

**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 29, 2021**

**Commission File Number: 001-38844**

**GENFIT S.A.**

**(Translation of registrant's name into English)**

**Parc Eurasanté  
885, avenue Eugène Avinée 59120 Loos, France  
(Address of principal executive office)**

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

Form 20-F       Form 40-F

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

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

---

EXHIBIT LIST

**Exhibit**

[99.1](#)

**Description**

[Press Release dated September 29, 2021](#)

---

## 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 29, 2021

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



## GENFIT Reports First Half-Year 2021 Financial Results and Provides Corporate Update

- **Financial highlights**
  - o Cash and cash equivalents totaled €104 million as of June 30, 2021 (including €11 million non-dilutive financing obtained in the first half 2021)
  - o Net income totaled €9 million for the first half 2021, due to a one-off revenue following the successful outcome of the convertible debt restructuring in January and the OCEANEs conversions in the first quarter
- **Positive developments with elafibranor in PBC (ELATIVETM Phase 3)**
  - o Foresee completion of enrolment in first quarter 2022
  - o Timeline for potential FDA filing now estimated in second half 2023, based on a successful Phase 3 trial outcome
- **New clinical data expected in several indications, starting as early as the third quarter 2022**
  - o NTZ in ACLF (Phase 1)
  - o Elafibranor in PSC (Phase 2 PoC)
  - o Elafibranor in PBC (exploratory and complementary study to ELATIVE™ in treatment-naïve patients)

**Lille, France; Cambridge, MA; September 29, 2021** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, today announced its first half-year financial results and provided a corporate update.

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) today. The condensed consolidated financial statements are included in this press release and the complete financial statements are available on the “Investors” page of the GENFIT website.

**Conference Call in English on September 29, 2021 at 4:15pm EDT | 9:15 BST | 10:15pm CEST, and in French on September 30, 2021 at 7:30am CEST | 1:30am EDT**



---

## PRESS RELEASE

Both the English and French conference calls will be accessible on the investor page of our website, under the events section at <https://ir.genfit.com/> or by phone five minutes prior to the start time:

- English session dial-in information:

- o United States/Canada Tollfree: 800-289-0438 | United Kingdom Tollfree: 0800 358 6377 | France Tollfree: 0805 101 219
- o Confirmation Code: 6014676

- French session dial-in information:

- o United States/Canada Tollfree: 866-548-4713 | United Kingdom Tollfree: 0800 358 6377 | France Tollfree: 0805 101 219
- o Confirmation Code: 3525672 A replay will be available shortly after the call.

**Pascal Prigent, CEO of GENFIT**, commented: *“We are pleased with the progress made in the first half of 2021. Our lead program, the development of elafibranor in PBC, is on track, with the pace of patient enrolment for our Phase 3 ELATIVETM clinical trial broadly in line with our expectations. Our updated R&D strategy, announced in May 2021, has allowed us to concentrate our efforts on new growth drivers in therapeutic areas with significant unmet medical needs and, as a result, we will start generating new clinical data as early as September next year. Financially, we are pleased with the successful outcome of the convertible debt restructuring. It has given us, in addition to the €11 million State Guaranteed Loan, more visibility and flexibility. Lastly, on the diagnostics side, the first qualitative feedback obtained from our partner Labcorp confirms the interest for NASHnextTM, although the conditions for commercial success have not yet been met.”*

### I. Key aspects of business activity

#### o *Elafibranor development program in PBC*

Patient enrolment for the Phase 3 ELATIVETM clinical trial progressed well throughout the first half of 2021 and we expect to complete enrolment in the first quarter of 2022. We anticipate being able to announce ELATIVETM topline data between the end of the first quarter and the middle of the second quarter 2023. We now expect to file our new drug application (NDA) with the Food and Drug Administration (FDA) during the second half 2023, subject to a successful trial outcome. Based on these projections, we are targeting a potential approval of elafibranor in PBC in the US in the second half 2024.

In February 2021, the Company announced the publication, in the *Journal of Hepatology*, of the positive results of the Phase 2 clinical trial evaluating elafibranor in patients with PBC and an incomplete response to ursodeoxycholic acid (UDCA). These results show a clinically significant improvement on the primary and composite biochemical evaluation criteria and a positive trend on the improvement of pruritus, while preserving a favorable tolerability profile.



## PRESS RELEASE

During a KOL analyst event organized the same month, the Company provided details of the results of three market studies undertaken by IQVIA<sup>1</sup> evaluating the commercial opportunity presented by elafibranor if approved as a second-line treatment in PBC. The presentation and the related references are available on the Company's website. These studies support that elafibranor is expected to gain a significant market share in the PBC market, the size of which is expected to reach about \$1billion a year at the time of elafibranor's commercial launch.<sup>2</sup>

### *o Re-focusing our R&D efforts on programs with high potential*

In May, the Company announced the new strategic direction for its research and development (R&D) programs, with a pipeline now focused on two therapeutic areas with serious health implications: cholestatic diseases and Acute on Chronic Liver Failure. The rationale behind this approach is to maximize our chances of success in the therapeutic areas that represent high costs for the healthcare system and in which there are significant unmet medical needs for patients. More details on this new strategic positioning are available on the "News" section of the Company's "Investors & Media" website page.

Clinical data is expected as early as the third quarter of 2022 in the two franchises : for NTZ in ACLF (Phase 1), for elafibranor in PSC (Phase 2 PoC) and for elafibranor in PBC (exploratory and complementary study to ELATIVE™ in treatment-naïve patients).

### *o Diagnostic program in NASH*

In May, the Company announced the launch of the non-invasive diagnostic test NASHnext™, based on GENFIT's NIS4® technology, by our partner Labcorp. NASHnext™ is now commercially available in the US and Canada and its purpose is to diagnose at-risk NASH in patients presenting with at least one metabolic risk factor. The initial feedback from Labcorp confirms interest in this test and its market, however, significant commercial success is going to be dependent upon availability of approved therapeutic options as well as re-imburement for NASHnext™, which is not expected in the immediate future.

<sup>1</sup> IQVIA is a well-known leader in research and consulting services in the pharmaceutical industry

<sup>2</sup> IQVIA Commercial Opportunity Presentation, 2020 – Research on File, November 2019



---

## PRESS RELEASE

We continue to see strong interest in the research area and the use of NIS4® in clinical trials continues to grow. We are also committed to continue to grow the body of evidence supporting the use of NIS4®. In June, the Company presented new data on NIS4® at the International Liver Congress™ 2021, organized by the European Association for the Study of the Liver (EASL) and at the 81st Scientific Sessions of the American Diabetes Association (ADA). These data show the clinical performance of NIS4® for diagnosing at-risk NASH in patients with type 2 diabetes compared to other non-invasive tests. They highlight the potential of NIS4® technology to be a valuable clinical tool, either alone or in sequential combination with other blood-based non-invasive tests, in identifying at-risk NASH in patients with and without type 2 diabetes.

### *o Governance*

At the Company's annual shareholders meeting in June, where the new strategic directions and perspectives for the Company were presented, shareholders adopted, by a large majority of the votes cast, all the resolutions recommended by the Board of Directors, including the financial authorizations to allow the Company to access financing solutions that are adapted to future market conditions, and to seize new opportunities.

Several additions were also made in the first half of 2021 to our Board of Directors and Executive Committee. In March, the Board of Directors appointed Mr. Jean-François Tiné to replace Mr. Philippe Moons, and two new members were added to the Executive Committee: Thomas Baetz, Chief Finance Officer and Stefanie Magner, Chief Compliance Officer and VP International Legal Affairs.

## **II. Key financial events of the first half-year 2021**

### *o Partial buyback operation and amendment of the terms of the OCEANES*

In January, the Company announced the success of the partial buyback offer and amendment of the terms of 6,081,081 bonds convertible or exchangeable into new or existing shares (OCEANES) due in October 2022, and issued in the context of the convertible loan of €180 million in October 2017. The renegotiation of the bond debt – approved by more than 98% of shareholders that took part in the vote – has enabled the Company to defer its final maturity date to October 16, 2025 and reduce its nominal amount by half. The conversion ratio went from 1 OCEANE for 1 share to 1 OCEANE for 5.5 shares.



***o Reduction of the residual bond debt amount thanks to the conversion of OCEANEs into shares***

Following the implementation of the partial buyback operation and the approval of the amendment of the terms of the OCEANEs, the Company received OCEANE conversion notifications as follows: 552,238 of the new OCEANEs were converted in January 2021; 483, 330 of the new OCEANEs were converted in February 2021 and 216, 591 of the new OCEANEs were converted at the end of March 2021. As a result, at June 30, 2021, the Company's share capital was €11, 443, 812.50, represented by 45,775,250 shares. In August 2021, after the half-year period, 10,000 OCEANEs were converted, and the Company therefore recognized a capital increase of €13,750, corresponding to the issuance of 55,000 new shares.

At the date of the current half-year report, the par value of residual bond debt is approximately €56.9 million, i.e. less than a third of the initial nominal debt amount of €180 million.

***o New non-dilutive financing for shareholders***

In June, the Company announced the signing of a loan agreement for €11 million. The loan, granted in the context of the COVID-19 pandemic by a syndicate of 4 French banks (BNP Paribas, Natixis, CIC Nord Ouest et Crédit du Nord), is 90% guaranteed by the French government. In July, after the first half-year period, the Company obtained an additional loan of €2 million from BPI France, also 90% guaranteed by the French government. These two loans have an initial term of one year with repayment options up to six years.

**III. Key aspects of the first half 2021 financial results**

***o Cash and cash equivalents***

As of June 30, 2021, GENFIT had €104.4 million in cash and cash equivalents (€171 million as of December 31, 2020) which essentially came from using €47.5 million for the partial buyback of the OCEANEs in January 2021 and the State-guaranteed loan amounting to €11 million in June 2021.

***o Operating income***

Operating income amounted to €3.4 million in the first half 2021 (compared with €5.9 million in the first half 2020), which essentially came from the Research Tax Credit of €3.2 million (€5.2 million for the first half 2020).

***o Operating expenses***

Operating expenses amounted to €33 million in the first half 2021 (compared with €55 million in the first half 2020), of which 70% represented R&D expenses.





The decrease in operating expenses is due to:

- The decrease in R&D expenses which amounted to €23.1 million in the first half 2021 compared with €36.9 million in the first half 2020, mainly due to the termination of the RESOLVE-IT trial from July 2020;
- The decrease in marketing and pre-commercialization expenses, which amounted to €0.8 million in the first half 2021 (as opposed to €9.5 million in the first half 2020), is mainly due to the discontinuation of the pre-commercialization work for elafibranor in NASH;
- The decrease in general and administrative expenses, which amounted to €7.6 million in the first half 2021 (compared with €8.3 million in the first half 2020) was due to the execution of a cost-saving plan over 3 years, announced in September 2020. Savings on administrative expenses (-9.6%) were realized despite restructuration and reorganization expenses of €1.8 million in the first half 2021 (including a €0.2 million reversal of a provision and €1.9 million in fees related to the renegotiation of the OCEANEs in January 2021).

**o Financial results**

In the first half 2021, GENFIT registered a one-off financial income of €35.6 million corresponding to a repurchase bonus following the renegotiation of the OCEANEs in January 2021. The financial result, including the one-off financial income and foreign exchange gains and losses amounted to €35.7 million in the first half 2021 (compared with €4 million in the first half 2020).

**o Net gains (net losses)**

Taking into account the cash and cash equivalents, operating income and one-off financial income, GENFIT generated a half-year net gain of €9.1 million at June 30, 2021 (compared with a net loss of €53.0 million at June 30, 2020). The net loss in 2020 amounted to €101.2 million.

The table below presents the condensed Consolidated Statement of Operations under IFRS for the first half 2021, with comparative figures for the first half 2020.

## PRESS RELEASE

(in € thousands, except earnings per share data)

	For the six-month period ended	
	June 30, 2020	June 30, 2021
<b>Revenues and other income</b>		
Revenue	122	11
Other income	5 745	3 417
<b>Revenues and other income</b>	<b>5 867</b>	<b>3 428</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research and development expenses	(36 867)	(23 079)
General and administrative expenses	(8 251)	(7 632)
Marketing and market access expenses	(9 490)	(783)
Reorganization and restructuring expenses	—	(1 786)
Other operating income (expenses)	(423)	301
<b>Operating income (loss)</b>	<b>(49 163)</b>	<b>(29 551)</b>
Financial income <sup>(1)</sup>	2 095	40 822
Financial expenses	(6 102)	(5 107)
<b>Financial profit (loss)</b>	<b>(4 007)</b>	<b>35 714</b>
<b>Net profit (loss) before tax</b>	<b>(53 170)</b>	<b>6 163</b>
Income tax benefit (expense)	159	2 895
<b>Net profit (loss)</b>	<b>(53 011)</b>	<b>9 058</b>
Attributable to owners of the Company	(53 011)	9 058
Attributable to non-controlling interests	—	—
<b>Basic and diluted earnings (loss) per share</b>		
Basic earnings (loss) per share (€/share)	(1,36)	0,21
Diluted earnings (loss) per share (€/share)	(1,36)	0,19
(1): Of which Financial income incurred by renegotiating the convertible bond debt OCEANE	—	35 578

Further information is provided in the above “Key aspects of business activity” and “Key financial events of the first half 2021” sections of this press release and in the condensed consolidated financial statements at June 30, 2021 under IFRS as well as the management discussion of the results are provided in the appendix at the end of this press release. The condensed consolidated financial statements as well as the statutory auditors' report on those financial statements are included in the 2021 Half Year Business and Financial Report and available on the “Investors” page of the GENFIT website.

We encourage investors to take into consideration all the information presented in our 2020 Annual Report on Form 20-F (“Form 20-F”) filed with the U.S. Securities Exchange Commission and the 2020 Universal Registration Document filed under n°D.20-0503 with the French Autorité des Marchés Financiers (AMF) on April 23, 2021 and in this Half-Year Business and Financial Report before deciding to invest in Company shares; these documents are available on GENFIT’s website: [www.genfit.com](http://www.genfit.com) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)). This includes, in particular, the risk factors described in Item 2 of the Form 20-F (and the contents of this section) and section 2 of the 2020 Universal Registration Document, as well as the update provided in section 8 of the 2021 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, 2021

The Condensed Consolidated Statements of Financial Position, Statements of Operations and Statements of Cash Flow of the Group were prepared in accordance with International Financial Reporting Standards (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, 2021 were approved by Board of Directors on September 29, 2021.

The condensed consolidated financial statements as well as the notes to the consolidated financial statements for the period ended June 30, 2021 and the statutory auditor's report on the consolidated financial statements are included in appendices of the Half Year Business and Financial Report at June 30, 2021 and available on the "Investors" page of the GENFIT website.

#### Condensed Consolidated Statement of Financial Position

ASSETS (in € thousands)	As of	
	December 31, 2020	June 30, 2021
<b>Current assets</b>		
Cash and cash equivalents	171 029	104 379
Current trade and others receivables	11 919	13 842
Other current assets	1 765	3 058
Inventories	4	4
<b>Total - Current assets</b>	<b>184 717</b>	<b>121 283</b>
<b>Non-current assets</b>		
Intangible assets	791	704
Property, plant and equipment	11 648	10 328
Other non-current financial assets	1 458	1 398
Deferred tax assets	—	—
<b>Total - Non-current assets</b>	<b>13 897</b>	<b>12 429</b>
<b>Total - Assets</b>	<b>198 614</b>	<b>133 712</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
(in € thousands)	As of	
	December 31, 2020	June 30, 2021
<b>Current liabilities</b>		
Current convertible loans	1 312	417
Other current loans and borrowings	3 035	2 457
Current trade and other payables	25 564	27 231
Current deferred income and revenue	124	122
Current provisions	1 031	736
<b>Total - Current liabilities</b>	<b>31 067</b>	<b>30 964</b>
<b>Non-current liabilities</b>		
Non-current convertible loans	169 470	46 913
Other non-current loans and borrowings	11 873	21 144
Non-current trade and other payables	450	447
Non-current employee benefits	1 148	1 071
Deferred tax liabilities	767	608
<b>Total - Non-current liabilities</b>	<b>183 709</b>	<b>70 183</b>
<b>Shareholders' equity</b>		
Share capital	9 722	11 444
Share premium	379 057	416 965
Retained earnings (accumulated deficit)	(303 629)	(404 849)
Currency translation adjustment	(92)	(52)
Net profit (loss)	(101 221)	9 058
<b>Total shareholders' equity - Group share</b>	<b>(16 162)</b>	<b>32 566</b>
Non-controlling interests	—	—

Total - Shareholders' equity	(16 162)	32 566
<b>Total - Shareholders' equity &amp; liabilities</b>	<b>198 614</b>	<b>133 712</b>

## PRESS RELEASE

### Condensed Consolidated Statement of Operations

(in € thousands, except earnings per share data)	For the six-month period ended	
	June 30, 2020	June 30, 2021
<b>Revenues and other income</b>		
Revenue	122	11
Other income	5 745	3 417
<b>Revenues and other income</b>	<b>5 867</b>	<b>3 428</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research and development expenses	(36 867)	(23 079)
General and administrative expenses	(8 251)	(7 632)
Marketing and market access expenses	(9 490)	(783)
Reorganization and restructuring expenses	—	(1 786)
Other operating income (expenses)	(423)	301
<b>Operating income (loss)</b>	<b>(49 163)</b>	<b>(29 551)</b>
Financial income <sup>(1)</sup>	2 095	40 822
Financial expenses	(6 102)	(5 107)
<b>Financial profit (loss)</b>	<b>(4 007)</b>	<b>35 714</b>
<b>Net profit (loss) before tax</b>	<b>(53 170)</b>	<b>6 163</b>
Income tax benefit (expense)	159	2 895
<b>Net profit (loss)</b>	<b>(53 011)</b>	<b>9 058</b>
Attributable to owners of the Company	(53 011)	9 058
Attributable to non-controlling interests	—	—
<b>Basic and diluted earnings (loss) per share</b>		
Basic earnings (loss) per share (€/share)	(1,36)	0,21
Diluted earnings (loss) per share (€/share)	(1,36)	0,19
(1): Of which Financial income incurred by renegotiating the convertible bond debt OCEANE	—	35 578

## PRESS RELEASE

### Condensed Statement of Cash Flows

(in € thousands)	For the six-month period ended June 30, 2020	For the year ended December 31, 2020	For the six-month period ended June 30, 2021
<b>Cash flows from operating activities</b>			
+ Net profit (loss)	(53 011)	(101 221)	9 058
+ Non-controlling interests	—	—	—
<b>Reconciliation of net loss to net cash used in operating activities</b>			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets	1 737	3 559	1 511
+ Impairment and provision for litigation	124	3 015	(1 424)
+ Expenses related to share-based compensation	513	1 236	217
- Gain on disposal of property, plant and equipment	(2)	80	330
+ Net finance expenses (revenue)	5 848	10 335	2 590
+ Income tax expense (benefit)	(159)	(428)	(2 895)
+ Other non-cash items including Research Tax Credit litigation	92	(1 818)	(35 506)
	(44)	(85)	(26)
Operating cash flows before change in working capital	859)	242)	118)
<b>Change in:</b>			
Decrease (increase) in trade receivables and other assets	1 523	318	(3 216)
(Decrease) increase in trade payables and other liabilities	(2 026)	(11 447)	1 518
Change in working capital	(504)	(11 129)	(1 698)
Income tax paid	—	—	6
<b>Net cash flows used in operating activities</b>	<b>(45 362)</b>	<b>(96 371)</b>	<b>(27 810)</b>
<b>Cash flows from investment activities</b>			
- Acquisition of property, plant and equipment	(785)	(900)	(21)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	—	—	224
- Acquisition of financial instruments	(49)	(66)	12
<b>Net cash flows provided by (used in ) investment activities</b>	<b>(834)</b>	<b>(966)</b>	<b>215</b>
<b>Cash flows from financing activities</b>			
+ Proceeds from issue of share capital (net)	—	7	—
+ Proceeds from subscription / exercise of share warrants	—	—	—
+ Proceeds from new loans and borrowings net of issue costs	—	—	10 905
- Repayments of loans and borrowings	—	207	(48 028)
- Payments on lease debts	(1 601)	(2 150)	(1 009)
- Financial interests paid (including finance lease)	(3 230)	(7 762)	(1 058)
+ Financial interests received	—	1 442	224
<b>Net cash flows provided by (used in ) financing activities</b>	<b>(4 831)</b>	<b>(8 256)</b>	<b>(38 966)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(51 027)</b>	<b>(105 593)</b>	<b>(66 561)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>276 748</b>	<b>276 748</b>	<b>171 029</b>
Effects of exchange rate changes on cash	—	(126)	(88)
<b>Cash and cash equivalents at the end of the period</b>	<b>225 721</b>	<b>171 029</b>	<b>104 379</b>



**Discussion of the 2021 half-year results**

**Comments on the condensed statement of net income for the periods ended June 30, 2020 and June 30, 2021**

**(i) Revenue and other income**

The Company's revenue and other income results primarily from the research tax credit.

Revenue and other income (in € thousands)	For the six-month period ended	
	June 30, 2020	June 30, 2021
Revenues	122	11
Government grants and subsidies	3	(0)
	5	3
CIR tax credit	224	244
Other operating income	519	174
	5	3
<b>TOTAL</b>	<b>867</b>	<b>428</b>

Revenue and other income was €3,428 thousand at June 30, 2021 compared with € 5,867 thousand at June 30, 2020. The change in revenue results mainly from a decrease from one half-year to another of the estimated amount of the research tax credit, proportional to the amount of eligible R&D expenses.

## PRESS RELEASE

### (ii) Operating expenses by destination

The tables below break down operating expenses by destination mainly into research and development expenses, general and administrative expense, markets and market access expenses and reorganization and restructuring expenses for the half years ended June 30, 2021 and 2020.

Operating expenses and other operating income (expenses) (in € thousands)	For the six-month period ended June 30, 2020	Of which:					
		Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes...)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(36 867)	(1 197)	(24 337)	(6 591)	(3 287)	(1 455)	—
General and administrative expenses	(8 251)	(133)	(41)	(3 845)	(3 963)	(269)	—
Marketing and market access expenses	(9 490)	(4)	(1)	(744)	(8 697)	(44)	—
Reorganization and restructuring expenses	—	—	—	—	—	—	—
Other operating income and (expenses)	(423)	—	—	—	(425)	—	2
<b>TOTAL</b>	<b>(55 031)</b>	<b>(1 333)</b>	<b>(24 379)</b>	<b>(11 180)</b>	<b>(16 372)</b>	<b>(1 769)</b>	<b>2</b>

Operating expenses and other operating income (expenses) (in € thousands)	For the six-month period ended June 30, 2021	Of which:					
		Raw materials and consumables used	Contracted research and development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes...)	Depreciation, amortization and impairment charges	Gain / (loss) on disposal of property, plant and equipment
Research and development expenses	(23 079)	(642)	(15 029)	(4 842)	(2 334)	(225)	(6)
General and administrative expenses	(7 632)	(73)	(48)	(3 336)	(4 123)	(51)	—
Marketing and market access expenses	(783)	(2)	(1)	(465)	(316)	0	—
Reorganization and restructuring expenses	(1 786)	(3)	—	—	(1 942)	158	—
Other operating income (expenses)	301	—	—	—	637	—	(336)
<b>TOTAL</b>	<b>(32 979)</b>	<b>(721)</b>	<b>(15 078)</b>	<b>(8 643)</b>	<b>(8 078)</b>	<b>(117)</b>	<b>(343)</b>

Operating expenses in the first half 2021 amounted to €32,979 thousand compared to €55,031 in first half 2020.

They include, in particular:

- **research and development expenses**, which mainly include employee-related expenses for employees in research and development functions (€4,842 thousand at June 30, 2021 compared to €6,591 thousand at June 30, 2020), the cost of consumables





---

## PRESS RELEASE

and contracted research and development activities (particularly clinical and pharmaceutical expenses) (representing €15,671 thousand at June 30, 2021 compared to €25,534 thousand at June 30, 2020) and expenses related to intellectual property. These research and development expenses amounted to €23,079 thousand at June 30, 2021 compared to €36,867 thousand at June 30, 2020, or 70% and 67% of operating expenses, respectively.

The decrease in contracted research and development expenses is mainly due to the termination of RESOLVE-IT study from July 2020; the study was still active in the first half of 2020.

Changes in employee-related expenses for employees in research and development functions reflects a decrease in headcount (from 128 at June 30, 2020 to 74 at June 30, 2021).

**general and administrative expenses**, which include the costs of personnel not assigned to research (€3,336 thousand at June 30, 2021 compared to €3,845 thousand at June 30, 2020), and administrative costs. These general and administrative expenses amounted to €7,632 thousand in the first half 2021 compared to €8,251 thousand in the first half 2020, or 23% and 15% of operating expenses, respectively.

Changes in general and administrative expenses are mainly related to the increased cost of insurance premiums in the first half 2021 related to the Company's listing on the Nasdaq.

Changes in employee-related expenses paid to employees in general and administrative functions was primarily the result of a decrease in headcount (from 68 at June 30, 2020 to 44 at June 30, 2021).

**marketing and pre-marketing expenses**, which include the costs of personnel assigned to marketing and business development (€465 thousand in the first half 2021 compared to €744 thousand in the first half 2020), and costs related to the preparation of the commercialization of elafibrator and NIS4® in NASH (market research, marketing strategy, medical communication, market access...) (€316 thousand in the first half 2021 compared to €8,697 thousand in the first half 2020).

Marketing and pre-commercialization expenses decreased significantly starting in the second half 2020 due to the discontinuation of the pre-commercialization work for elafibrator in NASH following the termination of this program in July 2020.

## PRESS RELEASE

**reorganization and restructuring expenses**, which mainly include the expenses for the renegotiation of the OCEANES convertible bonds (representing an expense of €1,939 thousand in the first half 2021) and adjustments to provisions for employee expenses under the Workforce Reduction Plan begun in 2020 and the termination of the RESOLVE-IT study (reversal of provisions of €158 thousand in the first half 2021). By comparison, these expenses did not exist in the first half 2020.

### (iii) Operating expenses by type

Broken down by type instead of by destination, operating expenses mainly included the following:

#### Contracted research and development activities

Contracted research and development expenses amounted to €15,078 thousand in the first half 2021 compared to €24,379 thousand in the first half 2020, corresponding to a 38% decrease, which is mainly due to the termination of the RESOLVE-IT study.

#### Employee expenses

Employee expenses (in € thousands)	For the six-month period ended	
	June 30, 2020	June 30, 2021
Wages and salaries	(7)	(5)
	811)	734)
Social security costs	(2)	(2)
Changes in pension provision	769)	729)
Share-based compensation	(87)	37
	(513)	(217)
<b>TOTAL</b>	<b>(11)</b>	<b>(8)</b>
	<b>180)</b>	<b>643)</b>

Employee expenses excluding share-based compensation amounted to €8,426 thousand in the first half 2021 compared to €10,667 thousand in the first half 2020, or a 22% decrease, due to a decrease in headcount (from 203 at June 30, 2020 to 122 at June 30, 2021).

The amount recognized as share-based compensation (BSA, BSAAR, SO and AGA) without having any impact on cash and cash equivalents amounted to €217 thousand in the first half 2021 compared to €513 thousand in the first half 2020. The expenses recorded in the first half of 2021 relate to the BSA, SO and AGA plans implemented between 2016 and 2021.

#### Other expenses

Other expenses amount to €8,078 thousand in the first half 2021 compared to €16,372 thousand in the first half 2020. They include, in particular:



---

## PRESS RELEASE

- "fees," which mainly include legal, audit, and accounting, the fees of various advisors (press relations, investor relations, communication, IT), as well as the fees of certain scientific advisers. This amount also includes intellectual property expenditures corresponding to fees incurred by the Company in connection with the registration and protection of its patents;
- insurance premiums specific to the listing of the Company's shares on Nasdaq: a recurring Directors & Officers civil liability insurance policy;
- expenses related to the pre-marketing of elafibrator and NIS4 in NASH (market research, marketing strategy, medical communication, market access...);
- expenses related to the use and maintenance of Group offices;
- expenses related to external service providers (security, reception, clinical trial management and IT); and
- expenses related to business travel and conferences mainly for employees as well as the costs of participation in scientific, medical and financial conferences.

These changes are mainly related to a decrease in expenses following a cost savings plan implemented in the summer 2020.

**(iv) Financial income (expense)**

Financial income as of June 30, 2021 amounted to a gain of €35,714 thousand compared to financial expense of €4,007 thousand in the previous half year.

This change is mainly due to the buyback bonus obtained as part of the renegotiation of OCEANEs (€35,578 thousand), unrealized and realized foreign exchange gains in the amount of € 5,019 thousand in the first half of 2021 ( compared to € 938 thousand in the first half of 2020), partially offset by foreign exchange losses of € 2,291 thousand in the first half of 2021 (compared to € 246 thousand in the first half of 2020) and by interest expenses (€2,758 thousand in the first half of 2021 compared to € 5,777 thousand in the first half of 2020), the decrease of which is related to a decrease in the bond debt following the partial repurchase and the conversions of OCEANEs carried out during the first semester of 2021.



(v) **Net income (loss)**

The first half 2021 resulted in net income of €9,058 compared to a net loss of €53,011 thousand compared in the first half 2020. The net loss for the 2020 fiscal year amounted to €101,221 thousand.

**Comments on the Group's Statement of Financial Position at June 30, 2021**

At June 30, 2021 the total amount of the Group's Statement of Financial Position amounted to €133,712 thousand compared to €198,614 thousand as of December 31, 2020.

At June 30, 2021, the Group's cash, cash equivalents and other financial assets amounted to €105,777 thousand, compared to €172,486 thousand as of December 31, 2020.

**Cash management**

With €104 million in cash and cash equivalents at June 30, 2021, and taking into account payments made at the date of this report, we estimate that the cost reduction program initiated during the summer 2020 will allow us, as announced in September 2020, to limit our cash burn to an aggregate €120 million for both periods 2021 and 2022, (not including the partial OCEANes buyback completed in January 2021). The distribution between 2021 and 2022 should be modified as a result of new non-dilutive financing (state-guaranteed loan, or *PGE*) secured in 2021, the new orientations of our R&D programs communicated last May, the deferment of some payments from 2021 to 2022, notably related to the closure of the RESOLVE-IT trial and the anticipation of regulatory fees to prepare the submission of *elafibranor* in PBC to the regulatory authorities.

(i) **Non current assets**

Non-current assets, which include trade and other receivables, goodwill and intangible, tangible, and financial assets, decreased and amount to €12,429 thousand as of June 30, 2021 compared with €13,897 thousand at December 31, 2020.

(ii) **Current assets**

Current assets amounted to €121,283 thousand at June 30, 2021 compared to €184,717 thousand as of December 31, 2020.



Cash and cash equivalents went from €171,029 thousand at December 31, 2020 to €104,379 thousand at June 30, 2021, or a decrease of 39%. Cash is mainly placed in low risk, highly-liquid short term investments.

The variation of trade and other receivables is mainly due to the recognition of the estimated amount of the Research Tax Credit receivable for the first half 2021 and the repayment of the Research Tax Credit for 2020 during the first half 2021. Additional details regarding these receivables are provided in note 6.9 to the 2021 half year condensed consolidated financial statements.

The variation of other receivables corresponds to the increase in expenses recognized in advance related to current operating expenses, and in particular, the Directors & Officers civil liability insurance.

**(iii) Shareholders' equity**

As of June 30, 2021, the Group's shareholders' equity totaled €32,566 thousand compared to €16,162 thousand as of December 31, 2020.

The change in the Company's shareholders equity is mainly due to the recognition of income resulting from the bonus corresponding to the partial buyback of OCEANEs as well as capital increases following conversions of OCEANEs in the first half of 2021.

The Notes to the 2021 half year condensed consolidated financial statements summarized hereafter, as well as the Table of Changes in Shareholders' Equity established under IFRS provide details on the change in the Company's share capital and the Group's shareholders' equity, respectively.

**(iv) Non-current liability**

This mainly concerns:

- The convertible bond (OCEANE) renegotiated in January 2021 and due October 2025;
- As well as the part of contractual obligations of the following liabilities reaching maturity in more than one year:
  - o A conditional advance granted to GENFIT SA by Bpifrance for the purpose of financing the research programs detailed in Note 12.2.1 "Refundable and



## PRESS RELEASE

- o Conditional Advances" of the notes to the 2021 half year condensed consolidated financial statements included herein; and
- o bank loan, include the State-guaranteed Loan taken out in June 2021; and
- o the debt related to operating leases pursuant to IFRS 16, as of January 1, 2019.

(v) **Current liabilities**

Liabilities - Current (in € thousands)	As of	
	December 31, 2020	June 30, 2021
	1	
Current convertible loans	312	417
	3	2
Current other loans and borrowings	035	457
	25	27
Current trade and other payables	564	231
Current deferred income and revenue	124	122
	1	
Current provisions	031	736
	<b>31</b>	<b>30</b>
<b>TOTAL</b>	<b>067</b>	<b>964</b>

This balance sheet item mainly includes interest payments on the OCEANE due October 2025, bank loans and trade and social security payables and debts under operating leases. Changes in current liabilities are mainly due to changes in contracted research and development activities expenses.

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades.

Today, GENFIT has a robust and diversified pipeline, with different compounds and technologies evaluated at different development stages and in different liver diseases.

Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and Acute on Chronic Liver Failure (ACLF): two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ Phase 3 clinical trial evaluating elafibranor (elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority) in patients with Primary Biliary Cholangitis (PBC) is being conducted following [a successful Phase 2 clinical trial](#). A Phase 2 clinical development program is also underway with elafibranor in Primary Sclerosing Cholangitis (PSC), and a Phase 1 clinical program with nitazoxanide in ACLF has been initiated.

As part of GENFIT's comprehensive approach to clinical management of patients with liver diseases, the Company is also developing NIS4®, a new non-invasive blood-based diagnostic technology, which could enable easier identification of patients with at-risk NASH. Since May 2021,



## PRESS RELEASE

Labcorp® has commercialized NASHnext™, powered by NIS4®, for use in the clinic. GENFIT also continues to explore opportunities to obtain formal marketing authorization of an in vitro diagnostic (IVD) test.

GENFIT has facilities in Lille and Paris, France, 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). [www.genfit.com](http://www.genfit.com)

### GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding GENFIT's corporate strategy and objectives, the potential sizes of the markets for PBC, PSC and ACLF, commercial certainty within these markets and the outcome of the ELATIVE™ phase 3 trial of elafibranor in PBC, timelines for completion of the ELATIVE™ trial and receipt of market authorization if the results are positive, timelines for and success of the commercial deployment of the diagnostic test powered by NIS4® developed by GENFIT's partner Labcorp and the size of the market for which it is designed, the ability of the NIS4® technology to facilitate the development of an IVD test approvable by the regulatory authorities, and our ability to significantly reduce our projected cash burn over the next several years. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, the impact of the COVID-19 pandemic, exchange rate fluctuations and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French *Autorité des Marchés Financiers* ("AMF"), including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, which is available on the Company's website ([www.genfit.com](http://www.genfit.com)) and on the website of



---

## PRESS RELEASE

the AMF ([www.amf-france.org](http://www.amf-france.org)) and public filings and reports filed with the U.S. Securities and Exchange Commission (“SEC”) including the Company’s 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021. 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.

### CONTACT

**GENFIT** | Investors

Tel: +1 (617) 714 5252 | [investors@genfit.com](mailto:investors@genfit.com)

**PRESS RELATIONS** | Media

Stephanie Boyer – Press relations | Tel: +333 2016 4000 | [stephanie.boyer@genfit.com](mailto:stephanie.boyer@genfit.com)