18,799	22,159

Trade and other payables - Current	As of	
	2023/12/31	2024/06/30
<i>(in € thousands)</i>		
Trade payables	10,448	8,039
Social security costs payables	4,188	3,159
VAT payables	3,139	10,352
Taxes payables	110	214
Other payables	914	395
TOTAL	18,799	22,159

Trade and other payables - Non current	As of	
	2023/12/31	2024/06/30
<i>(in € thousands)</i>		
TOTAL	—	—

At June 30, 2024, trade payables amounted to €8,039 (€10,448 at December 31, 2023). This change is due to a reduction in accrued expenses relating to yet unbilled amounts from the clinical trial sites via the Clinical Research Organizations (CROs) in charge of the Company's clinical trials (€3,588 and €4,765 at June 30, 2024 and December 31, 2023 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.

20. 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. At June 30, 2024, the Company updated its initial budget and concluded that an additional €8.6 million of said balance should be recorded as additional revenue. This acceleration in revenue recognition is based on expected remaining costs as GENFIT's part of the double-blind ELATIVE® study is closer to completion than initially expected when the budget was first made.

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

During the first six months of 2024, €9.4 million of said balance was recognized as revenue.

As of June 30, 2024, €6.1 million of deferred income remains, in line with the updated budget.

See [Note 7 - "Revenues and Other income"](#).

21. PROVISIONS

Financial detail

At June 30, 2024 and at December 31, 2023, this line item amounted to €40 and €40, respectively.

Change in provisions (in € thousands)	As of 2023/12/31	Increase	Decrease (used)	Decrease (unused)	As of 2024/06/30
Provision for charges	40	—	0	0	40
TOTAL	40	—	0	0	40

22. EQUITY

Detailed breakdown

Share capital

Number of shares	As of	
	2023/12/31	2024/06/30
Ordinary shares issued (€0.25 par value per share)	49,834,983	49,906,483
Convertible preferred shares registered	—	—
Total shares issued	49,834,983	49,906,483
Less treasury shares	—	—
Outstanding shares	49,834,983	49,906,483

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 2024

During the six month period ended June 30, 2024:

- 8,000 bonds were converted to 44,000 ordinary GENFIT shares, and
- 27 500 free shares ("Actions Gratuites Attribuées") (from share based payment plan "AGA S 2021") became fully vested and were converted to ordinary GENFIT shares.

At June 30, 2024, the remaining unused authorizations to issue additional share-based compensation or other share-based instruments (stock options, free shares and share warrants) represent a total of 1,150,000 shares.

Currency translation adjustment

As of June 30, 2024, the currency translation adjustments on the consolidated statement of financial position amount to €(452) (compared to €996 as of June 30, 2023). For the six months ended June 30, 2024, exchange differences on translation of foreign operations on the consolidated statement of other comprehensive income (loss) amount to €(1,448) (compared to €205 for the six months ended June 30, 2023). The currency translation differences arise from the application of IAS 21 when converting the functional currencies of the Group's subsidiaries (i.e. the US dollar for GENFIT Corp and the Swiss franc for Versantis AG) into euros at each closing. The change period over period stems from the change of these two currencies' foreign exchange rates against the euro.

23. LITIGATION

Not applicable.

24. 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, 2024, 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 2024 or 2023, 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 and 2023, notably the Inventory Purchase Agreement, the Transition Services Agreement and the Part B 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.

25. COMMITMENTS, CONTINGENT LIABILITIES AND CONTINGENT ASSETS

25.1. 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 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, 2024.

Planned capital expenditures

Capital expenditures (Scientific and IT investments) for which the Group has already made firm commitments amount to €300 as of the date of this half-year financial report. The Group plans to finance these investments over the next 12 months with available cash or new borrowings.

In addition, the Company will evaluate any opportunity to acquire new molecules that may complement those in its existing portfolio. If such an opportunity were taken, the Group would therefore make significant investments in this regard in the years to come. As of the date of this half-year financial report, the Group has not made any commitments in this regard.

25.2. Contingent liabilities

Obligations under the terms of license agreement with Seal Rock

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, Washington.

Under the terms of the agreement, Seal Rock is eligible for payments of up to €100 million (of which €2 million have been paid in 2023), subject to certain regulatory, clinical and commercial outcomes.

Seal Rock is likewise eligible for tiered royalties, applied to the annual sales of licensed products realized by GENFIT.

In accordance with IAS 38, the conditional payments will be subject to analysis when they are incurred to determine if they are eligible for capitalization. If so, they will be capitalized. Otherwise, they will be expensed as incurred.

In accordance with IAS 37, the obligations under the terms of the agreement entered into with Seal Rock constitute contingent liabilities not recognized in the Company's consolidated financial statements at December 31, 2023 and June 30, 2024.

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.

In accordance with 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, 2023 and June 30, 2024.

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 therefore they constitute contingent liabilities not recognized in the Company's consolidated financial statements for the period ending June 30, 2024.

Milestone payments total up to 65 million CHF, contingent on the following outcomes:

- positive Phase 2 results related to VS-01-ACLF,
- regulatory approval of VS-01-ACLF, and
- positive Phase 2 results related to VS-02.

Furthermore, the former shareholders of Versantis are eligible to receive 1/3 of the net proceeds resulting from the potential sale of the Priority Review Voucher of VS-01's pediatric application by GENFIT to a third party, or 1/3 of the fair market value of this Voucher if GENFIT opts to apply it to one of its own programs.

In accordance with IAS 38, the conditional payments will be subject to analysis when they are incurred to determine if they are eligible for capitalization. If so, they will be capitalized. Otherwise, they will be expensed as incurred.

In accordance with IAS 37, the obligations under the terms of the agreement entered into with the former shareholders of Versantis constitute contingent liabilities not recognized in the Company's consolidated financial statements at December 31, 2023 and June 30, 2024.

Obligations related to the licensing agreement with Celloram

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.

Under the terms of the agreement:

1. Celloram is eligible for payments of up to €160 million (of which €50 thousand have been paid in 2023), subject to certain regulatory, clinical and commercial outcomes.
2. Celloram is likewise eligible for tiered royalties, applied to the annual sales of licensed products realized by GENFIT.

In accordance with IAS 38, the conditional payments will be subject to analysis when they are incurred to determine if they are eligible for capitalization. If so, they will be capitalized. Otherwise, they will be expensed as incurred.

In accordance with IAS 37, the obligations under the terms of the agreement entered into with Celloram constitute contingent liabilities not recognized in the Company's consolidated financial statements at December 31, 2023 and June 30, 2024.

25.3. Contingent assets

Contingent assets related to the licensing agreement with IPSEN

In December 2021, GENFIT and Ipsen Pharma SAS ("Ipsen") entered into an exclusive worldwide licensing agreement (except for China, Hong Kong, Taiwan and Macao, which apply to Terns as noted below) for elafibranor, a Phase 3 asset evaluated in Primary Biliary Cholangitis (PBC), as part of a long-term global partnership ("Collaboration and License Agreement"). Under this agreement 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, 2024.

- GENFIT is also eligible for total milestone payments up to €360 million. These milestone payments constitute future variable income, dependent on the completion of key steps related to the development and sales of the licensed products. As such, in accordance with IFRS 15, this income will be recognized as revenue depending on the completion of these milestones. GENFIT recognized its first milestone of €13.3 million in 2023 (received in February 2024) and its second milestone of €46.7 million in June 2024 (received in August 2024). Furthermore, we expect to receive future milestone revenue, subject to approval by applicable regulatory authorities, representing a total of approximately €26.5 million.
- GENFIT is eligible for tiered double-digit royalties of up to 20%, applied to the annual sales of licensed products realized by Ipsen. As such, in accordance with IFRS 15, this income will be recognized as revenue depending on the realization of these sales. Refer to [Note 7 - Revenues and other income](#).

Contingent assets related to the licensing agreement with Terns Pharma

The Company 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, 2024. The licensing agreement with Terns concerns China, Hong Kong, Taiwan and Macao.

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.

26. SUPPLEMENTAL CASH FLOW INFORMATION

Supplemental cash flow information

Disclosure of non-cash financing and investing activities

- Accrued property, plant and equipment, at June 30, 2023: €27
- Accrued property, plant and equipment, at June 30, 2024: €30

4. STATUTORY AUDITORS' LIMITED REVIEW REPORT ON 2024 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
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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 2024

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 2024;
- 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 limited review of interim financial information consists of making inquiries of persons responsible for financial and accounting matters, and of applying analytical procedures. This 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 limited 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 limited 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 Paris-La Défense, 19 September 2024

The Statutory Auditors
(French original signed by)

GRANT THORNTON
Membre français de Grant Thornton International

Samuel Clochard

ERNST & YOUNG et Autres

Alexis Hurtrel

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 19, 2024



Société anonyme à Conseil d'Administration
au capital social de 12 484 760,75 euros réparti en 49 939 043 actions de nominal 0,25 euro

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