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: 19 September 2024

Commission File Number: 001-38844



(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

INCORPORATION BY REFERENCE

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be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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

Description

<u>99.1</u> Press Release dated 19 September 2024.

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: 19 September 2024

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT Title: Chief Executive Officer



GENFIT Reports First Half-Year 2024 Financial Results and Provides Corporate Update

- Cash and cash equivalents totaled €61.6 million as of June 30, 2024, excluding the €48.7 million milestone invoiced in June 2024 (received in August 2024) upon first sale of Ipsen's Iqirvo® (elafibranor) in the U.S. for the treatment of Primary Biliary Cholangitis (PBC)
- €59.0 million in revenues, including the €48.7 million milestone invoiced in June 2024
- Positive opinion from the European Medicines Agency Committee in July 2024, with final decision on marketing authorization for Iqirvo anticipated in the second half of 2024, clearing the path to an additional €26.5 million milestone payment expected upon Iqirvo's pricing and reimbursement approval in three European countries

Lille (France), Cambridge (Massachusetts, United States), (Zurich, Switzerland); September 19, 2024 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced its first half-year 2024 financial results and provided a corporate update.

Pascal Prigent, CEO of GENFIT, commented:

"The approval of Iqirvo in the United States was a very significant milestone for the entire GENFIT team. We are proud to have developed elafibranor from its initial discovery through late-stage trials and are thrilled to now see it prescribed to U.S. patients. We believe Iqirvo can potentially address a significant unmet need for people living with PBC. Following the positive CHMP opinion in July 2024, we also anticipate a final decision on authorization in Europe by the end of the year."

Mr. Prigent continued, "We believe the recent approval in the U.S. of Iqirvo demonstrates our robust drug development capabilities and, along with our strong financial position enabled by our partnership with Ipsen, we are well positioned to continue to develop innovative therapies for challenging and underserved liver conditions that are life-threatening."

I. 1H24 Business highlights¹

PBC

Accelerated approval of Ipsen's Iqirvo^{&2} (elafibranor) was granted on June 10, 2024 by the U.S. Food and Drug Administration (U.S. FDA), as a first-inclass 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.

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.

² Iqirvo®, Elative®, NIS2+® and UNVEIL-IT® are registered trademarks of GENFIT SA



Following Ipsen's commercial launch in the U.S. in June 2024, first royalty invoicing began and a €48.7 million milestone payment was made.

On July 25, 2024, Ipsen announced an "encouraging early start for Iqirvo in the U.S." and indicated that "50% of Healthcare Professionals surveyed one week post launch were very likely to prescribe Iqirvo". Ipsen also reported "early positive coverage determinations from commercial and government payer segments"³.

On July 26, 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA) issued a positive opinion for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as a monotherapy in patients unable to tolerate UDCA.

Acute on-Chronic Liver Failure (ACLF) franchise

The UNVEIL-IT^{®2} 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 in June 2024, GENFIT presented blood and peritoneal metabolomics data suggesting that VS-01 actively captures metabolites associated with ACLF. Data indicating that NTZ (nitazoxanide) directly protects from stress-induced cell death to alleviate liver damage in preclinical models of ACLF were also presented.

June 2024 also marked the start of a research collaboration between GENFIT and the European Foundation for the Study of Chronic Liver Failure (EF CLIF), reinforcing our leadership in advancing the understanding of ACLF.

MASH diagnostics

In June 2024, new European Clinical Practice Guidelines on managing metabolic dysfunction-associated steatotic liver disease (MASLD) recognized $NIS2+^{\textcircled{R}2}$ as a key tool for detecting at-risk MASH⁴. This highlights the potential of our technology in identifying those who may benefit from emerging MASH treatments.

Corporate governance updates

 $^{^3}$ www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2024/07/24211739/H1-2024-results-presentation.pdf

⁴ Metabolic dysfunction-associated steatohepatitis



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 become 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 2024, the Board of Directors appointed Ms. Katherine Kalin as member of the ESG Committee.

II. 2H24 and beyond: key milestones and outlook

PBC

Following the positive CHMP recommendation, the European Commission is expected to take a final decision on marketing authorization for Iqirvo in the second half of 2024. After the \in 13.3 million milestone payment received in February 2024 and the \in 48.7 million milestone payment received in August 2024, a \in 26.5 million milestone payment is expected to be received upon Iqirvo's pricing and reimbursement approval in three European countries.

Over the Summer of 2024, Iqirvo's competitive landscape evolved as expected, reinforcing confidence in our revenue projections. We intend to provide royalty revenue forecasts once additional information is received from our commercial partner Ipsen⁵.

ACLF franchise

Previous guidance is reiterated:

- VS-01-ACLF: Phase 2 interim data readout still targeted for 2H24, taking into account the implementation of the new protocol
- NTZ in ACLF: reformulation and Phase 2 under preparation with a proof-of-concept study initiation targeted for 1H25
- SRT-015: First-in-Human study initiation targeted 1Q25
- CLM-022: preclinical Proof of Concept expected to be obtained by end of 2024
- VS-02-HE: completion of Investigational New Drug (IND) enabling studies expected in 2025

Other indications

Previous guidance is reiterated:

• Cholangiocarcinoma (CCA): The GNS561 Phase 1b/2a clinical trial is currently ongoing and preliminary data from Phase 1b is targeted by the end of 2024

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⁵ www.ipsen.com/investors/financial-calendar (www.ipsen.com/event/ytd-2024-sales)

VS-01 Urea Cycle Disorder (UCD) and Organic Acidemia (OA): Following completion of the non-clinical feasibility study, we plan to develop
formulation optimization for specific pediatric implementation and conduct IND enabling nonclinical studies with a target to complete such nonclinical studies in 2024.

MASH Diagnostics

The first-ever approved drug for MASH was approved in early 2024 and we anticipate that this should increase the focus on diagnosis over the coming years and the need for a non-invasive test such as NIS2+.

III. 1H24 Financial highlights

Cash and cash equivalents

As of June 30, 2024, GENFIT had \notin 61.6 million in cash and cash equivalents compared with \notin 77.8 million as of December 31, 2023. Cash and cash equivalents as of June 30, 2024 exclude the \notin 48.7 million milestone invoiced in June 2024 upon first sale of Ipsen's Iqirvo® (elafibranor) in the U.S. for the treatment of PBC, as this balance was received in August 2024.

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 \in 26.5 million.

In the first half of 2024, cash utilization is mainly the result of 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 our cholangiocarcinoma program; NTZ, as part of our ACLF program; and SRT-015, also as part of our ACLF program.

Revenues and other income

Revenues and other income amounted to €61.2 million in the first half of 2024, compared to €15.4 million in the first half of 2023.

Substantially all revenue is attributable to our Collaboration and License Agreement with Ipsen and related Transition Services Agreement. Revenue growth is due to a \in 48.7 million milestone invoiced to Ipsen in June 2024 following the first commercial sale of Iqirvo in the U.S. The milestone was collected in August 2024.

Operating expenses

Operating expenses amounted to €30.0 million in the first half of 2024, compared to €34.7 million in the first half of 2023).



Substantially all of the decrease in operating expenses is due to research and development expenses, which amounted to \in 19.0 million in the first half of 2024 (compared to \in 25.6 million in the first half of 2023).

Specifically, there was a decrease in:

- Contracting costs which amounted to €7.8 million in the first half of 2024 (compared to €14.4 million in the first half of 2023), primarily reflecting decreased activities related to Elative, following the FDA approval in June 2024, and
- Other expenses (maintenance, fees, travel and other taxes) which amounted to €2.8 million in the first half of 2024 (compared to €3.3 million in the first half of 2023), reflecting decreased activity as previously noted.

Financial results

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

Net loss

The first half of 2024 resulted in a net profit of €30.3 million, compared with a net loss of €20.9 million in the first half of 2023.

The table below presents the condensed Consolidated Statement of Operations under the International Financial Reporting Standards (IFRS) for the first half of 2024, with comparative figures for the first half of 2023.





	Half-year ended			
(in ϵ thousands, except earnings per share data)	2023/06/30	2024/06/30		
Revenues and other income				
Revenue	11,482	58,973		
Other income	3,893	2,226		
Revenues and other income	15,374	61,199		
Operating expenses and other operating income (expenses)				
Research and development expenses	(25,630)	(18,984)		
General and administrative expenses	(9,105)	(10,564)		
Marketing and market access expenses	(520)	(390)		
Reorganization and restructuring income (expenses)	633	0		
Other operating expenses	(52)	(39)		
Operating income (loss)	(19,299)	31,222		
Financial income	1,748	1,546		
Financial expenses	(2,890)	(2,419)		
Financial profit (loss)	(1,141)	(873)		
Net profit (loss) before tax	(20,440)	30,349		
Income tax benefit (expense)	(414)	(39)		
Net profit (loss)	(20,854)	30,311		
Basic and diluted earnings (loss) per share				
Basic earnings (loss) per share (€/share)	(0.42)	0.61		
Diluted earnings (loss) per share (€/share)	(0.42)	0.53		

Further information is provided in the condensed consolidated financial statements at June 30, 2024 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 2024 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 2023 Annual Report on Form 20-F ("Form 20-F") filed with the U.S. Securities Exchange Commission and the 2023 Universal Registration Document filed under D.24-0246 with the *French Autorité des Marchés Financiers* (AMF) on April 5, 2024 and the 2024 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 2023 Universal Registration Document, as well as the update provided in section 2.5 of the 2024 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.

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Half-year Consolidated Financial Results at June 30, 2024

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, 2024 were approved by the Board of Directors on September 18, 2024.

The condensed consolidated financial statements as well as the notes to the consolidated financial statements for the period ended June 30, 2024 and the statutory auditor's report on the consolidated financial statements are included in the Half Year Business and Financial Report at June 30, 2024 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 ϵ thousands)	2023/12/31	2024/06/30		
Current assets				
Cash and cash equivalents	77,789	61,645		
Current trade and others receivables	32,707	71,044		
Other current assets	2,615	3,690		
Inventories	4	4		
Total - Current assets	113,115	136,384		
Non-current assets				
Intangible assets	48,761	46,946		
Property, plant and equipment	7,872	8,059		
Other non-current financial assets	4,125	3,388		
Deferred tax assets	0	0		
Total - Non-current assets	60,758	58,393		
Total - Assets	173,872	194,777		

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Shareholders' equity and liabilities

	As of	As of		
(in ϵ thousands)	2023/12/31	2024/06/30		
Current liabilities				
Current convertible loans	415	413		
Other current loans and borrowings	7,510	7,605		
Current trade and other payables	18,799	22,159		
Current deferred income and revenue	11,692	6,095		
Current provisions	40	40		
Other current tax liabilities	23	118		
Total - Current liabilities	38,480	36,430		
Non-current liabilities				
Non-current convertible loans	52,206	53,233		
Other non-current loans and borrowings	10,047	6,553		
Non-current deferred income and revenue	3,755	0		
Non-current employee benefits	978	1,026		
Deferred tax liabilities	455	171		
Total - Non-current liabilities	67,441	60,983		
Shareholders' equity				
Share capital	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		

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Condensed Consolidated Statement of Operations

	Half-year ended		
(in \mathcal{E} thousands, except earnings per share data)	2023/06/30	2024/06/30	
Revenues and other income			
Revenue	11,482	58,973	
Other income	3,893	2,226	
Revenues and other income	15,374	61,199	
Operating expenses and other operating income (expenses)			
Research and development expenses	(25,630)	(18,984)	
General and administrative expenses	(9,105)	(10,564)	
Marketing and market access expenses	(520)	(390)	
Reorganization and restructuring income (expenses)	633	0	
Other operating expenses	(52)	(39)	
Operating income (loss)	(19,299)	31,222	
Financial income	1,748	1,546	
Financial expenses	(2,890)	(2,419)	
Financial profit (loss)	(1,141)	(873)	
Net profit (loss) before tax	(20,440)	30,349	
Income tax benefit (expense)	(414)	(39)	
Net profit (loss)	(20,854)	30,311	
Basic and diluted earnings (loss) per share			
Basic earnings (loss) per share (€/share)	(0.42)	0.61	
Diluted earnings (loss) per share (€/share)	(0.42)	0.53	

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Condensed Statement of Cash Flows

(in ϵ thousands)	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	(396)	105
 + Expenses related to share-based compensation - Loss (gain) on disposal of property, plant and equipment 	274 (52)	334 (62)
+ Net finance expenses (revenue)	763	542
+ Income tax expenses (benefit)	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	(4,858)	(39,413)
(Decrease) increase in trade payables and other liabilities	(2,398)	(5,572)
Change in working capital	(7,256)	(44,984)
Income tax paid	0	(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)	0	0
- Acquisition of other intangible assets	(2,000)	0
- Acquisition of property, plant and equipment	61	(737)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	62	78
- Acquisition of financial instruments	9	(28)
+Proceeds from disposal of financial instruments	4,500	0
Net cash flows provided by (used in) investment activities	2,682	(687)
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	0	0
+ Proceeds from new loans and borrowings net of issue costs	0	0
- Repayments of loans and borrowings	(464)	(3,143)
- Payments on lease debts	(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	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



Discussion of the 2024 half-year results

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

(1) Revenue and other income

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

(in \mathcal{E} 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 \notin 61,199, compared with \notin 15,374 for the same period in 2023.

Revenues

For the half-year ended June 30, 2024, revenue amounted to €58,973 compared with €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 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.
 - 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.

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- 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.

Research Tax Credit (CIR)

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

The CIR receivable amounted to \notin 7,738 as of June 30, 2024, which comprises balances from 2023 onward (compared to \notin 12,200 for the same period in 2023). Previously withheld balances from 2021 and 2022 have since been reimbursed on May 28, 2024 in the amount of \notin 6,570 which includes legally required related interest of \notin 177.

We were 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 CIR claimed for these periods), which started on December 10, 2021 and is still ongoing at the date of this document.

Other operating income

During the first six months of 2024, the Group recognized $\notin 97$ in "Other operating income" ($\notin 263$ for the same period in 2023), 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, and marketing and market access expenses.



	Half-year ended			Of w	which :		
(in € thousands)	2023/06/30	Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development		(1.0.10)		(6.000)	(2.2.51)		
income (expenses) General and administrative	(25,630)	(1,040)	(14,367)	(6,299)	(3,251)	(705)	33
expenses	(9,105)	(162)	(96)	(3,919)	(4,645)	(283)	0
Marketing and market access	(),100)	(102)	(>0)	(0,,,,,)	(1,010)	(200)	Ū
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

	Half-year ended		Of which :				
(in € thousands)	2024/06/30	Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development							
expenses	(18,984)	(1,056)	(7,838)	(6,610)	(2,806)	(675)	0
General and administrative							
expenses	(10,564)	(152)	(69)	(4,380)	(5,778)	(185)	0
Marketing and market access							
expenses	(390)	(2)	0	(295)	(89)	(3)	0
Reorganization and restructuring							
expenses	0	0	0	0	0	0	0
Other operating income							
(expenses)	(39)	0	0	0	(102)	0	62
TOTAL	(29,977)	(1,210)	(7,907)	(11,284)	(8,774)	(863)	62

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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 $\in 25.6$ million. These expenses were comprised of $\in 14.4$ million in contracted research and development conducted by third parties, $\in 6.3$ million in employee expenses, $\in 3.3$ million in other expenses, $\in 0.7$ million in depreciation, amortization and impairment charges and $\in 1.0$ million in raw materials and consumables.

For the first six months of 2024, research and development expenses totaled \notin 19.0 million. These expenses were comprised of \notin 7.8 million in contracted research and development conducted by third parties, \notin 6.6 million in employee expenses, \notin 2.8 million in other expenses, \notin 0.7 million in depreciation, amortization and impairment charges and \notin 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) 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 $\notin 0.5$ million in other expenses is mainly due to decreasing costs related to maintenance costs of $\notin 0.3$ million and decreasing costs related to consultants of $\notin 0.2$ million.

General and administrative expenses

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

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

The increase of $\notin 0.5$ 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 $\notin 1.2$ million in other expenses in the general and administrative function was mainly due to increases in i) maintenance costs of $\notin 0.7$ million, ii) consulting costs of $\notin 0.2$ million, iii) donations of $\notin 0.2$ million, et iv) recruiting fees of $\notin 0.1$ million.

Marketing and market access expenses

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

For the first six months of 2024, marketing and market access expenses totaled $\notin 0.4$ million. These expenses were mainly comprised of $\notin 0.3$ million in employee expenses and $\notin 0.1$ 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.

(3) Financial income (expense)

For the half-year ended June 30, 2024, financial income amounted to a 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 $\notin 2.3$ million, realized and unrealized foreign exchange loss of $\notin 0.6$ million, and $\notin 1.7$ million in accrued and realized interest income.

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

(4) 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.

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.

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

	Half-year en	ded
$(in \in thousands)$	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)
	(24,155)	(16,100)

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

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

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In the first half of 2023, this amount mainly stems from our net loss of \in 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 $\in 13.3$ million from IPSEN in 2024 (incurred and recorded in 2023, upon the acceptance of the new drug application 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.

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

Cash flow used in investing activities amounted to \notin -687 thousand in the first half of 2024, compared with \notin 2,682 thousand in cash flow provided in the first half of 2023.

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 €-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.



ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. 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 with the success of the 52-week Phase 3 Elative study evaluating elafibranor in Primary Biliary Cholangitis (PBC). Elafibranor, a 'first-in-class' molecule developed by GENFIT from initial discovery to the conclusion of a 52-week Phase 3 study, is now marketed and commercialized in the United States by Ipsen under the trademark Iqirvo® since June 2024.

Beyond therapies, GENFIT also has a diagnostic franchise, including $NIS2+^{\mbox{\scriptsize B}}$ 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. 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 Igirvo[®]/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 for VS-01 in ACLF and GNS561 in CCA, expected timing for potential regulatory approvals and the impact of the development of our programs, 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 others, 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, and 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 on April 5, 2024 (no. D.24-0246) with the *Autorité des marchés financiers* ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in the public documents 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 the Half-Year Business and Financial Report at June 30, 2024 or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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 forwardlooking 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.



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