UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

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

Date of report: September 20, 2023

Commission File Number: 001-38844

GENFIT S.A.

(Translation of registrant's name into English)

Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France

(Address of principal executive office)

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

☒ Form 20-F ☐ Form 40-F

EXHIBIT LIST

Exhibit	Description
99.1	Press Release dated September 20, 2023.

SIGNATURES

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

GENFIT S.A.

Date: September 20, 2023

By: /s/ Pascal PRIGENT
Name: Pascal PRIGENT
Title: Chief Executive Officer

PRESS RELEASE

GENFIT Reports First Half-Year 2023 Financial Results and Provides Corporate Update

- **Cash, cash equivalents and current financial assets totaled €111.8 million as of June 30, 2023**
- **Positive results in the pivotal Phase 3 ELATIVE® trial in June 2023, paving the way to:**
  - **a potential submission to the health authorities by Ipsen, and a potential first milestone met before the end of 2023, and**
  - **if approved, commercialization would trigger further milestone payments and royalty payments**
- **GENFIT's leadership in ACLF is further strengthened, with now 5 complementary assets in development, ranging from preclinical candidates to Phase 2 clinical stage programs**
- **Conference call in English on September 20, 2023 at 4.15pm ET / 9.15pm GMT / 10.15pm CET**

Lille (France), Cambridge (Massachusetts, United States), (Zurich, Switzerland); September 20, 2023 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases, today announced its first half-year 2023 financial results and provided a corporate update.

Pascal Prigent, CEO of GENFIT, commented :

"The positive interim results of our ELATIVE® Phase 3 study in PBC means that GENFIT is now entering into a new era, as we pivot from a focus on a single program to the development of a robust portfolio of exciting programs. Additional ELATIVE® data will be released in the coming months, and we are confident that this data will further demonstrate that elafibranor has a very competitive profile and the potential to add significant value to patients with PBC. We are pleased to see the commitment of our partner Ipsen and believe that they will make the most of the opportunity. For GENFIT, this means a potential first milestone in 2023 and, if elafibranor is approved in PBC, additional milestones and a regular revenue stream of royalty payments. These potential revenues would be used to finance the development of a very exciting pipeline of seven different programs ranging from preclinical to Phase 2. In particular we have five distinct programs in ACLF where the medical need is significant."

GENFIT will host a conference call in English on September 20, 2023 at 4.15pm EDT | 9.15pm GMT | 10.15pm CET

The conference call will be accessible on the investor page of our website, under the Events section at: https://ir.genfit.com/events%26presentations/events or by calling 888-204-4368 (toll-free United States/Canada), 0800 279 0425 (toll-free United Kingdom), 0805 101 219 (toll-free France) five minutes prior to the start time (confirmation code: **1615622**). A transcript of the conference call will be made available in French on the investor page of the GENFIT website soon after the call.

I. 1H23 Business highlights[1]

[1] *The Half Year Business and Financial Report is available to the public and was filed with the French Autorité des Marchés Financiers (French Financial Markets Authority) and filed with the U.S. Securities and Exchange Commission today. The condensed consolidated financial statements are included in this press release and the complete financial statements are included in the Half-Year Business and Financial Report which is available on the "Investors" page of the GENFIT website.*

PRESS RELEASE

PBC: positive results from pivotal Phase 3 ELATIVE® trial

GENFIT and Ipsen announced positive interim topline data from the pivotal ELATIVE® Phase 3 trial of elafibranor in PBC in the second quarter of 2023. The trial met its primary endpoint, with a statistically significant higher percentage of patients achieving a clinically meaningful cholestasis response compared to patients who received placebo. 51% of patients on elafibranor 80mg achieved a cholestasis response compared with 4% on placebo ($p<0.0001$). The first key secondary endpoint, normalization of ALP at Week 52, was also met with statistically significant improvements for investigational elafibranor compared with placebo. For the other key secondary endpoint, a trend for pruritus improvement was observed with a greater decrease from baseline in the PBC Worst Itch Numeric Rating Scale score for patients on elafibranor compared to placebo, which did not reach statistical significance. In the study, elafibranor was generally well tolerated with a safety profile consistent with that observed in previously reported studies.

ACLF franchise[2]

GENFIT's Acute on Chronic Liver Failure (ACLF) franchise now comprises 5 assets (VS-01, NTZ, SRT-015, CLM-022, VS-02-HE) based on differentiated mechanisms of action leveraging complementary pathways.

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

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

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

NTZ in ACLF: Phase 1 clinical data presented at DDW®

Data presented in May 2023 at Digestive Disease Week® (DDW®) showed that nitazoxanide (NTZ) was generally safe and well tolerated in subjects with moderate and severe hepatic impairment. Preliminary data from a similar Phase 1 study also showed that NTZ was well tolerated with a favorable safety profile in subjects with renal impairment.

Following engagement with the U.S Food and Drug Administration (FDA), and on the basis of the preclinical work and phase 1 data confirming the potential of NTZ in ACLF, GENFIT has decided to pursue the development of a new nitazoxanide formulation, which will permit greater dosing flexibility.

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

ASK1 Inhibitor SRT-015 in acute liver disease

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

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

Under the terms of the agreement, Seal Rock Therapeutics is eligible for payments of up to €100 million, including regulatory, clinical, and commercial milestone payments, plus tiered royalties. This agreement does not have any material impact on our current financial forecast, as specified in Part III of this press release.

CLM-022 in liver disease treatment

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

Under the terms of the agreement, Celloram is eligible for payments of up to €160 million, including regulatory, clinical and commercial milestones, as well as tiered royalties. This agreement does not have any material impact on our current financial forecast, as specified in Part III of this press release.

VS-02 in HE

VS-02-HE is in preclinical stages and is being developed in Hepatic Encephalopathy (HE), which is one of the major complications of advanced liver disease and portal hypertension. As many as 45% of patients with cirrhosis will experience at least one episode of HE. VS-02-HE is a urease inhibitor, designed to inhibit ureases by binding to nickel atoms in their active site.

CCA

CCA: Phase 1b/2a study evaluating GNS561

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

In the Phase 1b, patients are enrolled to evaluate the safety and tolerability of GNS561 when given in combination with a MEK inhibitor, and to identify the recommended doses of the combination to be administered in the Phase 2a study.

UCD and OA

GENFIT is also pursuing the development of preclinical programs in Urea Cycle Disorders (UCD) and Organic Acidemias (OA).

VS-01-HAC

VS-01-HAC is a potential first-line lifesaving treatment for acute hyperammonemic crisis associated with Inborn Errors of Metabolism in UCD and OA.

NASH diagnostic

In May 2023, the *Journal of Hepatology* published a manuscript on the development and validation of NIS2+™, followed by an article in August 2023 on NIS2+™ 's performance in older patients in *Hepatology Communications*.

At the EASL[3] Congress 2023, GENFIT presented NIS2+™ as an effective screening tool for optimizing patient selection in clinical trials targeting NASH[4] and as the most adapted Non-Invasive Test (NIT) for an efficient identification of at-risk NASH that is not impacted by age.

Corporate governance updates

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

[3] *European Association for the Study of the Liver*
[4] *It was decided at the EASL Congress 2023 that Metabolic dysfunction-associated steatohepatitis (MASH) is the replacement term for nonalcoholic steatohepatitis (NASH)*

In June 2023, Sandra Silvestri, M.D., Ph.D., replaced Steven Hildemann M.D., Ph.D., on the Board of Directors of the Company as representative of IPSEN, the legal entity that holds the board seat. Sandra Silvestri, M.D., Ph.D., joined Ipsen in 2023 as Executive Vice President, Chief Medical Officer and Head of Global Medical Affairs, Patient Safety and Patient Affairs.

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

ESG commitment

GENFIT's ESG commitment and performance were recognized by independent stakeholders.

In July 2023, GENFIT was awarded a gold medal by Ethifinance (compared to bronze in 2022) and ranked 2 out of 75 companies in the biopharmaceutical sector. This upgrade in the ratings is a testament to a company-wide effort in implementing CSR initiatives and ensuring transparent communications in relation to our CSR approach.

In June 2023, GENFIT was classified by ODDO Research as "Best-in-Class" in its sector, based on two main criteria: activity impact and ESG maturity.

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

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

II. 2H23 and beyond: key milestones and outlook

PBC

Additional data on the ELATIVE® study is expected to be disclosed by Ipsen at an upcoming scientific conference.

Ipsen is responsible for the development and commercialization of elafibranor, including the submission of regulatory applications for elafibranor following discussions with the FDA and the European Medicines Agency.

ACLF franchise

VS-01-ACLF: Interim data expected to be available in 1H24

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

NTZ in ACLF: Phase 2 clinical trial launch expected in 1H25

Subject to the successful development of a new nitazoxanide formulation, we have revised the expected launch date of a Phase 2 clinical trial to the first half of 2025.

ASK1 Inhibitor SRT-015 in acute liver disease: First-in-Human study planned in 2H24

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

VS-02-HE

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

CLM-022 in liver disease treatment

A preclinical proof-of-concept study is targeted for 2024.

CCA

GNS561 in CCA: First biomarker data targeted for 1H24

The first patient is expected to be screened in the second half of 2023.

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

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

UCD and OA

IND enabling nonclinical studies are targeted to be completed in 2024 for UCD and OA.

NIS2+™ in NASH

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

In the second half of 2023, GENFIT will continue to publish data in scientific publications and at scientific events on NIS2+™.

III. 1H23 Financial highlights

Cash, cash equivalents and other current financial assets

As of June 30, 2023, GENFIT had €111.8 million in cash, cash equivalents and other current financial assets compared with €140.2 million as of December 31, 2022. We expect that our existing cash, cash equivalents and current financial assets will enable us to fund our operating expenses and capital expenditure requirements until approximately the fourth quarter of 2024. This is based on current assumptions and without taking exceptional events into account, as well as potential milestones and royalties that the Company may receive pursuant to the licensing agreement with Ipsen.

In the first half of 2023, these cash flows are mainly 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 our cholangiocarcinoma program; and NTZ, as part of our ACLF program.

Revenues and other income

Revenues and other income amounted to €15.4 million in the first half of 2023 (compared with €12.2 million in the first half of 2022).

Substantially, all revenue is attributable to our Collaboration and License Agreement with Ipsen and related Transition Services Agreement. Revenue growth reflects certain services billed to Ipsen under the Transition Services Agreement, originally entered into in the first half of 2022.

Operating expenses

Operating expenses amounted to €34.7 million in the first half of 2023 (compared with €26.5 million in the first half of 2022).

Substantially, all of the increase in operating expenses is due to research and development expenses, which amounted to €25.6 million in the six months to June 30, 2023, compared with €17.6 million in the six months to June 30, 2022. Specifically, there has been an increase in:

- Contracting costs which amounted to €14.4 million in the first half of 2023 compared with €8.5 million in the first half of 2022, reflecting increased activities across multiple product candidates, including ELATIVE®, VS-01, GNS561 and NTZ,
- Employee expenses which amounted to €6.3 million in the first half of 2023 compared with €4.9 million in the first half of 2022, reflecting increased headcount, and
- Other expenses (maintenance, fees, travel and other taxes) which amounted to €3.3 million in the first half of 2023 compared with €2.4 million in the first half of 2022, reflecting increased activity overall, as previously noted.

Financial results

Financial income in the first half of 2023 was a loss of €1.1 million, compared to a gain of €4.0 million in the first half of 2022.

The change in financial results is mainly due to foreign exchange gains in 2022 which did not repeat in 2023, partially offset by increased interest income in 2023 relative to 2022.

Net loss

The first half of 2023 resulted in a net loss of €20.9 million, compared with a net profit of €10.4 million in the first half of 2022.

The table below presents the condensed Consolidated Statement of Operations under the International Financial Reporting Standards (IFRS) for the first half of 2023, with comparative figures for the first half of 2022. '

PRESS RELEASE

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

Further information is provided in the condensed consolidated financial statements at June 30, 2023 under the IFRS and the management discussion of the results are provided in the appendix of this press release. The condensed consolidated financial statements as well as the statutory auditors' report on those financial statements are included in the 2023 Half Year Business and Financial Report available on the “Investors” page of the GENFIT website.

We encourage investors to take into consideration all the information presented in our 2022 Annual Report on Form 20-F ("Form 20-F") filed with the U.S. Securities Exchange Commission and the 2022 Universal Registration Document filed under D.23-0304 with the French Autorité des Marchés Financiers (AMF) on April 18, 2023 and the 2023 Half-Year Business and Financial Report before deciding to invest in Company shares; these documents are available on GENFIT's website: www.genfit.com and on the website of the AMF (www.amf-france.org). This includes, in particular, the risk factors described in Item 3 of the Form 20-F (and the contents of this section) and section 2 of the 2022 Universal Registration Document, as well as the update provided in section 2.5 of the 2023 Half-Year Business and Financial Report, 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.

PRESS RELEASE

APPENDICES

Half-year Consolidated Financial Results at June 30, 2023

The Condensed Consolidated Statements of Financial Position, Statements of Operations and Statements of Cash Flow of the Group were prepared in accordance with the IFRS.

The limited review procedures on the condensed consolidated financial statements have been performed. The half-year consolidated financial statements for the period ended June 30, 2023 were approved by the Board of Directors on September 19, 2023.

The condensed consolidated financial statements as well as the notes to the consolidated financial statements for the period ended June 30, 2023 and the statutory auditor's report on the consolidated financial statements are included in the Half Year Business and Financial Report at June 30, 2023 available on the "Investors" page of the GENFIT website.

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

Condensed Consolidated Statement of Financial Position

Assets

	As of	
(in € thousands)	**2022/12/31**	**2023/06/30**
Current assets		
Cash and cash equivalents	136,001	111,826
Current trade and others receivables	15,906	20,184
Other current financial assets	4,550	0
Other current assets	1,998	2,578
Inventories	4	4
Total - Current assets	***158,459***	***134,592***
Non-current assets		
Intangible assets	43,957	46,182
Property, plant and equipment	8,210	8,144
Other non-current financial assets	4,914	4,986
Deferred tax assets	0	0
Total - Non-current assets	***57,081***	***59,313***
Total - Assets	**215,540**	**193,905**

PRESS RELEASE

APPENDICES

Shareholders' equity and liabilities

(in € thousands)	As of 2022/12/31	2023/06/30
Current liabilities		
Current convertible loans	415	415
Other current loans and borrowings	4,665	7,333
Current trade and other payables	14,845	21,705
Current deferred income and revenue	14,479	11,244
Current provisions	61	56
Other current tax liabilities	4,906	4,906
Total - Current liabilities	***39,370***	***45,660***
Non-current liabilities		
Non-current convertible loans	49,861	51,009
Other non-current loans and borrowings	20,334	16,665
Non-current trade and other payables	448	0
Non-current deferred income and revenue	9,706	4,746
Non-current employee benefits	782	813
Deferred tax liabilities	510	491
Total - Non-current liabilities	***81,641***	***73,725***
Shareholders' equity		
Share capital	12,459	12,459
Share premium	444,683	444,957
Retained earnings (accumulated deficit)	(337,550)	(360,902)
Currency translation adjustment	(1,344)	(1,139)
Net profit (loss)	(23,719)	(20,854)
Total - Shareholders' equity	***94,528***	***74,520***
Total - Shareholders' equity & liabilities	**215,540**	**193,905**

PRESS RELEASE

APPENDICES

Condensed Consolidated Statement of Operations

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

PRESS RELEASE

APPENDICES

Condensed Statement of Cash Flows

(in € thousands)	Half-year ended 2022/06/30	Half-year ended 2023/06/30
Cash flows from operating activities		
+ Net profit (loss)	(10,399)	(20,854)
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Depreciation and amortization on tangible and intangible assets	944	835
+ Impairment and provision for litigation	(74)	(396)
+ Expenses related to share-based compensation	148	274
- Gain on disposal of property, plant and equipment	1	(52)
+ Net finance expenses (revenue)	1,057	763
+ Income tax expense (benefit)	40	414
+ Other non-cash items	1,095	1,199
Operating cash flows before change in working capital	***(7,188)***	***(17,817)***
Decrease (increase) in trade receivables and other assets	(5,071)	(4,858)
(Decrease) increase in trade payables and other liabilities	(35,241)	(2,398)
Change in working capital	***(40,311)***	***(7,256)***
Income tax paid	0	0
Net cash flows provided by (used in) in operating activities	***(47,499)***	***(25,074)***
Cash flows from investment activities		
- Acquisition of intangible assets	(14)	(2,000)
- Acquisition of property, plant and equipment	265	61
+ Proceeds from disposal of / reimbursement of property, plant and equipment	0	62
- Acquisition of financial instruments	(449)	9
+ Proceeds from disposal of financial instruments	0	4,550
Net cash flows provided by (used in) investment activities	***(199)***	***2,682***
Cash flows from financing activities		
- Repayments of loans and borrowings	(310)	(464)
- Payments on lease debts	(593)	(530)

- Financial interests paid (including finance lease)	(1,057)	(1,106)
+ Financial interests received	17	337
Net cash flows provided by (used in) financing activities	***(1,943)***	***(1,764)***
Increase (decrease) in cash and cash equivalents	**(49,641)**	**(24,155)**
Cash and cash equivalents at the beginning of the period	258,756	136,001
Effects of exchange rate changes on cash	0	(20)
Cash and cash equivalents at the end of the period	**209,115**	**111,826**

PRESS RELEASE

APPENDICES

Discussion of the 2023 half-year results

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

(1) Revenue and other income

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

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

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

Revenues

For the half-year ended June 30, 2023, revenue amounted to €11,482 in 2023 compared with €8,790 for the same period in 2022.

Revenue is primarily composed of:

- The licensing agreement with Ipsen in December 2021 ("Collaboration and License Agreement"):
    - during the first six months of 2023, €8.2 million was attributable to the partial recognition of deferred revenue as noted in note 21 - Deferred income and revenue in the 2023 Half Year Business and Financial Report,
    - during the first six months of 2022, €8.2 million was attributable to the partial recognition of deferred revenue as noted in note 21 - Deferred income and revenue in the 2023 Half Year Business and Financial Report 2023.
- The Transition Services Agreement with Ipsen: in 2022 GENFIT and Ipsen entered into a Service Transition Agreement, which describes the scope of the services provided by GENFIT to Ipsen in order to facilitate the transition of certain activities related to the Phase 3 clinical trial, evaluating elafibranor in PBC.
    - during the first six months of 2023, services provided under this contract generated €3.2 million in revenue
    - during the first six months of 2022, services provided under this contract generated €0.6 million in revenue.

Research Tax Credit

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

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

Other operating income

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

(2) 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.

	Half-year ended 2022/06/30	**Of which :**					
(in € thousands)		**Raw materials and consumables used**	**Contracted research and development activities conducted by third parties**	**Employee expenses**	**Other expenses (maintenance, fees, travel, taxes…)**	**Depreciation, amortization and impairment charges**	**Gain / (loss) on disposal of property, plant and equipment**
Research and development expenses	(17,599)	(1,052)	(8,538)	(4,889)	(2,408)	(712)	0
General and administrative expenses	(8,229)	(133)	(38)	(3,230)	(4,580)	(248)	0
Marketing and market access expenses	(460)	(2)	0	(272)	(182)	(3)	0
Reorganization and restructuring income (expenses)	179	0	0	0	(1)	180	0
Other operating expenses	(423)	0	0	0	(422)	0	(1)
TOTAL	**(26,532)**	**(1,187)**	**(8,576)**	**(8,391)**	**(7,594)**	**(783)**	**(1)**

PRESS RELEASE

APPENDICES

(in € thousands)	Half-year ended 2023/06/30	Of which :					
		Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes…)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development income (expenses)	(25,630)	(1,040)	(14,367)	(6,299)	(3,251)	(705)	33
General and administrative expenses	(9,105)	(162)	(96)	(3,919)	(4,645)	(283)	0
Marketing and market access expenses	(520)	(2)	(1)	(275)	(236)	(6)	0
Reorganization and restructuring income (expenses)	633	0	0	0	0	633	0
Other operating income (expenses)	(52)	0	0	0	(75)	3	20
TOTAL	**(34,673)**	**(1,204)**	**(14,464)**	**(10,492)**	**(8,207)**	**(358)**	**52**

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

Research and development expenses

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

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

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

- Increasing costs related to the ELATIVE® product candidate of €2.8 million,

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

The increase of €1.4 million in employee expenses, consisting of wages, salaries, social security, pension costs and share-based compensation paid to employees in the research and development function, relates primarily to the increase in workforce (from 82 to 96 employees at June 30, 2022 and 2023, respectively). This includes a 7 person increase due to the Versantis acquisition.

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

General and administrative expenses

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

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

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

Marketing and market access expenses

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

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

Marketing and market access expenses remained stable period over period.

Reorganization and restructuring income (expenses)

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

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

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

(3) Financial income (expense)

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

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

For the first six months of 2023, the €1.1 million loss is a result of €2.3 million in interest expense coupled with €0.4 million in foreign exchange losses, partially offset by €1.6 million in accrued and realized interest income.

(4) Net income (loss)

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

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

As of June 30, 2023, cash and cash equivalents and other current financial assets amounted to €111,826.

Over the period, change in cash flow by type of flow was as follows:

	Half-year ended	Half-year ended
(in € thousands)	**2022/06/30**	**2023/06/30**
Cash flows provided by (used in) operating activities	(47,499)	(25,074)
Cash flows provided by (used in) investment activities	(199)	2,682
Cash flows provided by (used in) financing activities	(1,943)	(1,764)
	(49,641)	**(24,155)**

(1) Cash flows provided by (used in) operating activities

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

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

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

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

(2) Cash flows provided by (used in) investing activities

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

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

(3) Cash flows provided by (used in) financing activities

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

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

PRESS RELEASE

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts of a successful Phase 3 trial (ELATIVE®) evaluating elafibranor in Primary Biliary Cholangitis (PBC) and a growing and diversified pipeline of innovative therapeutic and diagnostic solutions. Its R&D pipeline covers six therapeutic areas via eight programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorders (UCD), organic acidemias (OA) and PBC. Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF. GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. For more information, visit www.genfit.com

FORWARD LOOKING STATEMENTS

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

PRESS RELEASE

CONTACT

GENFIT | Investors
Tel : + 33 3 20 16 40 00 | investors@genfit.com

GENFIT | Press relations
Stephanie BOYER | Tel : + 33 3 20 16 40 00 | stephanie.boyer@genfit.com