



GENFIT: H1 2019 RESULTS AND R&D PIPELINE PROGRESSION

- Cash position of €282 million (€207 million at December 31, 2018)
- USD \$155 million gross proceeds from the IPO on the Nasdaq Global Select market
- Signature of a license agreement with Labcorp to expand access to NIS4, a non-invasive diagnostic test to identify and monitor NASH patients, in the clinical research field
- Signature of a license and collaboration agreement with Terns Pharmaceuticals, granting a license to develop and market elafibranor in NASH and PBC in Greater China
- Launch of a pediatric phase 2 clinical trial evaluating elafibranor in children and adolescents with NASH
- Launch of a phase 2 clinical trial evaluating elafibranor's activity on liver fat composition in NAFLD patients
- FDA grants elafibranor Breakthrough Therapy designation for treatment of adults with PBC

Lille (France), Cambridge (Massachusetts, United States), September 30, 2019 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announces its first half 2019 financial results. 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.

Pascal Prigent, Chief Executive Officer of GENFIT, commented:

"The first half of the year was particularly eventful for GENFIT, whether in terms of financial, organizational, clinical or commercial aspects of our business.





The listing of the Company's securities on the NASDAQ and the related fundraising brought our closing cash position to €282 million while also raising our profile in the United States. Our half-year financial results also reflect the effort and significant progress made in the development of our portfolio of R&D programs, including the launch of two new Phase 2 clinical trials. In addition, elafibranor's potential in PBC was recognized by the major regulatory agencies, with the FDA's Breakthrough Therapy designation and Orphan Drug designation granted by both the FDA and EMA.

Our business development efforts to sign licensing agreements or collaboration agreements came to fruition with the signature of agreements with Labcorp and Terns Pharmaceuticals. We are preparing to ramp-up these efforts in 2020 if, as we hope, the intermediate results of the ongoing RESOLVE-IT Phase 3 trial evaluating the efficacy and safety of elafibranor in adult NASH are conclusive.

We have also been expanding our teams with the recruitment, during the first half of the year, of senior executives and experienced consultants, particularly to prepare for the potential market launch of elafibranor and NIS4 in NASH and, more broadly, to support the Company's international expansion and its gradual evolution towards a specialty biopharmaceutical company in liver diseases of metabolic origin and hepatobiliary diseases.

As we celebrate GENFIT's 20th anniversary, we want to warmly thank the doctors and the many patients who have participated and still participate in our ongoing clinical trials, our shareholders, and more broadly all stakeholders who share our ambition to be able to offer, in the near future for our most advanced programs, treatments and diagnostic solutions aimed at meeting largely unmet medical needs."

Main financial results:

Key aspects of the half-year 2019 results are:

- Cash and cash equivalents of €281.9 million at June 30, 2019 (€207.2 million at December 31, 2018).
- Operating income of €5.4 million (€5.1 million at June 30, 2018), essentially from the Research Tax Credit, which amounted to €5.3 million for the first half 2019 (€5 million in the preceding half year), reflecting the increase in operating expenses related to the progression of the R&D portfolio over the two half-years. Given the date of the signature of the agreement with Terns Pharmaceuticals (June 24, 2019) and the obligations thereunder, the revenues from the USD\$35 million upfront payment will be recognized in the second half of 2019.





- Operating expenses of €51.3 million (€36.7 million at June 30, 2018) of which 76% represented R&D expenses. The increase in operating expenses is due to increases in:
 - o contracted research and development expenses (from €22.7 million at June 30, 2018 to €25.9 million at June 30, 2019) resulting from the start of new phase 3 RESOLVE-IT satellite studies, work necessary to prepare the new drug application for elafibranor in NASH, and the increase in production of active principal ingredient required to carry out the various clinical studies;
 - o employee-related expenses (from €6 million excluding share-based payments on June 30, 2018 to €10.8 million excluding share-based payments as of June 30, 2019) mainly due to an increase in headcount (174 vs 130 employees), changes in employee profiles, a related increase in salaries, as well as bonuses that were awarded to employees for their contribution to the Group's development; and
 - o other operating expenses (from €5.9 million at June 30, 2018 to €9.8 million at June 30, 2019) mainly related to the cost of insurance premiums in relation to the listing of the Company's shares on the Nasdaq, accounting and statutory auditor fees related to the listing, expenses for market access and pre-marketing projects.

As a result of changes in revenues and expenses, the net loss amounted to €51.1 million at June 30, 2019 (€36.7 million at June 30, 2018). The net loss for the 2018 was €79.5 million.





The table below presents the condensed Consolidated Statement of Operations under IFRS for the first half 2019, with comparative figures for the first half 2018.

	Half-year	Half-year ended		
(in € thousands, except earnings per share data)	2018/06/30	2019/06/30		
	corrected (*)			
Revenues and other income				
Revenue	64			
Other income	5 057	5 35		
Revenues and other income	5 122	5 35		
Operating expenses and other operating income (expenses)				
Research and development expenses	(32 072)	(38 899		
General and administrative expenses	(4 565)	(12 402		
Other operating income (expenses)	(40)			
Operating loss	(31 555)	(45 936		
Financial income	331	1 75		
Financial expenses	(5 572)	(7 240		
Financial loss	(5 241)	(5 485		
Net loss before tax	(36 796)	(51 422		
Income tax expense	121	28		
Net loss	(36 675)	(51 132		
Attributable to owners of the Company	(36 675)	(51 132		
Attributable to non-controlling interests	0	(
Basic and diluted loss per share				
Basic loss per share (€/share)	(1.18)	(1.64		

^{*}See note 6.3.3 "Correction of Errors" to the 2019 half year consolidated financial statements.

The condensed consolidated financial statements at June 30, 2019 under IFRS as well as the management discussion of the results are provided in the appendix at the end of this document. The full consolidated financial statements as well as statutory auditors' report on the consolidated financial statements are included in appendices to the 2019 Half Year Business and Financial Report and available on the "Investors" page of the GENFIT website.





Key events of the first half 2019 and main post closing event

GENFIT's R&D Programs

Elafibranor development program in NAFLD/NASH

RESOLVE-IT Phase 3 study in NASH

Enrollment of patients in the RESOLVE-IT Phase 3 clinical trial of elafibranor in NASH progressed actively during the course of the first half 2019. All patients required for the interim analysis have already been enrolled and the last biopsy to be performed on the last patient required for the interim analysis is expected to occur in the fourth quarter of 2019. In May, the Company also announced the results of the 36 month review of the Data Safety Monitoring Board (DSMB), based on tolerability and safety data. The DSMB issued a positive recommendation for the continuation of the RESOLVE-IT Phase 3 trial in NASH without any modifications. This sixth DSMB planned review did not identify any safety issues, as was the case with the previous reviews.

Pediatric Program in NASH

In March, we announced protocol clearance by the FDA for a Phase 2 trial evaluating elafibranor in children and adolescents with non-alcoholic steatohepatitis (NASH).

The trial, which is enrolling patients, is designed as follows:

- Study to assess the pharmacokinetic and pharmacodynamic profile and the safety and tolerability of two dose levels of elafibranor (80 mg and 120 mg);
- 20 patients between 8 to 17 years of age, with NASH;
- 12-week trial duration;
- Open-label study;
- Randomized across two arms;
- U.S. multicenter study.

Disease awareness program in NASH

In 2017, the Company launched a disease awareness initiative through the endowment fund it founded, *The NASH Education Program* $^{\text{TM}}$, confirming its leadership in NASH, and sparked an unprecedented wave of interest in the French media. This initiative is crucial in the context of enrollment for a little known and asymptomatic pathology like NASH.





During the first half of 2019, the Company continued its disease awareness effort by participating in the 2nd Annual International NASH Day that was organized on June 12, 2019 by the Global Liver Institute, with support from organizations including the American Liver Foundation, EASL International Liver Foundation, European Liver Patients Association, NASH Knowledge and Fatty Liver Foundation.

Opportunities in NASH combination therapy

After having identified several molecules having a synergistic activity with elafibranor, we presented our ongoing approach to evaluating elafibranor as the basis for combination therapies in NASH during the 2019 International Liver Congress (ILC), which was held in Vienna, Austria from April 10-14, 2019. The abstract of the poster presented at the ILC "Elafibranor, a drug candidate for first line NASH monotherapy and a universal backbone for drug combination treatment," is available on the ILC's website.

In May and on this basis, we announced our intention to launch a Phase 2 study to evaluate synergies between elafibranor and certain diabetes medications, namely between elafibranor and a GLP-1 receptor agonist, and elafibranor in combination with an SGLT2 inhibitor. This clinical trial, which is expected to launch in the first quarter of 2020, will be a proof of concept study evaluating safety, tolerability and exploratory markers of efficacy in both combinations for the treatment of NASH.

Trial Design:

- Study to assess safety, tolerability and exploratory markers of efficacy of elafibranor (120mg) in combination with a GLP1 analogue or in combination with an SGLT2 inhibitor;
- Study will enroll and monitor patients with suspected NASH and significant to advanced fibrosis, through the use of non-invasive technologies;
- U.S. multi-center study with 24-week trial duration.

The study will also utilize non-invasive diagnostic tools, including NIS4, GENFIT's innovative diagnostic blood test for NASH patient identification and monitoring.

New Phase 2 clinical trial in NAFLD

In June, the Company announced the launch of a Phase 2 clinical trial evaluating elafibranor's activity on liver fat quantity and – most importantly – fat composition in nonalcoholic fatty liver disease (NAFLD) patients.





NAFLD is a common disorder referring to a condition associated with an accumulation of fat in the liver. Although persistent fat in the liver is common and can remain static, NAFLD is known to be a precursor for a much more serious condition, non-alcoholic steatohepatitis or NASH. The composition of hepatic lipids is altered in NASH, especially in patients with diabetes, where polyunsaturated fatty acids are more prominent and give rise to toxic lipid species, such as hepatic ceramides. It is therefore crucial for NASH-targeted drugs to preferentially eliminate lipid species that are substrates for toxic lipid production.

In this context, elafibranor's pluripotent mechanism of a PPAR alpha and delta and its beneficial effects on cardiometabolic lipids (LDL decrease, HDL increase, and TG decrease), glucose metabolism (HbA1c, HOMA-IR, FPG, FFA, C-peptide) could be beneficial in improving the quantity and quality of fat in the liver, specifically targeting the more harmful, lipotoxic fat subtypes that buildup in NAFLD and drive progression to NASH.

The trial, for which patient enrolment is underway, is a Phase 2 randomized, placebo-controlled, double-blind, cross-over study in sixteen patients with NAFL as identified with magnetic resonance spectroscopy (H-MRS). The primary objective will evaluate the effects of treatment with elafibranor (120mg/daily) for 6-weeks vs. placebo on changes in hepatic lipid composition in subjects with fatty liver. Secondary measurements include impact on hepatic glucose production (HGP), glucose homeostasis, lipid metabolism, inflammatory markers and liver function, as well as safety. The trial is conducted in The Netherlands.

• Elafibranor development program in Primary Biliary Cholangitis (PBC)

In April, during the 2019 ILC, GENFIT presented new data from the positive Phase 2 results of elafibranor in PBC, for which the top line results had been published by the company in December 2018, in particular on the primary endpoint of ALP percentage change from baseline to week 12. The anti-cholestatic effects of elafibranor were evaluated in a 12-week double-blind randomized placebo-controlled Phase 2 trial of non-cirrhotic patients with PBC and with inadequate response to ursodeoxycholic acid (UDCA). Patients were randomly assigned to receive elafibranor 80 mg/day, 120 mg/day or placebo (15 patients per group).

In addition to significant reductions in ALP already published in December 2018, the new data set presented at the 2019 ILC showed that patients, in both elafibranor-treated groups, showed improvements in other PBC markers. The effect on gamma-glutamyl transferase (GGT) was highly significant as compared to placebo: -39% (80mg) and -40% (120mg), (p=0.001 and p=0.002 respectively). Improvements in lipid markers including total cholesterol, low-density lipoprotein and triglycerides, as well as reduction of anti-inflammatory markers (such as IgM, CRP,





haptoglobin and fibrinogen); and a decrease in C4, an intermediate of bile acid synthesis, were also noted.

This new data set also suggests an improvement in pruritus – a major symptom of PBC. By self-reported visual analogue scale (VAS) in patients with pruritus at baseline (10/group), the VAS median percentage change from baseline to week 12 was -24%, -49% and -7% in the 80mg, 120 mg and Pbo groups, respectively.

On the basis of this positive data set and the results announced in December 2018, the Company announced its plans to launch a phase 3 trial of elafibranor in PBC, expected in the first quarter of 2020.

Also in April, the Company announced that the FDA had granted elafibranor Breakthrough Therapy Designation for the treatment of PBC in adults with inadequate response to UDCA

Breakthrough Therapy Designation is granted by the FDA to expedite the development and review of drugs designed to treat serious conditions for which preliminary data and evidence indicate that the product candidate may demonstrate substantial improvements over existing therapies on one or more clinically significant endpoints.

Finally, in July 2019, the Company announced that the FDA and EMA had granted Orphan Drug designation to elafibranor for the treatment of PBC.

• Diagnostic biomarker program in NASH (NIS4)

At the 2019 ILC, the Company presented a poster entitled "Assessment of NIS4 clinical utility for identification of patients with active NASH (NAS>=4) and significant fibrosis (F>=2) in patients at risk of NASH".

This poster, the abstract of which can be viewed and downloaded on the ILC's website, provides key insights on the use of clinically meaningful threshold NIS4 values for non-invasive screening of patients with risk factors for NASH and accurate identification of patients who should be considered for pharmacological intervention (NASH with NAS \geq 4 and significant fibrosis defined as F \geq 2).





As indicated below, in January 2019, the Company signed a license agreement with Covance regarding NIS4 (see section 2.2 below).

Repurposing of nitazoxanide in fibrosis (TGFTX4 program)

Enrollment of patients in the Phase 2 proof-of-concept study to evaluate nitazoxanide in NASH patients with advanced fibrosis continued throughout the first half of 2019. We expect to publish the top line results of this trial in mid-2020.

In April, at the 2019 ILC, GENFIT presented its ongoing approach to evaluating elafibranor as the basis for combination therapies in NASH in an oral presentation "Elafibranor and nitazoxanide synergize to reduce fibrosis in a NASH model" that highlighted new results on the complementary actions of both GENFIT drug candidates, elafibranor and nitazoxanide, to reduce fibrosis in NASH. The abstract is available to view and download on the ILC's website.

Business Development Activities

Our business development efforts to sign licensing agreements or joint marketing agreements with one or more pharmaceutical companies with the financial capacity and specific expertise required to successfully complete clinical trials and bring medicines and/or diagnostic tools to market materialized in the first half of 2019 with the signature of two agreements, one in the field of diagnostics and the other concerning the development of elafibranor in China.

In January, the Company signed a licensing agreement with Covance, LabCorp's drug development business. The licensing agreement aims to expand access to NIS4, a non-invasive IVD test developed by GENFIT to identify and monitor NASH patients, in the clinical research space. The primary focus of the licensing agreement is to deploy NIS4 in the clinical research space through Covance's central laboratories to further validate the test's use for better identification and characterization of patients, and to generate new biological insights on NASH disease pathogenesis.

Both LabCorp Diagnostics and Covance have been involved in the development of drugs and diagnostics for more than 20 years, and Covance is a recognized global leader in NASH clinical trials.

At the end of June, the Company announced the signing of a licensing and collaboration agreement with Terns Pharmaceuticals ("Terns"), granting Terns the rights to develop and





commercialize elafibranor, GENFIT's proprietary compound, in Greater China. Under the terms of the licensing agreement, GENFIT received an upfront payment from Terns of \$35 million and will be eligible to receive up to \$193 million in potential clinical, regulatory and commercial milestone payments. Terns obtains the exclusive rights to develop, register and market elafibranor in mainland China, Hong Kong, Macau and Taiwan ("Greater China") for both NASH and PBC. Upon commercial launch of elafibranor for the treatment of NASH in Greater China, GENFIT will be entitled to receive mid-teen percentage royalties from Terns based on sales in the territory.

As part of the deal, GENFIT and Terns will also undertake joint R&D projects in liver disease, including the development of elafibranor in combination with Terns' proprietary compounds.

Backed by experienced investors in the pharmaceutical industry, including Orbimed, Lilly Asia Ventures, Vivo Capital and Decheng Capital, Terns, an international company based in the United States and China, has extensive clinical development capabilities in China and a robust pipeline of early-stage candidates that present promising opportunities for potential combination therapy with elafibranor.

We believe that, with a strong presence in China, a seasoned leadership team, and roots in the San Francisco Bay Area biotechnology hub, Terns is well-positioned to maximize elafibranor's value in China. Terns' large footprint in both geographies provides an advantage in navigating the development and regulatory processes required to obtain approvals in Greater China territories, while also ensuring the preparation for a strong commercial launch and long-term sales growth.

Corporate development activities

At the end of March, the Company completed its initial public offering on the Nasdaq Select Global Market, raising a total gross amount of approximately US \$ 155.4 million in a global offer of American Depositary Shares (ADS) in the United States and a private placement of shares in Europe (including in France) and other countries outside the United States. GENFIT placed 7,647,500 new shares at an issue price of USD 20.32 per ADS and EUR 18.00 per new share. The offer represented approximately 20% of the share capital before the transaction and brought the total number of shares after IPO to 38,831,421.

GENFIT's ordinary shares are listed on the regulated market of Euronext in Paris under the symbol "GNFT". Since March 27, 2019, our ADSs are listed on the Nasdaq Global Select Market in the United States, under the symbol "GNFT".

Main events after the reporting period





At the end of July, the Company announced that the FDA and EMA had granted Orphan Drug designation to elafibranor for the treatment of PBC.

Early September, following the decision of Jean-François Mouney to focus exclusively on his roles as Chairman of the Board and member/chairman of several of its committees, the Company announced that it would separate the roles of Chairman and CEO. On his recommendation, Pascal Prigent, currently the EVP of Marketing and Commercial Development, has been appointed as CEO by the Board, starting from September 16, 2019. Dr. Dean Hum, Chief Operating Officer and Chief Scientific Officer, was named Chairman of GENFIT Corp, the Company's US subsidiary.

Since joining GENFIT in May 2018, Pascal Prigent has worked closely with Jean-François Mouney and Dr. Hum, since his arrival. A member of the Executive Committee, Pascal is instrumental in establishing a global team of high profile collaborators and consultants with the objective to prepare for the potential commercialization of elafibranor and NIS4. Prior to GENFIT, Pascal had over 20 years of experience in the pharmaceutical industry, including international management roles with Eli Lilly and GlaxoSmithKline.

In September, we also announced the:

- arrival of Dr. Carol L. Addy as Chief Medical Officer. Dr. Addy, who is based in the Cambridge, M.A. office, will drive the medical strategy of the Company, including clinical development and medical affairs. She brings with her over 20 years of experience in the healthcare space, and over 10 years leading clinical development teams in the pharmaceutical industry, supporting early and late-stage investigation of novel drugs and creating innovative solutions for the life-cycle management of approved therapies in obesity and diabetes. Prior to joining GENFIT, she held various leadership roles, including most recently, Chief Medical Officer at Health Management Resources, a subsidiary of Merck & Co., and as Associate Director, Director and Senior Principal Scientist at Merck Research Laboratories.
- the promotion of Dr. Suneil Hosmane to Head of Global Diagnostics. Suneil, who joined GENFIT Corp. in 2018 as Executive Vice President of Strategic Development, will manage the development and marketing activities related to NIS4. Beyond NIS4, Suneil will also be spearheading the in-house biomarker discovery program and designing additional noninvasive diagnostic solutions for metabolic and liver diseases.

Dr. Addy and Dr. Hosmane have both joined the Company's Executive Committee.





Finally, through its strategic partnership with Terns Pharmaceuticals, the Company received, after the reporting period, the USD \$35 million upfront payment under the license and collaboration agreement.

See also Note 6.27 to the 2019 half year consolidated financial statements for other events after the reporting period.





APPENDICES

GENFIT

Half-year Consolidated

Financial Results

At June 30, 2019

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, 2019 were approved by Board of Directors on September 30, 2019.

The full consolidated financial statements as well as the notes to the consolidated financial statements for the period ended June 30, 2019 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, 2019 and available on the "Investors" page of the GENFIT website.





Condensed Consolidated Statement of Financial Position

ASSETS	As of	:	
(in € thousands)	2018/12/31	2019/06/30	
Current assets			
Cash and cash equivalents	207 240	281 920	
Current trade and others receivables	8 794	19 161	
Other current assets	2 078	3 303	
Inventories	4	4	
Total - Current assets	218 116	304 389	
Non-current assets			
Intangible assets	796	1 017	
Property, plant and equipment	7 764	17 250	
Non-current trade and others receivables	1 489	(
Other non-current financial assets	1 313	1 055	
Deferred tax assets	0	(
Total - Non-current assets	11 362	19 322	
Total – Assets	229 478	323 710	
SHAREHOLDERS' EQUITY AND LIABILITIES	As of		
(in € thousands)	2018/12/31	2019/06/30	
Current liabilities			
Current convertible loans	1 312	1 312	
Other current loans and borrowings	1 848	3 061	
Current trade and other payables	35 974	40 948	
Current deferred income and revenue	1	10 3 10	
Current provisions	112	1 906	
Total - Current liabilities	39 248	47 229	
Non-current liabilities			
Non-current convertible loans	159 176	161 612	
Other non-current loans and borrowings	7 255	16 048	
Non-current employee benefits	1 085	1 291	
Deferred tax liabilities	1 773	1 486	
Total - Non-current liabilities	169 291	180 437	
Shareholders' equity			
Share capital	7 796	9 708	
Share premium	251 554	376 477	
Accumulated deficit	(158 897)	(239 014)	
Currency translation adjustment	6	7	
Net loss	(79 521)	(51 132)	
Total shareholders' equity - Group share	20 939	96 044	
Non-controlling interests	0	0	
Total - Shareholders' equity	20 939	96 044	





Total - Shareholders' equity & liabilities

229 478

323 710





Condensed Consolidated Statement of Operations

	Half-year ended		
(in € thousands, except earnings per share data)	2018/06/30 corrected (*)	2019/06/30	
Revenues and other income			
Revenue	64		
Other income	5 057	5 3.	
Revenues and other income	5 122	5 3	
Operating expenses and other operating income (expenses)			
Research and development expenses	(32 072)	(38 89	
General and administrative expenses	(4 565)	(12 40	
Other operating income (expenses)	(40)		
Operating loss	(31 555)	(45 93	
Financial income	331	17	
Financial expenses	(5 572)	(7 24	
Financial loss	(5 241)	(5 48	
Net loss before tax	(36 796)	(51 42	
Income tax expense	121	2	
Net loss	(36 675)	(51 13	
Attributable to owners of the Company	(36 675)	(51 13	
Attributable to non-controlling interests	0		
Basic and diluted loss per share			
Basic loss per share (€/share)	(1.18)	(1.6	

^{*} See note 6.3.3 "Correction of errors" to the 2019 half year consolidated financial statements.





Condensed Statement of Cash Flows

(in € thousands) 30/06/2018 corrected (*) Cash flows from operating activities + Net loss (36 675) (79 521) + Non-controlling interets 0 0 Reconciliation of net loss to net cash used in operating activities Adjustments for: + Amortization 832 1 819 + Depreciation and impairment charges (25) (208) + Expenses related to share-based compensation 271 787 - Gain on disposal of property, plant and equipment (2) (2) + Net finance expenses 5 469 10 971 + Income tax expense (121) (354) + Other non-cash items 1 0 Change in: Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade receivables and other liabilities 4 300 11 056 Change in working capital (1 356) 10 332	30/06/2019 (51 132
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+ Net finance expenses 5 469 10 971 + Income tax expense (121) (354) + Other non-cash items 1 0 Operating cash flows before change in working capital (30 250) (66 507) Change in: Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	350
+ Income tax expense (121) (354) + Other non-cash items 1 0 Operating cash flows before change in working capital (30 250) (66 507) Change in: Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	(1
+ Other non-cash items 1 0 Operating cash flows before change in working capital (30 250) (66 507) Change in: Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	5 669
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Change in: Decrease / (increase) in inventories Increase in trade receivables and other assets Increase in trade payables and other liabilities Change in: (0) (0) (724) (724) (725) (724) (726) (726) (727) (727) (728)	(11
Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	(42 062
Decrease / (increase) in inventories (0) (0) Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	
Increase in trade receivables and other assets (5 657) (724) Increase in trade payables and other liabilities 4 300 11 056	(
Increase in trade payables and other liabilities 4 300 11 056	(10 103
	5 30
Change in working capital (1 356) 10 332	5 50.
Change in Working capital	(4 797
Income tax paid 59 93	(
Net cash flows used in operating activities (31 547) (56 081)	(46 859
Cash flows from investment activities	
- Acquisition of property, plant and equipment (983) (2 938)	(65
+ Proceeds from disposal of property, plant and equipment 0 3	(0)
- Acquisition of financial instruments (48) (1 050)	(128
+ Proceeds from sale of financial instruments 0 0	(123
- Acquisition of subsidiary, net of cash acquired 0 0	(
Net cash flows used in investment activities (1 031) (3 986)	(193
Cash flows from financing activities	106 17
+ Proceeds from issue of share capital (net) 0 0	126 47
+ Proceeds from subscription / exercise of share warrants 0 37	(
+ Proceeds from new loans and borrowings net of issue costs 800 1 800	
- Repayments of loans and borrowings (961) (2 000)	
- Financial interests paid (including finance lease) (3 071) (6 351)	(1 513)
Net cash flows provided by / (used in) financing activities (3 232) (6 514)	(1 513 (3 234





Increase / (decre	ease) in cash and cash equivalents	(35 810)	(66 580)	74 680
Cash and cash e	quivalents at the beginning of the period	273 820	273 820	207 240
Cash and cash e	quivalents at the end of the period	238 010	207 240	281 920

^{*}See note 6.3.3 "Correction of errors" to the 2019 half year consolidated financial statements.





Discussion of the 2019 half year results

Comments on the condensed statement of net income for the periods ended June 30, 2018 and June 30, 2019

(i) Revenue and other income

The Company's revenue and other income results was primarily the result of the research tax credit

Given the date of the signature of the agreement with Terns Pharmaceuticals (June 24, 2019) and the obligations there under, the Company considered that the revenues from the USD\$35 million upfront payment would be recognized in the second half of 2019 (see Note 6.4.2 of the condensed consolidated 2019 half year financial statements).

Revenue and other income	Half-year	Half-year ended		
(in € thousands)	2018/06/30	2019/06/30		
Revenues	64	1		
Government grants	0	2		
Research Tax Credit	4 981	5 350		
Other operating income	76	4		
TOTAL	5 122	5 357		

Revenue and other income was \leq 5,357 thousand at June 30, 2019 compared to \leq 5,122 thousand for the same period in the previous year.

(i) 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, and general and administrative expenses on the other, for the half years ended June 30, 2018 and 2019.





Operating expenses and	Half-year ended	Of which:					
other operating income (expenses)	2018/06/30	Raw materials	Contracted	Employee	Other	Depreciation,	Gain / (loss)
		and consumables	research and	expenses	expenses	amortization	on disposal of
		used	development		(maintenance, fees,	and impairment	property, plant
			activities		travel, taxes)	charges	and equipment
			conducted by				
(in € thousands)			third parties				
Research and development expenses	(32 072)	(922)	(22 745)	(4 624)	(3 000)	(781)	(1)
General and administrative expenses	(4 565)	(70)	(2)	(1 687)	(2 882)	74	2
Other operating income and (expenses)	(40)	0	0	0	(40)	0	0
TOTAL	(36 677)	(992)	(22 747)	(6 311)	(5 921)	(707)	2

Operating expenses	Half-year ended				Of which:		
and other operating income (expenses)	2019/06/30	Raw materials	Contracted	Employee	Other	Depreciation,	Gain / (loss)
		and consumables	research and	expenses	expenses	amortization	on disposal of
		used	development		(maintenance, fees,	and impairment	property, plant
			activities		travel, taxes)	charges	and equipment
			conducted by				
(in € thousands)			third parties				
Research and development expenses	(38 899)	(1 068)	(25 909)	(6 206)	(2 564)	(3 152)	0
General and administrative expenses	(12 402)	(114)	(1)	(4 964)	(7 206)	(117)	0
Other operating income and (expenses)	7	0	0	0	6	0	1
TOTAL	(51 294)	(1 182)	(25 910)	(11 170)	(9 764)	(3 269)	1





Operating expenses in the first half 2019 amounted to €51,294 thousand compared to €36,677 thousand in first half 2018, or a 40% increase. They include, in particular:

• research and development expenses, which include employee-related expenses for employees in research and development functions (€6,206 thousand at June 30, 2019 compared to €4,624 thousand at June 30, 2018), the cost of consumables and contracted research and development activities (particularly clinical and pharmaceutical expenses) representing €26,977 thousand at June 30, 2019 compared to €23,667 thousand at June 30, 2018) and expenses related to intellectual property. These research and development expenses amounted to €38,899 thousand at June 30, 2019 compared to €32,072 thousand at June 30, 2018, or 76% and 87% of operating expenses, respectively.

The increase in contracted research and development expenses is mainly due to the start of new phase 3 RESOLVE-IT satellite studies, work necessary to prepare the new drug application for elafibranor in NASH, and the increase in production of active principal ingredient required to carry out the various clinical studies.

Changes in employee-related expenses for employees in research and development functions is mainly due to increased headcount (117 vs. 89), changes in employee profiles, related increases in compensation as well as bonuses granted to employees for their contributions to the Group's development.

The increase in depreciation, 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 and the application as from January 1, 2019 of IFRS 16 to leases.

We expect that our research and development expenses will continue to increase in the near future, as we begin new clinical trials and advance our clinical development pipeline and the development of our NIS4 IVD test.

• **general and administrative expenses**, which include the costs of personnel not assigned to research (€4,964 thousand at June 30, 2019 compared to €1,687 thousand at June 30, 2018), and administrative and commercial costs.





These general and administrative expenses amounted to €12,402 thousand in the first half 2019 compared with €4,565 thousand in the first half 2018, or 24% and 12% of operating expenses and other operating income, respectively.

Changes in general and administrative expenses are mainly related to increases in the cost of insurance premiums in relation to the listing of the Company's shares on the Nasdaq, accounting and statutory auditor fees related to the listing, and expenses for market access and pre-marketing projects.

Changes in employee-related expenses paid to employees in general and administrative functions was primarily the result of an increase in headcount (57 vs. 41 employees), changes in employees profiles, a related increase in salaries, in particular for GENFIT Corp, as well as bonuses that were granted to employees for their contribution to the Group's development.

We expect that our general and administrative expenses will continue to increase in correlation with the growth of our support functions, in light of the expected increase in research and development activities and the potential commercialization of our drug candidates and diagnostics.

(ii) Operating expenses and other operating income 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 €25,910 thousand in the first half 2019 compared to €22,747 thousand in the first half 2018, corresponding to a 14% increase, which is mainly due to the new phase 3 RESOLVE-IT satellite studies, work necessary to prepare the new drug application for elafibranor in NASH, and the increase in production of active principal ingredient required to carry out the various clinical studies.





Employee expenses

Employee expenses	Half-year ended	
(in € thousands)	2018/06/30	2019/06/30
Wages and salaries	(4 387)	(7 998)
Social security costs	(1 617)	(2 748)
Changes in pension provision	(36)	(69)
Share-based compensation	(271)	(356)
TOTAL	(6 311)	(11 170)

Employee expenses excluding share-based compensation amounted to €10,814 thousand in the first half 2019 compared to €6,040 thousand in the first half 2018, or a 79% increase, mainly due to an increase in headcount (174 vs. 130 employees), changes in employee profiles, a related increase in salaries, as well as bonuses that were granted to employees for their contribution to the Group's development.

The amount recognized as share-based compensation (BSA, BSAAR, SO and AGA) free of any impact on cash flow amounted to €356k in the first half 2019 compared to €271 thousand in the first half 2018. The expenses recorded in the first half of 2019 relate to the SO and AGA plans put in place in December 2016, and to the BSA, SO and AGA plans put in place in December 2017, and to the SO and AGA plans put in place in November 2018.

Other expenses

Other expenses amount to $\leq 9,764$ thousand in the first half 2019 compared to $\leq 5,921$ thousand in the first half 2018. 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 the
 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 nonrecurring Public Offering of Securities insurance policy and a recurring Directors & Officers civil liability insurance policy;





- 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 costs of insurance premiums in relation to the listing of the Company's shares on the Nasdaq, accounting and statutory auditor fees related to the listing, and expenses for market access and pre-marketing projects.

(iii) Financial income (expense)

Financial income (expense) as of June 30, 2019 amounted to a loss of €5,485 thousand compared to financial loss of €5,241 thousand in the previous half year, consisting primarily of realized and unrealized foreign currency exchange rate loss of €1,563k partially compensated by foreign exchange rate gains and an increase in financial income due to the increase of cash held in US dollars and to investments in US dollars where the return is significantly higher than investments in euros.

(iv) Net income (loss)

The first half 2019 resulted in a net loss of €51,132 thousand compared to a net loss of €36,675 thousand in the first half 2018. The net loss for the 2018 fiscal year amounted to €79,521 thousand.

Liquidity and capital resources at June 30, 2019

At June 30, 2019 the total amount of the Group's Statement of Financial Position amounted to €323,710 thousand compared to €229,478 thousand as of December 31, 2018.

At June 30, 2019, the Group's cash, cash equivalents and other financial assets amounted to €282,975 thousand, compared to €208,553 thousand as of December 31, 2018.





(i) Non current assets

Non-current assets, which include trade and other receivables, goodwill and intangible, tangible, and financial assets, increased from €11,362 thousand as of December 31, 2018 to €19,322 thousand at June 30, 2019. This increase is mainly due the impact of first time IFRS 16 application that lead to recording a right of use to leased premises (for more information, see the 2019 half year consolidated financial statements).

(ii) Current assets

Current assets amounted to €304,389 thousand at June 30, 2019 compared to €218,116 thousand as of December 31, 2018.

Cash and cash equivalents went from €207,240 thousand at December 31, 2018 to €281,920 thousand at June 30, 2019, or a decrease of 36%, in a period where the Company carried out an approximately USD\$155.4 capital raise (gross) at the end of March 2019.

Cash is mainly placed in low risk, highly-liquid short term placements.

The variation of trade and other receivables is mainly due to the €3,000k (tax included) due by the lessor following delivery of the extension of the Company's headquarters and by the recognition of the estimated amount of the Research Tax Credit receivable for the first half 2019. Additional details regarding these receivables are provided in note 6.9 to the 2019 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 2019.

(iii) Shareholders' equity

As of June 30, 2019, the Group's shareholders' equity totaled €96,044 thousand compared to €20,939 thousand as of December 31, 2018.

The change in the Company's shareholders' equity is mainly due to capital raising during the first half 2019 and 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 2019 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 2019 half year consolidated financial statements included herein; and
- bank loans; and
- the liabilities related to operating leases pursuant to IFRS 16, as of January 1, 2019.

(v) **Current liabilities**

Current liabilities	As	of
(in € thousands)	2018/12/31	2019/06/30
Current convertible loans	1 312	1 312
Current loans & borrowings	1 848	3 061
Current trade & other payables	35 974	40 948
Current deferred income and revenue	1	1
Current provisions	112	1 906
Total	39 248	47 229

This balance sheet item mainly includes interest payments on the OCEANE issued in October 2017, bank loans and trade and social security payables and debts under operating leases. The change in current liabilities is mainly due to the increase in operational subcontracting expenses and the impact of IFRS 16 as of January 1, 2019. See also notes 6.12 and 6.13 to the consolidated financial statements for the first half of 2019 below.





ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product candidate. Elafibranor is an oral, once-daily, first-inclass drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation. GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

ABOUT NIS4

GENFIT is developing an *in vitro* diagnostic (IVD) test to identify and monitor patients eligible for therapeutic intervention. This program is based on the in-house discovery of a 4-biomarker algorithm potentially replacing biopsy with a single blood test. In January, 2019, GENFIT signed a licensing agreement with Labcorp® to roll out the diagnostic kit in the clinical research field, and plans to file for regulatory submission for NIS4 as early as 2020.

ABOUT NASH

"NASH" is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.

ABOUT RESOLVE-IT

RESOLVE-IT is a phase 3 study evaluating the efficacy and safety of elafibranor 120mg versus placebo in patients with nonalcoholic steatohepatitis (NASH) and fibrosis. It is a multicenter, randomized, double-blind, placebo-controlled study with 2 arms. It is conducted under Subpart H (FDA) and conditional approval (EMA). Treatment duration until interim analysis for accelerated approval is 72 weeks.

ABOUT PBC

"PBC" is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis. Elafibranor has shown promising results for the treatment of PBC in a





Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC later this year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 160 employees. GENFIT is a public company listed on the Nasdaq Global Select Market and in compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including, but not limited to statements about the potential for the RESOLVE-IT interim results to be conclusive, the timing and potential success of the market launch of elafibranor in NASH and of NIS4, the Company's future expansion and growth, the Company's capacity and the timeline on which it will be able to offer treatments and diagnostic solutions, the preparation of the NDA for elafibranor in NASH, the launch of a Phase 3 clinical trial evaluating elafibranor in PBC, the launch of a POC clinical trial evaluating elafibranor in combination with a GLP1 agonist and SGLT2 inhibitor, the potential for elafibranor to improve the quantity and quality of fat in the liver, the Company's capacity to publish the top line results of the trial evaluating NTZ in mid-2020, the Company's capacity to ensure a strong commercial launch and long-term sales growth for elafibranor in NASH and PBC and the beginning of new clinical trials and advancement of our clinical development pipeline and development of our NIS4 IVD test. 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 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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