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# GENFIT Reports Full-Year 2020 Financial Results and Provides Corporate Update

- Cash position of €171 million as of December 31, 2020, excluding the €47.5 million partial buyback of the OCEANEs completed in January 2021, that cancelled €85.7 million nominal amount of convertible debt
- Additional €30.6 million nominal amount of convertible debt cancelled following conversion by bondholders, bringing outstanding nominal debt down to €63.6 million as of March 12, 2021 (i.e. <1/3 of initial debt value)
- 3 of the 4 corporate objectives announced in the Fall 2020 already successfully achieved (refocus on PBC and NIS4™, cash burn reduction, debt restructuring) - Next update on corporate strategy to take place in June 2021.

**Lille (France), Cambridge (Massachusetts, United States), April 1, 2021** – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced its annual financial results for the full year ended December 31, 2020. A summary of the consolidated financial statements is included below.

**Pascal Prigent, CEO of GENFIT**, commented: *“Since we announced data from RESOLVE-IT™ in May 2020, the teams at GENFIT have worked relentlessly. Our quick roll-out of the new strategy announced in September allowed us to already meet many priority objectives. First, we rolled-out and completed a restructuring plan targeting approximately 40% of our workforce, reorganized and reprioritized our R&D programs, and put in place an ambitious cost-saving plan. Consequently, we have managed to reduce our cash burn by half our (excluding debt renegotiation and costs associated with the termination of the RESOLVE-IT™ trial). Second, we renegotiated our debt, reducing it to a little over €60MM with a maturity in 2025 from €180MM and a maturity in 2022. Third, our Phase 3 ELATIVE™ clinical trial in PBC is ongoing, patient enrolment is moving forward as expected and we anticipate data early 2023. Our market research shows our strong competitive potential in this market, estimated at over \$1bn by 2025. Finally, use of our NIS4™ technology is on the rise in ongoing NASH clinical trials. A diagnostic test powered by NIS4™ will be made available in the coming weeks by our partner Labcorp to all prescribers in the US. GENFIT is a company that managed to reinvent itself in just a few months... We have set up the right conditions to rebound and are moving to the future with confidence.”*

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### Financial results

KEY FIGURES (CONSOLIDATED)		
(in € thousands, except earnings per share data)	2019/12/31	2020/12/31
<b>Revenues and other income</b>	40 961	7 758
Research and development expenses	(66 170)	(59 097)
General and administrative expenses	(17 265)	(14 270)
Marketing and market access expenses	(13 708)	(11 216)
Reorganization and restructuring expenses	—	(5 308)
Other operating income (expenses)	(1 649)	(764)
<b>Operating income (loss)</b>	<b>(57 832)</b>	<b>(82 897)</b>
Financial income	5 221	6 544
Financial expenses	(13 110)	(25 296)
<b>Financial profit (loss)</b>	<b>(7 889)</b>	<b>(18 752)</b>
Net profit (loss) before tax	(65 721)	(101 649)
Income tax benefit (expense)	576	428
<b>Net profit (loss)</b>	<b>(65 144)</b>	<b>(101 221)</b>
Basic and diluted earnings (loss) per share (€/share)	(1,76)	(2,60)
Cash and cash equivalents	276 748	171 029

\* Financial statements are not audited. The audit procedures by the Statutory Auditors are underway.

### Revenues and other incomes

Revenues for 2020 amounted to €765 thousand compared to €31 million for 2019.

Revenues included revenues from the licensing agreements with Covance/Labcorp to roll out the NIS4™ diagnostic technology in NASH and the sale of goods and services provided pursuant to the collaboration and license agreement with Terns Pharmaceuticals. As a comparison, revenues for 2019 mainly consisted of the \$35 million upfront payment received from Terns Pharmaceuticals as part of the collaboration and license agreement.

In this context, the operating income for 2020 amounted to €6 million (€7.9 million in 2020 minus the €1.9 million associated with the Research Tax Credit litigation from 2010 to 2014) essentially from the Research Tax Credit, compared to €8.1 million the previous year.

### Operating results and expenses

R&D expenditures, general and administrative expenses, marketing and market access expenses and other operating expenses were reduced in 2020 compared to the previous year. These expenses, amounting to approximately €98.9 million in 2019 were reduced to approximately €85.3

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million in 2020. This reduction in operating expenses is the first translation of the multi-year cost reduction plan and the reorganization begun during Q4 2020. As indicated, the effects of this plan and reorganization will become clearer in 2021 and will be fully realized in 2022.

In the meantime, reorganization and restructuring costs associated with cost saving measures have decreased the operating results by about €5.3 million in 2020.

### ***Financial results***

2020 resulted in a financial loss of €18.7 million (compared to a loss of €7.9 million the previous year). A significant part of this financial loss, amounting to €8.4 million, can nonetheless be qualified as dormant as it is associated with exchange rate differences in cash investments that were made in U.S. dollars and that have been kept in their original currency since they were made.

### ***Cash position***

As of December 31, 2020, the Company's cash and cash equivalents amounted to €171.0 million compared with €276.7 million, as of December 31, 2019. As a reminder, the Company completed its initial public offering on the Nasdaq in March 2019, raising gross proceeds of \$155 million.

The cash position as of December 31, 2020 omits the cost of the partial buyback by the Company of its €180 million nominal amount of convertibles bonds (OCEANE) issued in October 2017. Following the completion of this transaction, €85.7 million of convertible debt was canceled by spending a gross amount of only €47.5<sup>1</sup> million.

Following conversion of OCEANEs into shares up until March 12, 2021, which led to the creation of 5,695,621 new shares, the residual convertible debt, initially reduced to a nominal amount of €94.3 million through the partial buyback transaction, was further reduced by a nominal amount of €30.6 million, with approximately €63.6 million outstanding as of March 12, 2021.

### **2020 Key Highlights**

#### ***May 2020: topline data from the Phase 3 clinical trial in NASH (RESOLVE-IT™)***

GENFIT announced in May 2020 that the Phase 3 clinical trial RESOLVE-IT™ did not meet the predefined primary surrogate efficacy endpoint of NASH resolution without worsening of fibrosis in the ITT population.

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<sup>1</sup> Excluding costs related to the operation

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### ***September 2020: New corporate strategy***

Following the detailed review of the full dataset of the RESOLVE-IT™ Phase 3 data, GENFIT announced in September 2020 a series of decisions defining its new roadmap, now focused on two priority areas: the development of elafibranor in Primary Biliary Cholangitis and the commercialization by Labcorp of a diagnostic test for NASH based on the NIS4™ technology.

The overall clinical development program for elafibranor in NASH and all activities associated with the commercial launch of elafibranor in NASH have been terminated given the low probability of success compared to required expenses.

A comprehensive cost-saving plan has been implemented with the goal of reducing by more than 50% the cash burn rate over two years, going from a €110 million rate annually before our RESOLVE-IT™ Phase 3 data, to approximately €45 million annually, beginning in 2022. 2021 will be a transition year with a cash burn of approximately €75 million (excluding the partial OCEANEs buyback transaction for €47.48 million in cash) mainly due to the residual expenses related to the termination of the RESOLVE-IT™ clinical trial, and to costs associated with the workforce reduction plan and the OCEANEs renegotiation expenses. This plan included:

- the redirection of R&D activities and the termination of secondary programs, including the program evaluating the potential of the RORgT target;
- workforce restructuring plan aims to reduce the overall workforce by 40%, encompassing both the U.S and France in order to align the company size to the new scope of activity;
- an ambitious expenditure control plan.

### ***November 2020 – January 2021: partial buyback and amendment of the terms of the bonds debt***

In November, GENFIT launched a plan for a partial buyback and amendment of the terms of the OCEANEs 2022, with several objectives:

1. Preserve funding capacity for the Company's operational functionality;
2. Reduce the amount of financial debt to be redeemed;
3. Defer the OCEANEs maturity date in line with the next milestones in the Company's two main programs: the ELATIVE™ Phase 3 clinical trial evaluating elafibranor in PBC and the NIS4™ technology for NASH diagnosis;
4. Maximize the potential value-creation for shareholders and the OCEANEs holders.

In January 2021, this project was met with sweeping approval of the new terms, by 98.5% of shareholders and 88% of bondholders who voted. The debt was reduced by more than half its original amount, and its maturity extended to October 2025.

With this significant restructuring plan now behind us, 2021 will be a year to execute on our strategy.

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### 2021 Outlook

#### *Continuation of priority programs*

#### **Clinical development of our drug candidate elafibranor for the treatment of Primary Biliary Cholangitis (PBC)**

In 2021, we will continue the development of elafibranor in Primary Biliary Cholangitis (PBC) and the enrolment of patients in ELATIVE™, our Phase 3 clinical trial.

As a reminder, elafibranor obtained promising results in a Phase 2 clinical trial evaluating its efficacy and safety in this indication that have been published in February 2021 in the Journal of Hepatology. Following 12 weeks of treatment, elafibranor demonstrated statistically significant efficacy results on the composite endpoint that was the basis for regulatory approval of a second line treatment when assessed at 12 months. Furthermore, a positive trend on pruritus – that will need to be confirmed in the Phase 3 trial – could reinforce elafibranor’s differentiated potential. In addition, the abundance of data derived from the RESOLVE-IT™ trial have shown a good safety profile.

The enrolment for this trial began in September 2020 and the topline data is expected early 2023. If successful in early 2023, by 2025 elafibranor could potentially be a new therapeutic option for patients with high unmet needs despite existing therapies (UDCA as first line treatment and Ocaliva as second line treatment), and become the first alternative to Ocaliva in a market estimated to \$1 billion in 2025.

IQVIA, a recognized leader in research and consulting services for the pharmaceutical industry, was commissioned by GENFIT to conduct three comprehensive market research studies evaluating the potential market opportunity, should it be granted regulatory approval, of elafibranor as a second line treatment. IQVIA estimates the total PBC market could reach \$1.5 billion annually in 2035, and elafibranor, if approved, could achieve \$515 million in peak year revenue, as second line treatment for patients with PBC that cannot benefit from the first line therapy.

#### **Large scale commercial roll-out by Labcorp of a non-invasive NASH diagnosis test based on our NIS4™ technology**

It is essential to make a non-invasive solution available to healthcare professionals on a large scale. This is why our partner Labcorp is committed to launching as early as 2021 a molecular blood based diagnostic test powered by the NIS4™ technology throughout the U.S. and Canada. This test aims to facilitate the identification of patients with “at-risk” NASH, making it widely available to healthcare professionals. This step will make our technology available on a large scale, where its use was until now restricted to clinical research community stakeholders.

Although the market’s growth is tightly linked to the availability of the first therapies, market research shows that there is already an unmet medical need despite the setbacks some of the drug candidates

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in NASH have met. These studies show the benefit for millions of patients with diabetes, prediabetes, obesity or excess weight or with other risk factors to act and take control over the progression of their disease, even without drugs, or by implementing lifestyle changes, with a specific diet and/or more intense exercise.

In 2021, GENFIT will pursue its subsidiarization project that will allow for the creation in 2021 of a new independent operational entity aimed at ensuring a more independent steering and a more autonomous growth for the NASH diagnostics activity. The subsidiary will focus on the development of solutions to aid in the identification, evaluation and monitoring of patients with NASH. The new organization should facilitate the implementation of future partnerships for NIS4™, but also for other solutions.

### **R&D**

In 2021, GENFIT will pursue its R&D efforts. Several programs currently in preclinical development are expected to move into clinical development. More detail will be provided at the mid-year corporate update.

### **Conference Call on April 1, 2021 at 4:15pm EDT / 10:15pm CEST**

GENFIT will host a Full-Year 2020 Financial Results and Corporate Update conference call on April 1, 2021 at 4:15pm EDT / 10:15pm CEST. The conference call will be accessible on the investor page of our website, under the events section at <https://ir.genfit.com/> or by calling +1 (877) 407 9167 (toll-free U.S. and Canada), +1 (201) 493 6754 (international) or 0 800 912 848 (France) five minutes prior to the start time (no passcode needed). A replay will be available shortly after the call.

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### APPENDICES

#### Consolidated Statement of Financial Position\*

ASSETS (in € thousands)	As of	
	2019/12/31	2020/12/31
<b>Current assets</b>		
Cash and cash equivalents	276 748	171 029
Current trade and others receivables	12 033	11 919
Other current assets	1 968	1 765
Inventories	4	4
<b>Total - Current assets</b>	<b>290 753</b>	<b>184 717</b>
<b>Non-current assets</b>		
Intangible assets	920	791
Property, plant and equipment	16 453	11 648
Other non-current financial assets	1 727	1 458
Deferred tax assets	—	—
<b>Total - Non-current assets</b>	<b>19 099</b>	<b>13 897</b>
<b>Total - Assets</b>	<b>309 853</b>	<b>198 614</b>

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	As of	
	2019/12/31	2020/12/31
<b>Current liabilities</b>		
Current convertible loans	1 312	1 313
Other current loans and borrowings	3 226	3 035
Current trade and other payables	36 917	25 564
Current deferred income and revenue	139	124
Current provisions	2 061	1 031
<b>Total - Current liabilities</b>	<b>43 657</b>	<b>31 067</b>
<b>Non-current liabilities</b>		
Non-current convertible loans	164 142	169 470
Other non-current loans and borrowings	14 939	11 873

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Non-current trade and other payables	450	451
Non-current employee benefits	1 408	1 148
Deferred tax liabilities	1 193	767
<b>Total - Non-current liabilities</b>	<b>182 132</b>	<b>183 709</b>
<b><u>Shareholders' equity</u></b>		
Share capital	9 715	9 722
Share premium	377 821	379 057
Retained earnings (accumulated deficit)	(238 340)	(303 629)
Currency translation adjustment	14	(92)
Net profit (loss)	(65 144)	(101 221)
<b>Total shareholders' equity - Group share</b>	<b>84 065</b>	<b>(16 162)</b>
Non-controlling interests	—	—
<b>Total - Shareholders' equity</b>	<b>84 065</b>	<b>(16 162)</b>
<b>Total - Shareholders' equity &amp; liabilities</b>	<b>309 853</b>	<b>198 614</b>

\* Financial statements are not audited. The audit procedures by the Statutory Auditors are underway

### Statement of Operations\*

(in € thousands, except earnings per share data)	Year ended	
	2019/12/31	2020/12/31
<b><u>Revenues and other income</u></b>		
Revenue	30 839	765
Other income	10 122	6 993
<b>Revenues and other income</b>	<b>40 961</b>	<b>7 758</b>
<b><u>Operating expenses and other operating income (expenses)</u></b>		
Research and development expenses	(66 170)	(59 097)
General and administrative expenses	(17 265)	(14 270)
Marketing and market access expenses	(13 708)	(11 216)
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<b>Net profit (loss) before tax</b>	<b>(65 721)</b>	<b>(101 649)</b>
Income tax benefit (expense)	576	428



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<b>Net profit (loss)</b>	<b>(65 144)</b>	<b>(101 221)</b>
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### Statement of Cash Flows\*

(in € thousands)	Year ended 2019/12/31	Year ended 2020/12/31
<b>Cash flows from operating activities</b>		
+ Net profit (loss)	(65 144)	(101 221)
<b>Reconciliation of net loss to net cash used in operating activities</b>		
Adjustments for:	—	—
+ Depreciation and amortization on tangible and intangible assets	3 263	3 559
+ Impairment and provision for litigation	357	3 015
+ Expenses related to share-based compensation	1 657	1 236
- Gain on disposal of property, plant and equipment	(19)	80
+ Net finance expenses (revenue)	11 437	10 335
+ Income tax expense (benefit)	(576)	(428)
+ Other non-cash items including Research Tax Credit litigation	1 702	(1 818)
Operating cash flows before change in working capital	(47 324)	(85 242)
<b>Change in:</b>		
Decrease (increase) in trade receivables and other assets	(1 640)	318
(Decrease) increase in trade payables and other liabilities	1 284	(11 447)
Change in working capital	(356)	(11 129)
Income tax paid	—	—
<b>Net cash flows used in operating activities</b>	<b>(47 680)</b>	<b>(96 371)</b>
<b>Cash flows from investment activities</b>		
- Acquisition of property, plant and equipment	(2 030)	(900)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	2 517	—
- Acquisition of financial instruments	(160)	(66)
<b>Net cash flows provided by (used in ) investment activities</b>	<b>327</b>	<b>(966)</b>
<b>Cash flows from financing activities</b>		
+ Proceeds from issue of share capital (net)	126 486	7
+ Proceeds from subscription / exercise of share warrants	43	—
- Repayments of loans and borrowings	(6)	207
- Payments of lease debts	(1 877)	(2 150)

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- Financial interests paid (including finance lease)	(7 785)	(7 762)
+ Financial interests received	—	1 442
<b>Net cash flows provided by (used in ) financing activities</b>	<b>116 860</b>	<b>(8 256)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>69 508</b>	<b>(105 593)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	207 240	276 748
Effects of exchange rate changes on cash	—	(126)
<b>Cash and cash equivalents at the end of the period</b>	<b>276 748</b>	<b>171 029</b>

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### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with cholestatic and metabolic chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. GENFIT is currently enrolling in ELATIVE™, a Phase 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC). Elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority. As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which could enable easier identification of patients with at-risk NASH. NIS4™ technology has been licensed to LabCorp® in the U.S. and Canada for the development and commercialization of a blood-based molecular diagnostic test powered by NIS4™ technology. GENFIT has facilities in Lille and Paris, France, and Cambridge, MA, USA. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). [www.genfit.com](http://www.genfit.com)

### FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including statements regarding the Company's new strategy, its objectives, its capacity to achieve these objectives, size and access to the PBC market for elafibranor, expected results of the Phase 3 clinical trial ELATIVE™ evaluating elafibranor in PBC and calendar of the trial completion and probability to replicate the Phase 2 clinical trial results in the same indication, success and imminence of a commercial launch by our partner Labcorp of a diagnostic test integrating the NIS4™ technology

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in the diagnostic and clinical care fields, our capacity to roll-out our multi-year cost-saving plan, our capacity to drastically reduce operating expenses and provisional cash burn in the upcoming years. The use of certain words, including “consider”, “contemplate”, “think”, “aim”, “expect”, “understand”, “should”, “aspire”, “estimate”, “believe”, “wish”, “may”, “could”, “allow”, “seek”, “encourage” or “have confidence” or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and assumptions of the Company’s management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among other things, the uncertainties inherent in research and development, including in relation to safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, exchange rate fluctuations and the Company’s continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company’s public filings with the AMF, including those listed in Chapter 2 “Main Risks and Uncertainties” of the Company’s 2019 Universal Registration Document filed with the AMF on 27 May 2020 under n° D.20-0503 and in Section 2 “Risk Factors” of the Company’s Amendment to the Universal Registration Document filed with the AMF on 22 December 2020 under n° D.20-0503-A01, which are available on the Company’s website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)) and public filings and reports filed with the U.S. Securities and Exchange Commission (“SEC”) including the Company’s 2019 Annual Report on Form 20-F filed with the SEC on May 27, 2020. In addition, even if the Company’s results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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