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### **2017: a year of very significant reinforcement of the cash position (€274M at 12.31.2017), with all programs in the Company's pipeline moving forward.**

- **Financial results reflect in particular the significant ramp-up of the phase 3 RESOLVE-IT study of elafibranor in NASH and the €180M convertible bond issuance in Fall 2017**
- **Important progress in all of the Company's other development programs and in particular those that are the most advanced: in vitro diagnostic and pediatric NASH; clinical development of elafibranor in PBC**
- **Results of the phase 2 study of elafibranor in PBC and filing of an IND application for the launch of a phase 2 study in fibrosis expected in 2018**

**Lille (France), Cambridge (Massachusetts, United States), March 13, 2018** – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical group at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, today announces its annual financial results for 2017. A summary of the consolidated financial statements is included in this press release. The 2017 annual consolidated financial statements are available on the "Investors" page of the GENFIT website.

**Jean-François Mouney, Chairman & CEO of GENFIT**, commented: *"All programs in the pipeline, particularly those that are the most advanced, have moved forward or have reached significant milestones in 2017; whether it is the phase 3 clinical development program of elafibranor in NASH; phase 2 clinical development program evaluating elafibranor in PBC, which mid-year entered its active recruitment phase; or even our NASH in vitro diagnostic (IVD) program that successfully completed its feasibility phase and began its development phase last June.*

*Despite the increased costs engendered by these advances and which are reflected in our financial results, the success of the €180 million convertible bond issue last Fall has improved our cash position. It amounted to €274 million at the end of the financial year, compared to €152 million a year earlier. Beyond increasing our ability to invest in our various programs, the scale of this fundraising gives us significantly greater freedom in view of marketing elafibranor by 2020, with the unchanged view to generate a dual source of income - retaining rights in certain territories and reserving a significant share of the market for future partnerships.*

*In the meantime, the results of the phase 2 clinical trial evaluating elafibranor in PBC are expected by the end of 2018. We also hope that an authorization to launch another phase 2 trial with another pipeline product in liver fibrosis will be obtained in the coming months.*

*Finally, GENFIT will take advantage of the fact that the EASL Annual Meeting is taking place this year in Paris from April 11 to 15, 2018, to be particularly present during this event and to provide*



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*an update on the enrollment of the first group of approximately 1,000 patients in the RESOLVE-IT phase 3 study.”*

### **Main financial results:**

Key aspects of the 2017 results are:

- Cash, cash equivalents and other current financial assets of €273.8 million at December 31, 2017 (€152.4 million at December 31, 2016) reinforced by an issuance of convertible bonds (OCEANE) for a nominal amount of approximately €180 million in October 2017 in a context of a significant increase in current and projected operating expenses relating to the progression of the R&D portfolio;
- Operating income of €6.9 million (€6.8 million at December 31, 2016) essentially from the Research Tax Credit, which amounted to €6.5 million for 2017 compared with €6 million in 2016;
- Operating expenses of €63.6 million (€40.9 million in 2016) of which 85% represented R&D expenses. The increase in operating expenses is due:
  - to the increase in contracted research and development expenses resulting from the progress of the R&D program pipeline, of which the majority relate to expenses for the phase 3 study of elafibranor in NASH;
  - an increase in payroll expense, resulting from changes in employee profiles, salary increases, the impact of bonuses paid to employees in light of their implication in the Group’s development and finally, the increase in headcount (from 119 at December 31, 2016 to 125 at December 31, 2017);
  - an increase in other operating expenses relating to the yearly grant to The NASH Education Program™ endowment fund, the use of external service providers for clinical development and intellectual property expenses and fees.
- As a result of changes in revenues and expenses, a net loss of €58.6 million at December 31, 2017 (€33.7 million in 2016).

The following table summarizes the Consolidated Statement of Operations under IFRS for the 2017 fiscal year, with comparative figures for the 2016 fiscal year.



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(in € thousands, except earnings per share data)	Year ended	
	2016/12/31	2017/12/31
<b>Revenues and other income</b>		
Revenue	284	118
Other income	6 499	6 737
<b>Revenues and other income</b>	<b>6 783</b>	<b>6 856</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research & development expenses	(32 959)	(54 189)
General & administrative expenses	(7 938)	(9 421)
Other operating income	(2)	(9)
Other operating expenses	(42)	69
<b>Operating loss</b>	<b>(34 158)</b>	<b>(56 695)</b>
Financial revenue	729	642
Financial expenses	(203)	(2 168)
<b>Financial loss</b>	<b>526</b>	<b>(1 526)</b>
Income tax	(35)	(384)
<b>Net loss</b>	<b>(33 667)</b>	<b>(58 604)</b>

The summary IFRS consolidated financial statements at December 31, 2017 as well as the management discussion of the results, are presented in the appendix at the end of this document.

### Main developments in the R&D pipeline programs since January 1, 2017

#### **Clinical development program of elafibranor in NASH**

Elafibranor is GENFIT's lead pipeline product. It is an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (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 but also a severe increase in the risk of cardiovascular problems. Elafibranor has demonstrated its ability to treat the multiple factors in NASH, in particular necro-inflammation, the main cause of progression to cirrhosis, all the while improving the cardiometabolic risk profile.

#### ***RESOLVE-IT Phase 3 study***

Enrollment and treatment of patients in the RESOLVE-IT Phase 3 study continued during the course of 2017.



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RESOLVE-IT is a phase 3 study to evaluate the beneficial effect and safety of elafibranor against placebo in NASH patients with fibrosis. RESOLVE-IT is a multicenter a randomized, double-blind, placebo-controlled (2:1) trial. An interim analysis under an accelerate process for initial market approval under Subpart H (Food and Drug Administration (FDA)/US) and conditional approval (European Medicines Agency (EMA)/Europe) will be performed after 72 weeks.

Subject to satisfactory clinical results obtained during the first stage of this study in approximately 1,000 patients, which is expected to be made public at the end of 2019, if the timelines estimated by the Company for its completion and analysis are met, a conditional marketing authorization, in particular in the United States and Europe, could be obtained for elafibranor in NASH during the course of 2020 subject to approval by the regulatory agencies.

The Data Safety Monitoring Board (DSMB) -a monitoring committee set up as part of the RESOLVE-IT trial – conducted a safety and tolerability review of the safety data collected during the study, including adverse events and laboratory data, during its planned 18-month review. It recommended, in November 2017, the continuation of the clinical trial without any modification; which allowed for the continued active enrolment of patients.

The positive outcome of this review, based on a large number of patients already enrolled in RESOLVE-IT, confirmed the good safety and tolerability profile of elafibranor; which is crucial for any drug candidate designed to treat a chronic disease such as NASH.

### ***Pediatric program in NASH***

After the agreement on the pediatric investigation plan obtained from the EMA, in January 2018, the FDA accepted the initial pediatric study plan (PSP) in NASH in the United States. Data from the GOLDEN 505 Phase 2b trial presented in support of this application show the potential benefit of elafibranor in the pediatric population in terms of safety and histological efficacy and cardiometabolic benefit.

This agreement allows the launch of the pediatric clinical study to evaluate the safety and efficacy of elafibranor in children with NASH.

### ***Opportunities in combination therapy***

During 2017, the Company was proactive in its combination therapy approaches in NASH, with elafibranor as the background therapy.

To address the multifactoral nature of the disease and the multiple co-morbidities that NASH patients face, the Company is evaluating the following therapeutic potential of combinations with elafibranor:

- compounds from other GENFIT programs;
- already marketed drugs with complementary mechanisms of action;
- the most advanced compounds in the current NASH clinical landscape.

In this context, during the International Liver Congress organized by EASL in April 2017, the Company presented promising preclinical data on the therapeutic synergies of elafibranor with an FXR agonist illustrating the potential for new combination treatments with elafibranor.



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

Elafibranor is also evaluated in a phase 2 clinical trial in patients with Primary Biliary Cholangitis (PBC).

PBC is a rare, chronic disease with unmet needs and only two approved orphan drugs available to date. This disease is characterized by a gradual destruction of the bile ducts in the liver which can inhibit the liver's ability to rid the body of toxins, and lead to scarring of liver tissue known as cirrhosis. Current treatments treat only a portion of the patient population and/or generate significant side effects such as pruritus, a major and well-known symptom already affecting most patients with this disease.

The main objective of this study is to determine the effect of daily oral administration of elafibranor on serum alkaline phosphatase (ALP) in PBC patients with an inadequate response to ursodeoxycholic acid.

The first patient was enrolled in the study in May 2017 and patients have been actively enrolling in the study since then. The main characteristics of this international, multicenter study in the U.S. and in three European countries are as follows:

- 3 arms: elafibranor 80mg, 120mg, placebo;
- 45 patients (15 patients per arm);
- 12 weeks treatment.

The preliminary study results should be available, subject to meeting the Company's estimated timelines for carrying out the study and analyzing its results, at the end of 2018.

### **In vitro diagnostic program in NASH (BMGFT03)**

As a major player in NASH engaged in the development of an integrated approach to the clinical management of NASH patients, GENFIT is leading an ambitious research and development program (BMGFT03) aimed at providing patients and practitioners a non-invasive and easy to access diagnostic blood test for NASH. This in vitro diagnostic program entered the development phase in June 2017, and is expected to be commercialized in 2020/2021.

The test that the Company intends to develop will avoid the known risks and limitations of biopsy, and ideally, provide access to the greatest number of patients, including in primary care settings, to a tool able to diagnose NASH at risk of progression.

On the basis of a discovery program to identify circulating miRNAs as potential biomarkers of NASH and fibrosis in two independent cohorts of patients (Professor Sven Francque, LBP-535, EASL 2017), GENFIT presented in April 2017 data concerning the identification of a simple diagnostic score to identify NASH patients to be treated (Professor Stephen A. Harrison, LBP-534, EASL 2017).

This unique signature combining miR34a and three independent biomarkers was identified using advanced biostatistical approaches, and validated in samples from multiple cohorts, including patients selected for recruitment in the RESOLVE-IT phase 3 study.



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This validation thus concluded the numerous feasibility studies undertaken under the BMGFT3 program; work that suggests that this signature could answer different medical needs, at different steps of the patient journey, allowing general practitioners, endocrinologists, diabetologists and hepatologists to support their diagnosis including decision to treat a patient with an anti-NASH drug.

Based on this, starting in June 2017, GENFIT entered the development phase for this diagnostic score in the form of an in vitro diagnostic test/kit (IVD). GENFIT intends to partner with a major diagnostic company with particular expertise in microRNA application to IVD, for the development of the test within IVD regulatory requirements, as well as the manufacturing of the kits.

Although GENFIT is undertaking, through its BMGFT03 program, one of the most developed industrial programs in the field of NASH diagnostic biomarkers, but also recognizing the potential of industry-wide approaches to broaden the scope of research and develop its collaborative programs, in 2017, GENFIT signed onto the LITMUS program. LITMUS (Liver Investigation: Testing Marker Utility in Steatohepatitis) is a consortium funded by the European Innovative Medicines Initiative 2 Joint Undertaking (Grant Agreement No.777377), a public-private partnership between the European Union and the European pharmaceutical industry (via EFPIA). GENFIT will provide LITMUS with samples from its RESOLVE-IT clinical trial and, importantly thanks to the sizeable longitudinal cohorts it will be able to access through the consortium, will have the opportunity to further demonstrate clinical performance of GENFIT diagnostic solution, accelerating clinical adoption by the medical community through production of scientific publications and increased visibility.

### **Clinical development program of anti-fibrotic drug candidates (TGFTX4 program)**

In the context of the TGFTX4 program, the Company has identified several potential drug candidates that show strong anti-fibrotic activity in both cell-based assays and in vivo disease models.

These results were obtained either by the therapeutic repurposing of compounds approved in another indication – allowing the Company to shorten development time – or by a more classical hit-to-lead optimization of the Company's proprietary compounds using a phenotypic screening approach in TGF beta-activated human hepatic stellate cells.

Nitazoxanide, an antiparasitic drug with proven safety, was repurposed as a potent antifibrotic agent with efficacy demonstrated in two disease models of liver fibrosis, as presented at the International Liver Congress organized by EASL in April 2017.

An application for authorization to launch a first Proof-of-concept phase 2a study of nitazoxanide in NASH patients with advanced fibrosis is expected to be filed with the FDA in the coming months.

### **TGFTX1 program (RORgt)**

As part of ambitious efforts to diversify and expand its development pipeline in the treatment of autoimmune, inflammatory and fibrotic diseases, the Company has conducted significant work in the design and optimization of novel RORgt inverse agonists.



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The Company has recently launched pre-IND studies for a topically delivered treatment in mild to moderate *psoriasis vulgaris* and also for the treatment of certain respiratory illnesses by inhalation.

As the Company is not a specialist in preclinical and clinical development in these therapeutic areas, it is exploring the possibilities of partnering with a player with an established franchise in dermatology and respiratory diseases to further develop this program.

### **Main corporate developments**

#### **Issuance of convertible bonds**

In October 2017, GENFIT issued bonds convertible or exchangeable into new or existing shares (OCEANE) due October 16, 2022 via a private placement to institutional investors for a nominal amount of approximately €180 million.

The proceeds of the Offering will be used by the Company notably to:

- Complete the Phase 3 clinical development program for elafibranor in NASH and continue the Pediatric Investigation Plan in the same disease;
- Prepare, subject to the results of the Phase 3 pivotal study, the application for marketing approval of elafibranor in NASH;
- Prepare the potential commercialization of elafibranor in certain diseases and/or in certain territories;
- Finance the industrial development stage of a new in vitro diagnostic (IVD) test as part of the continuation of the biomarker program; and
- Reinforce the Company's pipeline through in-licensing or combination therapy strategies in therapeutic areas of interest to the Company.

#### **Governance**

At the June 16, 2017 Extraordinary Shareholders' Meeting, the shareholders approved the change in mode of administration and management of the Company proposed by the management and decided to change from the historical two-tiered board structure of the Company (Executive Board and Supervisory Board) to a one tiered board with a Board of Directors.

The same Meeting also appointed all of the new members of the Board of Directors proposed by management, which is now composed of the following members:

- Jean-François Mouney
- Xavier Guille des Buttes
- Anne-Hélène Monsellato
- Catherine Larue
- Frédéric Desdouits
- Philippe Moons
- Biotech Avenir, represented by Florence Séjourné

The new Board of Directors met following the Ordinary and Extraordinary Shareholders' Meeting and appointed Mr. Jean-François Mouney as Chairman of the Board of Directors and Chief



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Executive Officer of the Company. Mr. Xavier Guille des Buttes was appointed Vice-Chairman of the Board of Directors.

The members of the Audit Committee and the Nominations and Compensation Committee were also appointed:

### **Audit Committee:**

- Anne-Hélène Monsellato, Chairman
- Philippe Moons
- Xavier Guille des Buttes

### **Nominations and Compensation Committee:**

- Xavier Guille des Buttes, Chairman
- Jean-François Mouney
- Catherine Larue

By decision on September 22, 2017, the Board of Directors decided to create an Alliance Committee composed of the following members:

### **Alliance Committee**

- Jean-François Mouney, Chairman
- Frédéric Desdouts
- Xavier Guille des Buttes

Finally, by decision on November 21, 2017, GENFIT's Board of Directors made use of the authorizations granted by the Extraordinary Shareholders' Meeting of June 16, 2017 by granting stock options and free shares to its employees and chief executive officer.

The exercise of stock options and the definitive allocation of free shares are subject to internal and external collective performance conditions assessed over a period of three years, which reflect GENFIT's medium-term objectives. In addition, the Board of Directors used the authorizations granted by the same Shareholders' Meeting to allocate share subscription warrants to its independent board members and to a scientific consultant of the Company.

### **Disease awareness program run by the endowment fund founded by GENFIT**

In March 2017, the Company launched a disease awareness initiative through the endowment fund it founded in 2016, The NASH Education Program™, asserting its leadership in this area, and sparked an unprecedented wave of interest in the French media, even though it is a little known and asymptomatic disease.

This initiative was also intended to be launched in other countries. Encouraged by the interest in its initiatives, The NASH Education Program™ is organizing the first International NASH Information Day on June 12, 2018 to be held in several different countries.





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### Main upcoming events

- 30th Annual ROTH Conference  
March 11-14, 2018  
Dana Point, CA – USA
- Cowen & Co 38th Annual Healthcare Conference  
March 12-14, 2018  
Boston, MA – USA
- 2nd HC Wainwright & Co Annual NASH Investor Conference  
March 19, 2018  
New York, NY – USA
- EASL International Liver Congress  
April 11-15, 2018  
Paris – France
- 2nd Annual NASH Summit  
April 23-25, 2018  
Boston, MA – USA
- International NASH Information Day 2018  
June 12, 2018



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### APPENDICES

#### GENFIT

**Annual Consolidated  
Financial Results  
At December 31, 2017**

The 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 audit procedures on the consolidated financial statements have been performed. The consolidated financial statements for the period ended December 31, 2017 were approved by Board of Directors on March 12, 2018 and will be submitted to the shareholders at the Shareholders' Meeting on June 15, 2018.

The full consolidated financial statements as well as the notes to the consolidated financial statements for the period ended December 31, 2017 are available on GENFIT's website in the "Investors" tab. The annual financial report, included in the registration document, will be available on GENFIT's website in April 2018.



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### Consolidated Statement of Financial Position

ASSETS (in € thousands)	As of	
	2016/12/31	2017/12/31
<b>Non-current assets</b>		
Intangible assets	668	636
Property, plant & equipment	3 010	6 324
Non current trade & others receivables	0	1 921
Other non-current financial assets	541	729
<b>Total - Non-current assets</b>	<b>4 219</b>	<b>9 611</b>
<b>Current assets</b>		
Inventories	14	4
Current trade & others receivables	8 394	7 955
Other current financial assets	174	31
Other current assets	1 137	1 761
Cash & cash equivalents	152 277	273 820
<b>Total - Current assets</b>	<b>161 996</b>	<b>283 572</b>
<b>Total - Assets</b>	<b>166 214</b>	<b>293 183</b>
<b>EQUITY &amp; LIABILITIES</b>		
(in € thousands)	As of	
	2016/12/31	2017/12/31
<b>Shareholders' equity</b>		
Share capital	7 792	7 792
Share premium	237 305	257 580
Retained earnings	(68 654)	(102 531)
Currency translation adjustment	21	(8)
Net loss	(33 667)	(58 604)
<b>Total shareholders' equity - Group share</b>	<b>142 797</b>	<b>104 229</b>
Non-controlling interests	0	0
<b>Total - Shareholders' equity</b>	<b>142 797</b>	<b>104 229</b>
<b>Non-current liabilities</b>		
Non current convertible loans	0	153 611
Other non-current loans & borrowings	5 004	6 978
Non-current deferred income and revenue	3	2
Non-current employee benefits	849	936
Deferred tax liabilities	0	321
<b>Total - Non-current liabilities</b>	<b>5 855</b>	<b>161 848</b>
<b>Current liabilities</b>		
Current convertible loans	0	1 329
Other current loans & borrowings	1 248	1 834
Current trade & other payables	16 146	23 580
Current deferred income and revenue	1	1
Current provisions	167	361
<b>Total - Current liabilities</b>	<b>17 562</b>	<b>27 106</b>
<b>Total - Equity &amp; liabilities</b>	<b>166 214</b>	<b>293 183</b>



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### Statement of Operations

(in € thousands, except earnings per share data)	Year ended	
	2016/12/31	2017/12/31
<b>Revenues and other income</b>		
Revenue	284	118
Other income	6 499	6 737
<b>Revenues and other income</b>	<b>6 783</b>	<b>6 856</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research & development expenses	(32 959)	(54 189)
General & administrative expenses	(7 938)	(9 421)
Other operating income	(2)	(9)
Other operating expenses	(42)	69
<b>Operating loss</b>	<b>(34 158)</b>	<b>(56 695)</b>
Financial revenue	729	642
Financial expenses	(203)	(2 168)
<b>Financial loss</b>	<b>526</b>	<b>(1 526)</b>
Income tax	(35)	(384)
<b>Net loss</b>	<b>(33 667)</b>	<b>(58 604)</b>
Attributable to owners of the Company	(33 667)	(58 604)
Attributable to non-controlling interests	0	0
<b>Basic / diluted loss per share attributable to shareholders of GENFIT</b>		
Basic earnings per share (€/share)	(1.25)	(1.88)



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### Statement of Cash Flows

(in € thousands)	Year ended 31/12/2016	Year ended 31/12/2017
<b>Cash flows from operating activities</b>		
+ Net loss	(33 667)	(58 604)
+ Non-controlling interest		
<b>Reconciliation of net loss and of the cash used for operating activities</b>		
Adjustments for:		
+ Amortization	630	1 226
+ Depreciation & impairment charges	186	186
+ Expenses related to share-based compensation	11	278
- Gain / (loss) on disposal of property, plant & equipment	0	8
+ Net finance expenses / (revenue)	45	1 368
+ Income tax expense	35	384
+ Other non-cash items	(338)	17
<b>Operating cash flows before change in working capital</b>	<b>(33 098)</b>	<b>(55 137)</b>
<b>Change in:</b>		
Decrease (+) / increase (-) in inventories	14	10
Decrease (+) / increase (-) in trade receivables & other assets	(2 942)	(2 106)
Decrease (-) / increase (+) in trade payables & other liabilities	8 828	7 377
<b>Change in working capital</b>	<b>5 900</b>	<b>5 281</b>
Income tax paid	(28)	0
<b>Net cash flows provided by (used in) operating activities</b>	<b>(27 226)</b>	<b>(49 856)</b>
<b>Cash flows from investment activities</b>		
- Acquisition of property, plant & equipment	(2 036)	(2 800)
+ Proceeds from disposal of property, plant & equipment	(0)	15
- Acquisition of financial instruments	(51)	(163)
+ Proceeds from sale of financial instruments	0	0
- Acquisition of subsidiary, net of cash acquired	0	0
<b>Net cash flows provided by (used in) investment activities</b>	<b>(2 086)</b>	<b>(2 948)</b>
<b>Cash flows from financing activities</b>		
+ Proceeds from issue of share capital (net)	121 007	19 960
+ Proceeds from subscription / exercise of share warrants	50	37
+ Proceeds from new loans & borrowings	1 500	157 377
- Repayments of loans & borrowings	(1 034)	(1 655)
- Financial interests paid (including finance lease)	(43)	(1 372)
<b>Net cash flows provided by (used in) financing activities</b>	<b>121 480</b>	<b>174 348</b>
<b>Increase / (decrease) in cash &amp; cash equivalents</b>	<b>92 167</b>	<b>121 544</b>
<b>Cash &amp; cash equivalents at the beginning of the period</b>	<b>60 111</b>	<b>152 277</b>
<b>Cash &amp; cash equivalents at the end of the period</b>	<b>152 277</b>	<b>273 820</b>



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### Discussion of the 2017 results

#### Revenue and other income

The Company's revenue and other income results principally from the research tax credit, its revenues, government grants and other operating income.

Revenue and other income amounts to €6,856 thousand in 2017 compared to €6,783 thousand for the previous year representing an increase of 1%, broken down as follows:

Revenue and other income (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Revenues	284	118
Other income	6 499	6 737
<b>TOTAL</b>	<b>6 783</b>	<b>6 856</b>

#### – Revenues

Revenues amounted to €118 thousand in 2017 compared with €284 thousand in the preceding year, or a decrease of 58%. This decrease in revenues between the two periods is mainly due to the absence of research services performed on behalf of third parties.

#### – Other income

Other income (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Government grants	411	21
Research tax credit for the period	5 964	6 545
Other operating income	124	171
<b>TOTAL</b>	<b>6 499</b>	<b>6 737</b>

Other income includes the Research Tax Credit, government grants and other operating income which amounted to €6,737 thousand in 2017 compared to €6,499 thousand in the preceding year, or an increase of 4%. This increase is mainly due to an increase in the Research Tax Credit which amounted to €6,545 thousand in 2017 compared with €5,964 thousand in 2016, due to a continued increase in development expenses in 2017 in particular related to the advancement of the phase 3 RESOLVE-IT clinical study (see in particular, "operating expenses and other operating income by destination" below).



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### Operating expenses and other operating income by destination

The tables below breaks 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 years ended December 31, 2017 and 2016.

Operating expenses and other operating income (expenses)	Year ended 2016/12/31	Of which:					
		Raw materials & consumables used	Contracted research & development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes...)	Depreciation, amortization & impairment charges	Gain / (loss) on disposal of property, plant & equipment
(in € thousands)							
Research & development expenses	(32 959)	(1 894)	(19 187)	(7 334)	(3 876)	(667)	0
General & administrative expenses	(7 938)	(91)	(0)	(4 321)	(3 395)	(131)	0
Other operating income	(2)	0	0	0	0	0	(2)
Other operating expenses	(42)	0	0	0	(44)	(0)	2
<b>TOTAL</b>	<b>(40 941)</b>	<b>(1 985)</b>	<b>(19 187)</b>	<b>(11 656)</b>	<b>(7 315)</b>	<b>(799)</b>	<b>(0)</b>

Operating expenses and other operating income (expenses)	Year ended 2017/12/31	Of which:					
		Raw materials & consumables used	Contracted research & development activities conducted by third parties	Employee expenses	Other expenses (maintenance, fees, travel, taxes...)	Depreciation, amortization & impairment charges	Gain / (loss) on disposal of property, plant & equipment
(in € thousands)							
Research & development expenses	(54 189)	(2 117)	(35 088)	(7 915)	(7 973)	(1 095)	0
General & administrative expenses	(9 421)	(112)	(7)	(5 491)	(3 374)	(437)	0
Other operating income	(9)	0	0	0	0	0	(9)
Other operating expenses	69	0	0	0	68	1	1
<b>TOTAL</b>	<b>(63 550)</b>	<b>(2 229)</b>	<b>(35 095)</b>	<b>(13 406)</b>	<b>(11 280)</b>	<b>(1 532)</b>	<b>(8)</b>

Operating expenses amounted to -€63,550 thousand in 2017 compared to -€40,941 thousand in the previous year, or a 55% increase. They include, in particular:

- **research and development expenses**, which include the wages and salaries paid to the research staff (€7,915 thousand in 2017 compared to €7,334 thousand in 2016), the cost of consumables and operational outsourcing (particularly clinical and pharmaceutical) representing €37,205 thousand in 2017 compared to €21,081 thousand in 2016) and expenses related to intellectual property. These research and development expenses



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amounted to €54,189 thousand in 2017 compared to €32,959 thousand in 2016, or 85% and 80% of operating expenses, respectively.

The increase in operational outsourcing costs related to the advancement of the phase 3 RESOLVE-IT study of elafibranor in NASH initiated in 2016, increased during 2017 as the study advanced. Other programs also generated operational outsourcing costs in 2017 and 2016, but these amounts were less significant compared to those related to the development of elafibranor in NASH because they are in an earlier stage of R&D.

The expenses for research staff is mainly due to the change in employee profiles, an increase in wages and bonuses granted to these employees for their implication in the Group's development, as well as an increase in research personnel headcount (92 versus 89).

- **general and administrative expenses**, which include the costs staff not assigned to research (€5,491 thousand in 2017 compared to €4,321 thousand in 2016), and administrative and commercial costs.

These general and administrative expenses amounted to €9,421 thousand in 2017 compared with €7,938 thousand in 2016, or 15% and 19% of operating expenses and other operating income, respectively.

Changes in expenses for staff not assigned to research is mainly due to the change in employee profiles, an increase in wages and bonuses granted to these employees for their implication in the Group's development, as well as an increase in headcount (32 versus 30).

### **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 conducted by third parties

Contracted research and development expenses conducted by third parties amounted to -€35,095 thousand in 2017 compared to -€19,187 thousand in the previous year, corresponding to a 83% increase, which is mainly due to the advancement of the phase 3 study of elafibranor in NASH.

Contracted research & development activities conducted by third parties (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Research & development expenses	(19 187)	(35 088)
General & administrative expenses	(0)	(7)
Other operating income	0	0
Other operating expenses	0	0
<b>TOTAL</b>	<b>(19 187)</b>	<b>(35 095)</b>





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### – Employee expenses

Employee expenses (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Research & development expenses	(7 334)	(7 915)
General & administrative expenses	(4 321)	(5 491)
Other operating income	0	0
Other operating expenses	0	0
<b>TOTAL</b>	<b>(11 656)</b>	<b>(13 406)</b>

Employee expenses excluding share-based compensation amounted to -€13,128 thousand in 2017 compared to -€11,645 thousand in the preceding year, or a 13% increase, mainly due to the change in employee profiles, an increase in wages and bonuses granted to these employees for their implication in the Group's development, as well as an increase in headcount (125 versus 119).

The amount recognized as share-based compensation (BSA – warrants, BSAAR-redeemable warrants, SO – stock options and AGA – free shares) free of any impact on cash flow increased from €11 thousand in 2016 to €278 thousand in 2017 as a result of the SO and AGA plans implemented in December 2016 and the BSA, SO and AGA plans implemented in December 2017. The part of expenses related to the SO and AGA plans implemented in December 2016 were recognized in 2016. For further information, please refer to Note 6.21 of the Notes to the Consolidated Financial Statements for the period ended December 31, 2017 available on GENFIT's website.

### – Other expenses

Other expenses (maintenance, fees, travel, taxes...) (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Research & development expenses	(3 876)	(7 973)
General & administrative expenses	(3 395)	(3 374)
Other operating income	0	0
Other operating expenses	(44)	68
<b>TOTAL</b>	<b>(7 315)</b>	<b>(11 280)</b>

Other expenses amount to -€11,280 thousand in 2017 compared to -€7,315 thousand in 2016, or an increase of 65%. They include, in particular:

- "fees," which include legal, audit, accounting and recruiting fees, the fees of various advisors (press relations, investor relations, communication, IT), external service providers (security and security services, reception, clinical and IT services), as well as the fees of some of its scientific advisors. This amount also includes intellectual property expenditures corresponding to the fees incurred by the Company in connection with registering and maintaining its patents;
- expenses related to the rental, use, and maintenance of the Group's corporate offices;



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- contributions (*dons*) to the GENFIT endowment fund, The NASH Education Program™;
- expenses related to business travel and conferences of employees and external service providers' as well as the costs of participation in scientific, medical, financial, and business development conferences.

In particular, this increase is related to the increase in the contribution to The NASH Education Program™ endowment fund, the increase in the use of external staff for clinical development and an increase in expenses related to intellectual property.

### **Financial income**

Financial income amounted to a loss of €1,526 thousand in 2017 compared to financial income of €526 thousand in 2016.

This loss is due to the interest payments on the convertible bond (OCEANE) issued in October 2017 and in exchange rate loss.

### **Net income (loss)**

2017 resulted in a net loss of €58,604 thousand compared to a net loss of €33,667 thousand in the preceding year.

### **Comments on the statement of financial position**

At December 31, 2017, the total amount of the Group's Statement of Financial Position amounts to €293,183 thousand compared to €166,214 thousand in the previous year.

At December 31, 2017, the Group's cash, cash equivalents and other current financial assets amounts to €273,851 thousand, compared to €152,450 thousand as of December 31, 2016.

### **Non current assets**

Non-current assets, which include trade and other receivables and intangible, tangible, and financial assets, increased from €4,219 thousand as of December 31, 2016 to €9,611 thousand at December 31, 2017.

This increase is mainly due to investments made during the year (IT and medical equipment for the clinical trials, amenities and scientific equipment for the laboratories); although the change in trade and other receivables is due to the dispute with the tax administration in relation to the CIR. In this context, the Company settled an assessment notice of €1,141 thousand by way of compensation on the amounts due for the 2014 and 2016 CIR, and made an additional payment of €333 thousand. The tax authority has also withheld €447 thousand owed to the Company in respect of the 2014 CIR, and the Company has contested these adjustments and these amounts remain due. For more information, refer to note 6.21 - "Financial income and expenses" in the



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notes to the consolidated financial statements for the year ended December 31, 2017 available on GENFIT's website.

### **Current assets**

Current assets amount to respectively €283,572 thousand and €161,996 thousand as of December 31, 2017 and 2016.

Cash and cash equivalents went from €152,277 thousand as of December 31, 2016 to €273,820 thousand at December 31, 2017, an increase of 80%.

The variation is related to the cash generated by the issuance of OCEANE, after the impact of the cash burn for the period.

Cash is mainly invested in highly-liquid short term investments, with low risk of change in value.

Cash & cash equivalents (in € thousands)	As of	
	2016/12/31	2017/12/31
Short-term deposits	150 438	244 279
Cash & bank accounts	1 839	29 541
<b>TOTAL</b>	<b>152 277</b>	<b>273 820</b>



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### **Shareholders' equity**

At December 31, 2017, the amount of the Group's shareholders' equity totaled €104,229 thousand compared to €142,797 thousand at December 31, 2016.

The change in the Company's shareholders' equity results mainly from the annual loss reflecting the Company's efforts in particular for research and development, preclinical studies and clinical studies relating to elafibranor.

### **Non current liabilities**

This mainly concerns the following liabilities reaching maturity in more than one year:

- the convertible bond (OCEANE) issued in October 2017;
- conditional advances 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 consolidated financial statements for the year ended December 31, 2017 available on GENFIT's website; and
- bank loans.

### **Current liabilities**

This balance sheet item mainly includes liabilities reaching maturity in less than one year, such as conditional advances granted by Bpifrance to GENFIT, trade payables, and social security expenses. Please also refer to note 6.13 Trade and other payables of the notes to the consolidated financial statements for the year ended December 31, 2017 available on GENFIT's website.

Trade & other payables – Current (in € thousands)	As of	
	2016/12/31	2017/12/31
Trade payables	13 341	19 053
Social security costs payables	2 562	4 217
Employee profit sharing	17	17
VAT payables	24	19
Taxes payables	187	241
Other payables	14	34
<b>TOTAL</b>	<b>16 146</b>	<b>23 580</b>



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### **Cash flows**

Condensed consolidated statements of cash flows (in € thousands)	Year ended	
	2016/12/31	2017/12/31
Cash flows from operating activities	(27 226)	(49 856)
Cash flows from investing activities	(2 086)	(2 948)
Cash flows from financial activities	121 480	174 348
<b>Net increase / (decrease) in cash &amp; cash equivalents</b>	<b>92 167</b>	<b>121 544</b>

### ***Cash flows from operating activities***

In 2017, cash flow from operating activities amounted to -€49,856 thousand compared to -€27,226 thousand in 2016.

This negative cash flow is a direct consequence of the industry in which GENFIT operates, which requires significant research and development efforts and generates costs that fluctuate based on the state of development of the Company's proprietary research programs. There is currently no corresponding revenue stream to offset said expenditures.

### ***Cash flows from investing activities***

Cash flow from investment activities was -€2,948 thousand in 2017 compared to -€2,086 thousand in 2016. This change is essentially due to the acquisition of capital assets.

### ***Cash flows from financial activities-***

In the 2017 and 2016 fiscal years, cash flow from financing activities amounted to €174,348 thousand and €121,480 thousand, respectively. This significant change is mainly due to the issuance of OCEANEs in October 2017 for a nominal amount of approximately €180 million, compared with share capital increases in 2016 of €121 million.

Generally speaking, the OCEANE issuance have enabled GENFIT to improve its financial position and continue deploying its development strategy, by giving it the means to maintain investment levels in research for its various ongoing programs and, in particular, for its drug candidate elafibranor.

The other elements of cash flow are:

- New loans and public financing

In 2017, the Company took out new loans in a total amount of €2,400 thousand. A total amount of €2,441 thousand was drawn down from these new loans and from loans taken out in 2016 but not yet drawn down.

In 2015, the Company took out new loans in a total amount of €2,815 thousand. A total amount of €1,500 thousand was drawn down from these new loans.



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- Repayment of loans and public financing

In 2017, the Company repaid €131 thousand in repayable and conditional advances and €1,240 thousand in bank loans and a loan with participation features.

In 2016, the Company repaid €133 thousand in repayable and conditional advances and €892 thousand in bank loans and a loan with a participation feature.

### **Post year-end events**

None.

### **Registration Document including the Annual Financial Report**

The Group intends to file its registration document as well as the annual financial report for 2017 with the Autorité des marchés financiers. These documents are expected to be available on the Company's website ([www.GENFIT.com](http://www.GENFIT.com)) in April 2018.

### **About GENFIT**

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases that affect the liver (such as NASH – Nonalcoholic steatohepatitis), and more generally the gastrointestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, elafibranor, is currently in a Phase 3 study. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). [www.GENFIT.com](http://www.GENFIT.com)

### **Forward looking statement / disclaimer**

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous 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 biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial and the trial of elafibranor in PBC, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibranor in NASH and PBC, as well as other drug candidates in other indications and biomarkers candidates, the success of any inlicensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 7 of the 2017 Half Year Business and Financial Report and under Section 4 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité



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des marchés financiers on April 28, 2017 under n° R.17-034, 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)). Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements. This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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