

**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 30, 2020**

**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):

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EXHIBIT LIST

**Exhibit**

**Description**

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[99.1](#) [Press Release dated September 30, 2020.](#)

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**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 30, 2020

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



## GENFIT: First Half-Year 2020 Financial Report and New Corporate Strategy

- **Cash position of €226 million at June 30, 2020 (€277 million at December 31, 2019)**
- **New Corporate strategy focused on two priority areas:**
  - **Development of elafibranor in Primary Biliary Cholangitis (PBC): ongoing enrolment for Phase 3 clinical trial ELATIVE™**
  - **Commercialization of NIS4™ for NASH diagnosis: exclusive licensing agreement with Labcorp**
- **Plan to create two GENFIT SA subsidiaries by 2021, to facilitate decision-making and enable an independent management and growth**
- **Corporate restructuring plan to reprioritize capital for essential operating activities. Objective of cash burn reduction by more than 50% by 2022:**
  - **Termination of elafibranor’s clinical development in NASH**
  - **Termination of all activities associated with elafibranor’s launch preparations in NASH**
  - **Reallocation of our research program to focus efforts on key programs**
  - **Comprehensive cost-saving plan and restructuring plan, with a 40% workforce reduction in the Group**

**Lille, France; Cambridge, MA; September 30, 2020** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced its first half-year 2020 financial report, including the advances of its R&D portfolio and the new GENFIT corporate strategy. The Half Year Business and Financial Report, including the new corporate strategy 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 30, 2020 at 4:30pm EDT / 22:30 CEST, and in French on October 1, 2020 at 1:30am EDT / 7:30am CEST**

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 calling 877-407-9167 (toll-free U.S. and Canada), 201-493-6754 (international) or 0 800 912 848 (France) five minutes prior to the start time (no passcode needed). A replay will be available shortly after the call.



## New corporate strategy and prospects

The company's corporate strategy now focuses on two priority areas:

- Phase 3 clinical trial ELATIVE™ evaluating elafibranor in PBC:
  - Patient enrolment now started, and results expected early 2023, given the current constraints due to the COVID-19 pandemic;
  - Following the positive Phase 2 data of elafibranor in PBC, the U.S. Food and Drug Administration (FDA) granted elafibranor Breakthrough Therapy designation. The ELATIVE™ study aims to confirm elafibranor's previously successful results of efficacy, potential improvement in pruritus and safety in PBC patients;
  - Current market size for second line therapies in PBC is estimated at ~ \$300MM in 2020 and is anticipated to experience double digit growth and estimates for 2025 are up to \$1B. Elafibranor is a promising alternative therapy to the existing treatment in PBC, based on the significant unmet needs in this indication.
- NIS4™ technology for (NASH) diagnosis:
  - NIS4™ technology data, recently published in *The Lancet Gastroenterology & Hepatology*, confirmed the technology's diagnostic performance and garnered the support of leading NASH experts;
  - The recently announced exclusive licensing agreement with Labcorp for NIS4™ technology will enable a large-scale commercial launch as of next year;
  - NIS4™ addresses patients' and payers' requirements as liver biopsy remains the only – although imperfect – approved diagnostic option in the clinical development field and cannot be replicated on a large scale due to its painful and invasive nature, and its cost for healthcare systems. It would be impossible to diagnose all patients with biopsies given the limited number of procedures that can be performed. The blood test commercialized by Lacorp will address these multiple challenges;
  - The NASH therapeutic market is potentially significant, however, the opportunity is dependent on quick, reliable and easy to execute diagnostic solutions to identify patients. NIS4™ technology represents the essential first step in managing patients with NASH and is the first step for patients to take control, even in the absence of treatments, of their disease.

GENFIT's new strategy includes a **plan, which aims to create two distinct operational subsidiaries** by 2021 to enable more independent management and growth:



- The first entity would be dedicated to the development of specialty indications, starting with the Phase 3 trial in PBC;
- The second entity would house NASH solutions, including all programs related to the identification, evaluation and monitoring of patients with NASH. This independent structure would facilitate future partnerships for NIS4™.

The two entities would remain a part of GENFIT as a listed company, who would ensure adequate decision making between both “business” entities, the goal being to best highlight each of the activities to benefit the Group’s valuation.

Concurrently, GENFIT is adopting a plan to reallocate and rationalize all capital with an objective to **reduce the cash burn by more than 50% by 2022** compared to our cash burn prior to the RESOLVE-IT Phase 3 data. The program aims to reduce the current cash burn rate from €110M annually before our Phase 3 data, to approximately €45MM annually, beginning in 2022. Due to the residual expenses related to the termination of RESOLVE-IT, 2021 will be a transition year.

This plan incorporates the following key components:

- The overall clinical development program for elafibranor in NASH and all activities associated with the commercial launch of elafibranor in NASH have been terminated given the low probability of success compared to required expenses. The termination includes the NASH combination therapy trials, the pediatric trials, and other trials such as the evaluation of the impact of elafibranor on liver fat composition;
- A comprehensive cost-saving plan has been implemented, including the redirection of R&D activities and the termination of secondary programs (i.e. the RORgT program);
- A workforce restructuring plan aims to reduce the overall workforce by 40%, encompassing both the U.S and France in order to align the company size to the new scope of activity.

Lastly, GENFIT plans to propose to the holders of its OCEANE bond (€180 million nominal amount with a maturity of October 16, 2022) and its shareholders, an adjustment of the terms of the OCEANE convertible bond. The Company's objective is to begin this process towards the end of the year, in order to have a balance sheet which is structured in line with its new strategy.

**Pascal Prigent, CEO of GENFIT**, stated: *“The decisions we have taken allow us to move GENFIT forward towards 2021 with a clear and precise roadmap. We are confident in the probability of success, and the potential of our two priority programs. The evolution of the company also ensures the structure adapts to our strategy, with an approach that is both organizationally and financially sound.”*



## Key aspects of the half-year 2020 results

Key aspects of the half-year 2020 results are:

- Cash and cash equivalents of €225.7 million at June 30, 2020 (€276.7 million at December 31, 2019);
- Operating income of €5.9 million (€5.4 million at June 30, 2019), essentially from the Research Tax Credit, which amounted to €5.2 million for the first half 2020 (€5.3 million in the preceding half year);
- Operating expenses of €55.0 million (€51.3 million at June 30, 2019) of which 67% represented R&D expenses.

The increase in operating expenses is due to increases in marketing and pre-commercialization expenses, which amounted to €9.5 million in the first half 2020 (€2.9 million in the first half 2019). Marketing and pre-commercialization expenses will significantly decrease as of the second half 2020 due to the discontinuation of the pre-commercialization work for elafibranor in NASH following the termination of this program in July 2020.

General and administrative expenses (€8.2 million in the first half 2020 compared to €9.5 million in the first half 2019) and research and development expenses (€36.9 million in the first half 2020 compared to €38.9 million in the first half 2019) have decreased slightly between 2019 and 2020. These expenses will progressively decrease as of the second half 2020 following the Company's decision to begin the process of terminating the clinical trials for elafibranor in NASH, terminating secondary programs and to execute a comprehensive cost saving plan over 3 years. Significant expenses related to the termination of the RESOLVE-IT trial will be due in the second half 2020 and in 2021.

As a result of changes in revenues and expenses, the net loss amounted to €53.0 million at June 30, 2020 (€51.1 million at June 30, 2019). The net loss for 2019 was €65.1 million.



The table below presents the condensed Consolidated Statement of Operations under IFRS for the first half 2020, with comparative figures for the first half 2019.

<b>(in € thousands, except earnings per share data)</b>	<b>For the six-month period ended</b>	
	<b>June 30, 2019</b>	<b>June 30, 2020</b>
<b><u>Revenues and other income</u></b>		
Revenue	1	122
	5	5
Other income	356	745
	5	5
Revenues and other income	357	867
<b><u>Operating expenses and other operating income (expenses)</u></b>		
	(38)	(36)
Research and development expenses	908)	867)
	(9)	(8)
General and administrative expenses	517)	251)
	(2)	(9)
Marketing and market access expenses	876)	491)
	7	(423)
Other operating income (expenses)	(45)	(49)
Operating income (loss)	936)	163)
	1	2
Financial income	755	095
	(7)	(6)
Financial expenses	240)	102)
	(5)	(4)
Financial profit (loss)	485)	007)
	(51)	(53)
Net profit (loss) before tax	422)	170)
	289	159
Income tax benefit (expense)	(51)	(53)
<b>Net profit (loss)</b>	<b>132)</b>	<b>011)</b>
	(51)	(53)
Attributable to owners of the Company	132)	011)
	—	—
Attributable to non-controlling interests	—	—
<b>Basic and diluted earnings (loss) per share</b>		
Basic and diluted earnings (loss) per share (€/share)	(1,64)	(1,36)

Further information is described in the above New Corporate Strategy and Prospects section of this press release and in the condensed consolidated financial statements at June 30, 2020 under IFRS as well as the management discussion of the results are provided in the appendix at the end of this document. The condensed consolidated financial statements as well as the statutory auditors' report on those financial statements are appended to the 2020 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 2019 Annual Report on Form 20-F (“Form 20-F”) and in this Half-Year Business and Financial Report before deciding to invest in Company shares; these two 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 4 of the Form 20-F (and the contents of this section), of which the realization may have (or has had in some cases) material adverse effect on the Group and its activity, financial situation, results, development or perspectives, and which are of importance in the investment decision-making process.



## **Key events of the first half of 2020 and main events after the reporting period**

### **R&D Programs of the Company during H1 and After the Reporting Period**

#### ***Elafibranor Development Program in NASH***

##### **RESOLVE-IT Phase 3 Study in NASH**

In February, the Company announced that the final visit of the last patient for the interim cohort to support accelerated marketing approval had been completed on time, and the clinical trial database would be locked before the end of February. It also announced in late March 2020 that, despite the COVID-19 pandemic, it had decided to continue the extension phase of the RESOLVE-IT trial thanks to the implementation of measures allowing to ensure the safety of patients who were already enrolled in the study.

In May, the Company announced the topline results of the interim analysis of the RESOLVE-IT Phase 3 trial evaluating the efficacy of the daily administration of elafibranor 120 mg in adults with NASH.

The RESOLVE-IT Phase 3 trial evaluated the effect of elafibranor compared to placebo in 1,070 patients (ITT population) with biopsy proven NASH as defined by NAFLD activity score (NAS) greater than or equal to 4, fibrosis stage 2 or 3. Patients were randomized 2:1 to receive elafibranor 120mg or placebo once daily, with a follow-up liver biopsy at week 72 to evaluate histologic endpoints (resolution of NASH without worsening of fibrosis or fibrosis improvement of at least one stage).

Resolution of NASH is defined by a ballooning score of 0 and an inflammation score of 0 or 1, and the non-worsening of fibrosis corresponds to a fibrosis score that does not increase.

The trial did not meet the predefined primary endpoint of NASH resolution without worsening of fibrosis in the ITT population. In the ITT population, 19.2% of patients who received elafibranor (N=138) achieved NASH resolution without worsening of fibrosis compared to 14.7% of patients in the placebo arm (N=52) (p=0.07).



On the key secondary endpoint of fibrosis improvement of at least one stage, 24.5% of patients who received elafibranor (N=176) achieved fibrosis improvement of at least one stage compared to 22.4% (N=79) in the placebo arm (p=0.445).

Statistical significance was not achieved in the other key secondary endpoint related to metabolic parameters, which were: triglycerides, non-HDL cholesterol, HDL cholesterol, LDL cholesterol, HOMA-IR in non-diabetic patients, and HbA1c in diabetic patients.

The favorable safety and tolerability profile of elafibranor observed in our previously conducted trials was similar to what has been observed in the interim results of RESOLVE-IT, which is encouraging for the ongoing Phase 3 trial evaluating elafibranor in PBC (see below).

While the topline results do not support an application for accelerated approval of elafibranor by the FDA under Subpart H or conditional approval by the European Medicines Agency (“EMA”), the Company announced, also in May, its intention to review in detail the full dataset and conduct additional analyses in order to understand why the placebo response rate was higher than what was expected before making a decision regarding the future of the RESOLVE-IT trial.

On July 22, 2020, following the detailed review of the full RESOLVE-IT interim efficacy dataset, the Company determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the United States and Europe. The Company announced that it would engage with the RESOLVE-IT investigators to expedite the trial termination process –which is ongoing at the time of this report and due to last for several months– and that it would also meet with regulatory agencies to share key learnings, including results from the second reading of liver biopsies that will help better understand inter-reader variability and its impact. The Company also indicated that it is now focusing its efforts on developing its two major programs: elafibranor development in PBC, and the commercial growth of NIS4™ technology, for NASH diagnostics.

### **Pediatric NASH, Phase 2 Trial Addressing Liver Fat and Therapeutic Combination Program with elafibranor in NASH**

Due to the COVID-19 pandemic, the Company had announced in late March that:

- enrollment of patients in the PK/PD trial in pediatric patients with NASH as well as the Phase 2 study addressing liver fat had been paused;
- the initiation of the Phase 2 combination study in NASH with elafibranor had been put on hold.



In September and following its decision to terminate all development of elafibranor in NASH, the Company decided to initiate the termination process of the PK/PD trial in pediatric NASH as well as the Phase 2 study on hepatic lipid composition.

Considering that clinical trials in the NASH space involve a large number of patients, are long and very expensive, as well as the fact that the regulatory and competitive landscape in this therapeutic area is in constant evolution, the Company has considered that the cost in relation to the probability of success was too high to continue development of elafibranor in NASH.

### **Other Phase 1 trials**

The Company also announced in March, in the context of the COVID-19 pandemic, that all ongoing or upcoming phase 1 trials – which included pharmacokinetic, food effect and bioequivalence studies – had been put on hold. These studies were necessary to support a potential elafibranor NDA submission.

Since then, in line with the decision to end development of elafibranor in NASH, the following decisions have been made regarding these trials, given that some of them will be required for a new drug application for elafibranor in PBC:

- Pharmacokinetic and drug interaction studies have resumed;
- The bioequivalence study has restarted;
- The food interaction study will start in 2021.

### ***Phase 3 of elafibranor Development in PBC Program***

Due to the COVID-19 pandemic, the Company announced in late March that the start of the Phase 3 study in patients with PBC had been delayed.

In September, the Company has announced the completion of the first patient first visit in the ELATIVE™ Phase 3 trial. Appropriate measures will be implemented, including virtual appointments, biological evaluations performed by local laboratories, delivery of the drug candidate to the patients' home, to ensure the safety of participants in the study.

### ***NIS4™ Diagnostic Program in NASH***

During the first half of the year, the NIS4™ technology to support a diagnostic solution continued to be deployed in the clinical research field through Covance. While interest in NIS4™ technology is high, the Company announced in late March that there may be some limits in NIS4™ powered test utilization due to delays potentially experienced by some sponsors as the result of the COVID-19 pandemic.

In August, the Company announced that pivotal data describing the derivation and validation of NIS4™ technology has been accepted for publication by The Lancet Gastroenterology & Hepatology. This published study details NIS4™ algorithm development and clinical validation against the liver biopsy reference standard in two independent populations comprised of data from over 700 patients. In addition to the high overall performance in identifying patients with at-risk NASH, NIS4™ technology also provided consistent results in critical sub-populations (i.e. diabetic vs. non-diabetic, men vs. women) as compared to other non-invasive tests evaluated in the same individuals.

In September, the Company announced the signature of a new licensing agreement with Labcorp for the development and commercial deployment of an LDT integrating NIS4™ technology on the routine clinical care diagnostic test market in the United States and Canada. GENFIT also continues to explore the possibility to obtain regulatory approval to release an IVD test integrating NIS4™ technology on the US and European markets.



### ***NTZ Development Program in Liver Fibrosis***

Despite the COVID-19 pandemic and thanks to the implementation of appropriate measures by the clinical investigator leading the study, the recruitment of patients in the Phase 2 trial evaluating NTZ in NASH-induced liver fibrosis continued throughout the first half of the year.

See also the supplemental Note 6.2 “Major events after the reporting period” to the consolidated H1 2020 financial statements thereafter regarding other events occurring after the reporting period.

### **Governance**

The Company announced, following its annual Shareholders Meeting on June 30, 2020, the appointment of Ms. Katherine Kalin and Mr. Eric Baclet to the company’s Board of Directors. Together, they bring more than 50 years of combined pharmaceutical experience and deep subject matter expertise that will aid in the next phase of GENFIT’s growth.



Ms. Kalin’s healthcare industry expertise spans diagnostics, medical devices, and pharmaceuticals. Ms. Kalin is currently a director on the boards of Clinical Genomics, a molecular diagnostic firm, Brown Advisory, a strategic advisory and investment firm, and Primari Analytics, a startup in artificial intelligence. From 2012-17, Ms. Kalin led corporate strategy at Celgene, a global biopharmaceutical company, for 5 1/2 years. Prior to that, Ms. Kalin held executive leadership roles in marketing, sales, strategy and new business development at Johnson & Johnson (J&J) from 2002 to 2011. Prior to J&J, Ms. Kalin served as a Partner at McKinsey and Company, a global management consulting firm, where she negotiated and led consulting assignments, as a strategic advisor to pharmaceutical, medical device and other healthcare companies.

Mr. Eric Baclet has over 30 years of experience with Eli Lilly in international drug development, management, and commercialization, all expertise he gained as President and General Manager of Lilly Italia, General Manager of Lilly China, VP of Global Marketing, and Executive Directorship of International Marketing, to name a few. Throughout his tenure at Eli Lilly, Mr. Baclet spearheaded international drug launches across multiple geographies, and led multi-disciplinary teams involved in biopharmaceutical value-chain management in more than seven countries.

At the time of this report, the Board of Directors has appointed Ms. Katherine Kalin as a member of the Strategy and Alliances Committee, and Mr. Eric Baclet, as a member of the Nomination and Compensation Committee.



## **APPENDICES**

### **Half-year Consolidated Financial Results**

**At June 30, 2020**

The Condensed Consolidated Statements of Financial Position, Statements of Operations and Statements of Cash Flow of the Group were prepared in accordance 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, 2020 were approved by Board of Directors on September 29, 2020.

The condensed consolidated financial statements as well as the notes to the consolidated financial statements for the period ended June 30, 2020 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, 2020 and available on the "Investors" page of the GENFIT website.

**Condensed Consolidated Statement of Financial Position**

<b>ASSETS</b> <b>(in € thousands)</b>	<b>As of</b>	
	<b>December 31, 2019</b>	<b>June 30, 2020</b>
<b><u>Current assets</u></b>		
Cash and cash equivalents	276 748	225 721
Current trade and others receivables	12 033	8 938
Other current assets	1 968	3 540
Inventories	5	5
<b>Total - Current assets</b>	<b>290 753</b>	<b>238 204</b>
<b><u>Non-current assets</u></b>		
Intangible assets	920	894
Property, plant and equipment	16 453	15 507
Other non-current financial assets	1 727	1 595
<b>Total - Non-current assets</b>	<b>19 100</b>	<b>17 997</b>
<b>Total - Assets</b>	<b>309 853</b>	<b>256 200</b>

<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b> <b>(in € thousands)</b>	<b>As of</b>	
	<b>December 31, 2019</b>	<b>June 30, 2020</b>
<b><u>Current liabilities</u></b>		
Current convertible loans	1 313	1 313
Other current loans and borrowings	3 226	3 222
Current trade and other payables	36 917	34 961
Current deferred income and revenue	140	141
Current provisions	2 061	2 070
<b>Total - Current liabilities</b>	<b>43 657</b>	<b>41 706</b>
<b><u>Non-current liabilities</u></b>		
Non-current convertible loans	164 142	166 760
Other non-current loans and borrowings	14 939	13 342
Non-current trade and other payables	451	451
Non-current employee benefits	1 408	1 503
Deferred tax liabilities	1 193	1 057
<b>Total - Non-current liabilities</b>	<b>182 132</b>	<b>183 112</b>
<b><u>Shareholders' equity</u></b>		
Share capital	9 715	9 715
Share premium	377 821	378 334
Retained earnings (accumulated deficit)	(238 340)	(303 662)
Currency translation adjustment	14	7
Net profit (loss)	(65 145)	(53 011)
<b>Total shareholders' equity - Group share</b>	<b>84 065</b>	<b>31 382</b>
Non-controlling interests	—	—
<b>Total - Shareholders' equity</b>	<b>84 065</b>	<b>31 382</b>
<b>Total - Shareholders' equity &amp;</b>	<b>309 853</b>	<b>256 200</b>





**Condensed Consolidated Statement of Operations**

**For the six-month period ended**

**(in € thousands, except earnings per share data)**

	<b>June 30, 2019</b>	<b>June 30, 2020</b>
<b>Revenues and other income</b>		
Revenue	1	122
Other income	5 356	5 745
Revenues and other income	<u>5 357</u>	<u>5 867</u>
<b>Operating expenses and other operating income (expenses)</b>		
Research and development expenses	(38 908)	(36 867)
General and administrative expenses	(9 517)	(8 251)
Marketing and market access expenses	(2 876)	(9 491)
Other operating income (expenses)	7	(423)
Operating income (loss)	<u>(45 936)</u>	<u>(49 163)</u>
Financial income	1 755	2 095
Financial expenses	(7 240)	(6 102)
Financial profit (loss)	<u>(5 485)</u>	<u>(4 007)</u>
Net profit (loss) before tax	<u>(51 422)</u>	<u>(53 170)</u>
Income tax benefit (expense)	289	159
<b>Net profit (loss)</b>	<u><b>(51 132)</b></u>	<u><b>(53 011)</b></u>
Attributable to owners of the Company	(51 132)	(53 011)
Attributable to non-controlling interests	—	—
<b>Basic and diluted earnings (loss) per share</b>		
Basic and diluted earnings (loss) per share (€/share)	(1,64)	(1,36)

## PRESS RELEASE

### Condensed Statement of Cash Flows

(in € thousands)	For the six-month period ended	For the year ended	For the six- month period ended
	June 30, 2019	December 31, 2019	June 30, 2020
<b><u>Cash flows from operating activities</u></b>			
+ Net profit (loss)	(51 132)	145	011
+ Non-controlling interests	—	—	—
<b><u>Reconciliation of net loss to net cash used in operating activities</u></b>			
Adjustments for:			
+ Depreciation and amortization on tangible and intangible assets	1 542	263	737
+ Impairment and provision for litigation	1 804	357	124
+ Expenses related to share-based compensation	356	657	513
- Gain on disposal of property, plant and equipment	(1)	(19)	(2)
+ Net finance expenses (revenue)	5 669	437	848
+ Income tax expense (benefit)	(289)	(576)	(159)
+ Other non-cash items including Research Tax Credit litigation	(11)	702	92
Operating cash flows before change in working capital	(42 063)	324	859
<b><u>Change in:</u></b>			
Decrease (increase) in trade receivables and other assets	(10 103)	640	523
(Decrease) increase in trade payables and other liabilities	5 307	284	026
Change in working capital	(4 797)	(356)	(504)
Income tax paid	—	—	—
<b>Net cash flows used in operating activities</b>	<b>(46 859)</b>	<b>680</b>	<b>362</b>
<b><u>Cash flows from investment activities</u></b>			
- Acquisition of property, plant and equipment	(65)	030	(785)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	(0)	517	—
- Acquisition of financial instruments	(128)	—	—

		(160)	(49)
<b>Net cash flows provided by (used in ) investment activities</b>	<b>(193)</b>	<b>327</b>	<b>(834)</b>
<b>Cash flows from financing activities</b>			
+ Proceeds from issue of share capital (net)	126 479	126 486	—
+ Proceeds from subscription / exercise of share warrants	—	43	—
+ Proceeds from new loans and borrowings net of issue costs	—	—	—
- Repayments of loans and borrowings	(1 513)	(1 884)	(1 601)
- Financial interests paid (including finance lease)	(3 234)	(7 785)	(3 230)
<b>Net cash flows provided by (used in ) financing activities</b>	<b>121 732</b>	<b>116 860</b>	<b>(4 831)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>74 680</b>	<b>69 508</b>	<b>(51 027)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	207 240	207 240	276 748
<b>Cash and cash equivalents at the end of the period</b>	<b>281 920</b>	<b>276 748</b>	<b>225 721</b>



## Discussion of the 2020 half year results

### Comments on the condensed statement of net income for the periods ended June 30, 2019 and June 30, 2020

#### (i) Revenue and other income

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

<b>Revenue and other income (in € thousands)</b>	<b>For the six-month period ended</b>	
	<b>June 30, 2019</b>	<b>June 30, 2020</b>
Revenues	1	122
Government grants and subsidies	2	3
CIR tax credit	5 350	5 224
Other operating income	4	519
<b>TOTAL</b>	<b>5 357</b>	<b>5 867</b>

Revenue and other income was € 5,867 thousand at June 30, 2020 compared to €5,357 thousand for the same period in the previous year.

(ii) **Operating expenses and other operating income by destination**

The tables below break down operating expenses by destination mainly into research and development expenses on the one hand, marketing and pre-marketing and general and administrative expenses on the other, for the half years ended June 30, 2020 and 2019.

Operating expenses and other operating income (expenses) (in € thousands)	For the six-month period		Contracted research and development activities		Other expenses (maintenance, fees, travel, taxes...)		Depreciation, amortization and impairment charges		Gain / (loss) on disposal of property, plant and equipment
	ended	ended	conducted by third parties	Employee expenses	fees, travel, taxes...)	impairment charges	plant and equipment		
	June 30, 2019	June 30, 2019							
Research and development expenses	908)	(38	909)	(25 206)	(6 564)	(2	—	—	
General and administrative expenses	517)	(9	(1)	082)	(4 244)	(5	—	—	
Marketing and market access expenses	876)	(2	—	(883)	963)	(1	—	—	
Other operating income and (expenses)	7	—	—	6	1	1	1		
<b>TOTAL</b>	<b>293)</b>	<b>(51</b>	<b>910)</b>	<b>(25 170)</b>	<b>(11 764)</b>	<b>(9</b>	<b>1</b>	<b>1</b>	

Operating expenses and other operating income (expenses) (in € thousands)	For the six-month period		Contracted research and development activities		Other expenses (maintenance, fees, travel, taxes...)		Depreciation, amortization and impairment charges		Gain / (loss) on disposal of property, plant and equipment
	ended	ended	conducted by third parties	Employee expenses	fees, travel, taxes...)	impairment charges	plant and equipment		
	June 30, 2020	June 30, 2020							

**thousands)**

Research and development expenses	867)	(36	337)	(24	591)	(6	287)	(3	455)	(1	—
General and administrative expenses	251)	(8	(42)	845)	(3	963)	(3	(269)	—	—	
Marketing and market access expenses	491)	(9	(1)	(744)	697)	(8	(44)	—	—		
Other operating income (expenses)	(423)	—	—	(425)	—	—	—	—	2		
<b>TOTAL</b>	<b>031)</b>	<b>(55</b>	<b>379)</b>	<b>(24</b>	<b>180)</b>	<b>(11</b>	<b>372)</b>	<b>(16</b>	<b>769)</b>	<b>(1</b>	<b>2</b>



Operating expenses in the first half 2020 amounted to €55,031 thousand compared to €51,293 thousand in first half 2019.

They include, in particular:

**research and development expenses**, which include employee-related expenses for employees in research and development functions (€6,591 thousand at June 30, 2020 compared to €6,206 thousand at June 30, 2019), the cost of consumables and contracted research and development activities (particularly clinical and pharmaceutical expenses) (representing €25,534 thousand at June 30, 2020 compared to €26,977 thousand at June 30, 2019) and expenses related to intellectual property. These research and development expenses amounted to €36,867 thousand at June 30, 2020 compared to €38,908 thousand at June 30, 2019, or 67% and 76% of operating expenses, respectively.

The decrease in contracted research and development expenses is mainly due to the suspension or termination of some clinical studies in the context of the COVID-19 pandemic.

Changes in employee-related expenses for employees in research and development functions is mainly due to increased headcount (128 vs. 116), compensated by the absence of incentive bonuses in 2020.

The decrease in amortization and provisions related to research and development is mainly due to the provisions recorded in the dispute with the tax authorities concerning the CIR in 2019 and the application as from January 1, 2019 of IFRS 16 to leases.

**general and administrative expenses**, which include the costs of personnel not assigned to research (€3,845 thousand at June 30, 2020 compared to €4,082 thousand at June 30, 2019), and administrative costs. These general and administrative expenses amounted to €8,251 thousand in the first half 2020 compared with €9,517 thousand in the first half 2019, or 15% and 19% of operating expenses, respectively.

Changes in general and administrative expenses are mainly related to the cost of insurance premiums in relation to Company listing on the Nasdaq.

Changes in employee-related expenses paid to employees in general and administrative functions was primarily the result of an increase in headcount (68 vs. 51 employees), compensated by the absence of incentive bonuses in 2020.





·**marketing and pre-marketing expenses**, which include the costs of personnel assigned to marketing and business development (€744 thousand in the first half 2020 compared to €883 thousand in the first half 2019), and costs related to the preparation of the commercialization of elafibranor and NIS4™ in NASH (market research, marketing strategy, medical communication, market access...) (€9,491 thousand in the first half 2020 compared to €2,876 thousand in the first half 2019).

Marketing and pre-commercialization expenses will significantly decrease as of the second half 2020 due to the discontinuation of the pre-commercialization work for elafibranor in NASH following the termination of this program in July 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 €24,379 thousand in the first half 2020 compared to €25,910 thousand in the first half 2019, corresponding to a 6% decrease, which is mainly due to the suspension or discontinuation of some studies in the context of the COVID-19 pandemic.

**Employee expenses**

<b>Employee expenses (in € thousands)</b>	<b>For the six-month period ended</b>	
	<b>June 30, 2019</b>	<b>June 30, 2020</b>
Wages and salaries	(7 998)	811
Social security costs	(2 748)	770
Changes in pension provision	(69)	(87)
Individual training entitlement	—	—
Share-based compensation	(356)	(513)
<b>TOTAL</b>	<b>(11 170)</b>	<b>180</b>

Employee expenses excluding share-based compensation amounted to €10,667 thousand in the first half 2020 compared to €10,814 thousand in the first half 2019, or a 1% decrease, mainly due to the absence of incentive bonuses in 2020 despite an increase in headcount (203 vs. 174 employees)



The amount recognized as share-based compensation (BSA, BSAAR, SO and AGA) free of any impact on cash flow amounted to €513k in the first half 2020 compared to €356 thousand in the first half 2019. The expenses recorded in the first half of 2020 relate to the SO and AGA plans put in place in December 2016, the BSA, SO and AGA plans put in place in 2017, the SO and AGA plans put in place in 2018 and the BSA, SO and AGA plans put in place in 2019.

### **Other expenses**

Other expenses amount to €16,372 thousand in the first half 2020 compared to €9,764 thousand in the first half 2019. They include, in particular:

- "fees," which 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 elafibranor 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 (guard, 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, financial, and business development conferences.

These changes are mainly related to increases in expenses for pre-marketing projects.



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

Financial income (expense) as of June 30, 2020 amounted to a loss of €4,007 thousand compared to financial loss of €5,485 thousand in the previous half year.

This change is mainly due to realized and unrealized foreign currency exchange rate loss of €246k in the first half 2020 compared to €1,563k in the first half 2019, partially compensated a notable increase in financial income (€1,154k in the first half 2020 compared to €103k in the first half 2019<sup>1</sup>) due to the increase of cash held in US dollars and to investments in US dollars where the return has been significantly higher than investments in euros.

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

The first half 2020 resulted in a net loss of €53,011 thousand compared to a net loss of €51,132 thousand in the first half 2019. The net loss for the 2019 fiscal year amounted to €65,144 thousand.

**Comments on the Group's Statement of Financial Position at June 30, 2020**

At June 30, 2020 the total amount of the Group's Statement of Financial Position amounted to €256,200 thousand compared to €309,853 thousand as of December 31, 2019.

At June 30, 2020, the Group's cash, cash equivalents and other financial assets amounted to €227,316 thousand, compared to €278,474 thousand as of December 31, 2019.

**(i) Non current assets**

Non-current assets, which include trade and other receivables, goodwill and intangible, tangible, and financial assets, decrease from €19,100 thousand as of December 31, 2019 to €17,997 thousand at June 30, 2020.

**(ii) Current assets**

Current assets amounted to €238,204 thousand at June 30, 2020 compared to €290,753 thousand as of December 31, 2019.

Cash and cash equivalents went from €276,748 thousand at December 31, 2019 to €225,721 thousand at June 30, 2020, or a decrease of 18%. Cash is mainly placed in low risk, highly-liquid short term investments.

<sup>1</sup> Note: the impact of the reclassification of foreign exchange income from trade receivables recognized as "other income" for the first half of 2020 while these gains were recognized as "financial income" in the first half of 2019 (see note 17 to the 2020 half year condensed consolidated financial statements)



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 2020 and the repayment of the Research Tax Credit for 2019 during the first half 2020. Additional details regarding these receivables are provided in note 6.9 to the 2020 half year consolidated financial statements.

The variation of trade and other receivables corresponds to the increase in expenses recognized in advance related to current operating expenses. This increase follows the increase in operating expenses in the first half 2020.

**(iii) Shareholders' equity**

As of June 30, 2020, the Group's shareholders' equity totaled €31,382 thousand compared to €84,065 thousand as of December 31, 2019.

The change in the Company's shareholders' equity is mainly due to the recognition of the half year loss reflecting the Company's efforts in research and development, carrying out pre-clinical studies, and clinical studies related to elafibranor.

The Notes to the 2020 half year consolidated financial statements included herein, 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 liabilities**

This mainly concerns:

·The convertible bond (OCEANE) issued in October 2017 and due October 2022;

As well as the part of contractual obligations of the following liabilities reaching maturity in more than one year:

- A conditional advance granted to GENFIT SA by Bpifrance for the purpose of financing the research programs detailed in Note 6.12.2.1 "Refundable and Conditional Advances" of the notes to the 2020 half year consolidated financial statements included herein; and
- bank loans; and
- and the debt related to operating leases pursuant to IFRS 16, as of January 1, 2019.



**(i) Current liabilities**

**Liabilities - Current**

<b>(in € thousands)</b>	<b>December 31, 2019</b>	<b>June 30, 2020</b>	
			1
Current convertible loans	1 313	313	
Current other loans and borrowings	3 226	222	3
			34
Current trade and other payables	36 917	961	
Current deferred income and revenue	140	141	
			2
Current provisions	2 061	070	
			<b>41</b>
<b>TOTAL</b>	<b>43 657</b>	<b>706</b>	

This balance sheet item mainly includes interest payments on the OCEANE due October 2022, 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.

See also notes 6.12 and 6.13 to the consolidated financial statements for the first half of 2020 below.

**ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and 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. GENFIT initiated a Phase 3 clinical trial of elafibranor in patients with primary biliary cholangitis (PBC). As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which, if approved, could enable easier identification of patients with at-risk NASH. 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)



## 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 statements about GENFIT's new corporate strategy and objectives, the potential size of the market for PBC, commercial certainty within this market and the outcome of the ELATIVE phase 3 trial of elafibranor in PBC, timelines for completion of the ELATIVE trial, timelines for and success of a commercial launch of a diagnostic test powered by NIS4 by GENFIT's partner LabCorp, the success and benefits of corporate restructuring projects, including a workforce reduction program, our ability to significantly reduce operating expenses, our projected cash burn over the next several years and our ability to adjust the terms of our convertible bond. The use of certain words, including "believe," "potential," "expect" 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 related 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 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 Section 2.1 "Main Risks and Uncertainties" of the Company's 2019 Universal Registration Document filed with the AMF on May 27, 2020 under n° D.20-0503, which is 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)) and revised as indicated in Section 8 of the Half-Year Business and Financial Report as of June 30, 2020, and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 20-F dated May 27, 2020. 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.



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