

GENFIT Reports Full-Year 2022 Financial Results and Provides Corporate Update

- Cash, cash equivalents and current financial assets totaled €140.2 million¹ as of December 31, 2022, expected to fund operations through third quarter 2024
- Transformative milestone expected towards end of second quarter 2023, with topline data readout for Phase 3 ELATIVE® evaluating elafibranor in primary biliary cholangitis (PBC)
- Multiple events in second quarter 2023:
 - 1st patient screening in a Phase 2 study evaluating VS-01 in acute on-chronic liver failure (ACLF)
 - 1st patient screening in a Phase 1b/2 evaluating GNS561 in cholangiocarcinoma (CCA)
 - Phase 1 data for NTZ in ACLF, for 2 studies in hepatic impaired and renal impaired patients (Phase 2 study initiation targeted for the second half of 2023)
- Successful acquisition of Versantis AG at end of 2022 strengthens GENFIT's pipeline that now includes 4 clinical-stage programs and 2 preclinical-stage programs
- Conference call (English and French) on April 14, 2023 at 8am ET / 1pm GMT / 2pm CET

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); April 13, 2023 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases characterized by high unmet medical needs, today announced annual financial results for the year ended December 31, 2022. A summary of the consolidated financial statements is included further below.

Pascal Prigent, CEO of GENFIT, commented:

"2022 was a transformative year for GENFIT. It was marked by both the fast progression of our lead program and the expansion of our pipeline in rare and severe liver diseases, notably with the acquisition of Versantis AG. We are now approaching an inflection point: this quarter we expect to report data from our pivotal Phase 3 study in PBC. There is still an important unmet medical need in this market, and we are very encouraged by the previous Phase 2 data reported as part of this program. We believe elafibranor has significant potential, and we hope it will be demonstrated soon. Beyond this exciting milestone, we have built a rich pipeline, that now includes 3 additional phase 2-stage programs and 2 preclinical-stage programs. This pipeline, combined with a robust cash position and the near-term commercial perspectives for elafibranor, provide us with a unique opportunity to drive transformative value in 2023."

I. 2022 Key Highlights

PBC program executed according to plan

Patient enrollment for the ELATIVE® Phase 3 trial evaluating elafibranor in PBC was completed mid-2022. Throughout 2022 GENFIT and Ipsen stepped up their collaboration in order to minimize the time to filing as well as prepare for the commercial launch next year, if approved.

¹ Amount is net of cash in transit of €0.3m, earmarked for payment in early January 2023

Pipeline progress

– Acquisition of the clinical-stage biopharmaceutical company Versantis

In September 2022, GENFIT acquired clinical-stage biopharmaceutical company Versantis based in Zurich (Switzerland), significantly expanding its pipeline. This acquisition has reinforced GENFIT's position as a leader in ACLF and other severe liver diseases. Given the unmet need related to target diseases, it is expected that the programs qualify for some of the expedited regulatory pathways provided by health authorities.

Two Pipeline Days were organized in October 2022 in Paris and New York, to present these programs in detail. A replay of these events is available here: <https://ir.genfit.com/events/event-details/genfit-pipeline-day-nyc>

– Assessment of Nitazoxanide (NTZ) in hepatic and renal impaired patients

Two Phase 1 studies were conducted, aimed at providing insight into NTZ pharmacokinetics and safety in the setting of hepatic impairment or renal impairment, in order to prepare for the launch of a Phase 2 study in ACLF in the second half of 2023.

– Orphan Drug Designation granted to GNS561 for the treatment of cholangiocarcinoma

In September 2022 the US Food and Drug Administration (FDA) granted Orphan Drug Designation to GNS561 (ezurpimtrostat), a novel clinical-stage autophagy/PPT1 inhibitor, for the treatment of cholangiocarcinoma (CCA).

– Compelling results for NIS2+™ in NASH

In October 2022, GENFIT announced the development of NIS2+™, a next-generation technology for the diagnosis of at-risk NASH, and the presentation of results on NIS2+™'s clinical performance in three poster presentations at The Liver Meeting® 2022 organized by the AASLD². The NIMBLE initiative of the FNIH³ highlighted in 2021 the strong and unique performance of NIS4® technology in identifying patients with at-risk NASH.

II. 2023 Anticipated Milestones

Topline Phase 3 data for elafibranor in PBC: towards the end of 2Q23

Topline results for the ELATIVE® study are now imminent and expected to be announced towards the end of the second quarter of 2023.

Phase 2 results showed a statistically significant improvement on both the primary and composite biochemical evaluation criteria, the latter now being the primary endpoint of the pivotal Phase 3 trial to support accelerated approval. In addition, the results showed a positive trend on the improvement of pruritus, while preserving a favorable safety and tolerability profile. These

² American Association for the Study of Liver Diseases

³ Non-Invasive Biomarkers of Metabolic Liver Disease of the Foundation for the National Institutes of Health's Biomarkers Consortium

positive conclusions were published in the *Journal of Hepatology* in 2021.⁴ Safety data derived from more than 1,000 patients in the biopsy-based Phase 3 RESOLVE-IT® trial of elafibranor in NASH also supported further development in PBC.

Under the agreement with Ipsen, GENFIT is eligible to receive regulatory, commercial, and sales-based milestone payments up to €360 million, with a potential first significant milestone payment as early as 2023 and an additional potential milestone payment in 2024, if ELATIVE® is successful. In addition, GENFIT is eligible for double-digit royalties of up to 20%. In the case of a positive trial outcome, the well-established global commercial footprint of Ipsen will be an important driver of commercial success. By 2024, if approved, elafibranor could potentially become a new therapeutic option for PBC patients not responding to UDCA⁵, and become the first alternative to currently approved second line treatment in a market estimated at \$1.5bn in the coming years, and \$3.1 billion in the US and in the five main European countries by 2030.⁶

Additional clinical programs underway

– 1st patient screening in a Phase 2 study evaluating VS-01 in ACLF: 2Q23

An international Phase 2, open-label, randomized, controlled, multi-center, proof of concept study will assess the efficacy, safety and tolerability of VS-01 in addition to standard of care (SOC), compared to SOC alone, in approximately 60 adult patients with ACLF grades 1 and 2 and who also have ascites. A Phase 1 trial highlighted the favorable safety and tolerability profile of VS-01 and provided encouraging preliminary efficacy results, with >80% of treated patients improving or stabilizing their disease (Child-Pugh Score assessment). It is anticipated that the first patient will be screened in this trial in the second quarter of 2023. Given the high unmet need in this indication and the Orphan Drug Designation obtained from the FDA for VS-01, it is expected that the program qualifies for some of the expedited regulatory pathways provided by health authorities.

The overall market size of ACLF is estimated to be almost \$4 billion in the US and in the five main European countries by 2030.⁷

– NTZ Phase 1 outcome in ACLF: May 2023

GENFIT is developing a second program in ACLF in which it is evaluating NTZ. Two Phase 1 studies were completed in the fourth quarter of 2022 and the first quarter of 2023, and are expected to provide preliminary insight into NTZ pharmacokinetics and safety in the setting of hepatic impairment or renal impairment. Outcome of both the hepatic impairment study and the renal impairment study will be announced in May 2023. A Phase 2a proof of concept study in patients with ACLF grades 1 and 2 is currently under discussion with the FDA, and study initiation is targeted for the second half of 2023.

– 1st patient screening in a Phase 1b/2a study evaluating GNS561 in cholangiocarcinoma (CCA): targeted towards the end of 2Q23

A Phase 1b/2a trial will evaluate GNS561 in patients with advanced KRAS mutated CCA. In the Phase 1b, patients will be enrolled to evaluate the safety and tolerability of GNS561 when given in combination with a MEK inhibitor, and to identify the recommended doses of the combination to be administered in the Phase 2a study. GENFIT targets to screen the first patient

⁴ Schattenberg JM et al. *J. Hepatol.* 2021, 74(6), 1344-1354

⁵ Ursodeoxycholic acid

⁶ IQVIA forecast

⁷ IQVIA forecast

towards the end of the second quarter of 2023. Given the high unmet need in this indication and the Orphan Drug Designation obtained from the FDA for GNS561, it is expected that the program qualifies for some of the expedited regulatory pathways provided by health authorities.

The overall market size of CCA is estimated to be more than \$3 billion in the US and in the five main European countries by 2030.⁸

Preclinical programs

In addition to clinical programs, GENFIT is also pursuing the development of two preclinical programs:

- VS-01-HAC is a potential first-line lifesaving treatment for acute hyperammonemic crisis associated with Inborn Errors of Metabolism in Urea Cycle Disorders (UCD) and Organic Acidemias (OA). Investigational New Drug (IND) enabling nonclinical studies are targeted to be completed in 2024.
- VS-02-HE is developed in Hepatic Encephalopathy (HE), which is one of the major complications of advanced liver disease and portal hypertension. As many as 45% of patients with cirrhosis will experience at least one episode of HE. VS-02-HE is a urease inhibitor, and a hydroxamic acid derivative, designed to inhibit ureases by binding to nickel atoms in their active site. IND enabling nonclinical studies are targeted to be completed in 2025.

Although these are early-stage programs, they represent a significant potential due to the high unmet medical need. Market size for severe hepatic encephalopathy (HE) alone is estimated to be \$3 billion in the US and in the five main European countries by 2030.⁹ For UCD and OA, estimations for 2030 go as high as \$1.1 billion in the US and in the five main European countries.¹⁰

III. Financial results(*)

⁸ IQVIA forecast

⁹ IQVIA forecast

¹⁰ IQVIA forecast

(in € thousands, except earnings per share data)

	31/12/2021	31/12/2022
Revenues and other income	85,579	26,566
Research and development expenses	(35,166)	(35,818)
General and administrative expenses	(16,153)	(16,405)
Marketing and market access expenses	(1,539)	(992)
Reorganization and restructuring income (expenses)	(142)	11
Other operating expenses	(763)	(652)
Operating income (loss)	31,816	(27,289)
Financial income	44,780	8,212
Financial expenses	(7,122)	(4,758)
Financial profit (loss)	37,658	3,453
Net profit (loss) before tax	69,474	(23,836)
Income tax benefit (expense)	(2,215)	116
Net profit (loss)	67,259	(23,719)
Basic/diluted earnings (loss) per share (€/share)	1.51	(0.48)
Diluted earnings (loss) per share (€/share)	1.23	(0.48)
Cash, cash equivalents and current financial assets	258,756	140,551

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

Revenues and other incomes

Revenue and other operating income for 2022 amounted to €26.6 million compared to €85.6 million for 2021.

In 2022, our revenue totaled €20.2 million and came from three streams related to Ipsen:

- In December 2021, we received a €120m non-refundable upfront payment from Ipsen as part of our Collaboration and Licencing agreement. €80m was recognized as revenue in 2021, and €40m was booked as deferred revenue and is gradually recognized as revenue in subsequent periods following the progress of the ELATIVE® double-blind study. As such, of that initial €40m in the deferred revenue balance, €15.9m was recognized as revenue in 2022.
- €3.3 million was recognized as revenue in 2022 in accordance with the Inventory Purchase Agreement signed with Ipsen, pursuant to which Ipsen purchased inventory of elafibranor active pharmaceutical ingredient and drug product during the second half of 2022, with the prospect of transferring the conduct of the ELATIVE® study to Ipsen.
- €1.0 million in revenue was generated from the services rendered by GENFIT to Ipsen in accordance with the Transition Services Agreement signed in 2022, which essentially outlines the scope of services to facilitate the transition of some activities related to the Phase 3 clinical trial evaluating elafibranor in PBC.

In 2022, other operating income totaled €6.4 million. This included mainly the research tax credit (known as Crédit d'Impôt Recherche or CIR) granted by the French tax authorities, which amounted to €6.0m. This is up from €5.3 million for 2021. This is due to an increase in our research activities in 2022.

Operating results and expenses

Operating expenses for 2022 amounted to €53.9 million, compared to €53.8 million for 2021. This is comprised of research and development expenses, general and administrative expenses, marketing and market access expenses, reorganization and restructuring expenses, and other operating expenses.

The slight increase is due to multiple factors:

- The increase in research and development costs of €0.6 million, explained by the increase in costs related to new programs and product candidates, in particular NTZ, VS-01 and GNS561, offset by the sharp reduction in study costs related to RESOLVE-IT®,
- The increase in general and administrative expenses of €0.2 million, explained by the increase in costs related to liability insurance, the increase in costs related to consulting fees, and other charges in the normal course of business,
- The decrease in marketing and market access expenses of €0.5 million, mainly explained by the decrease in marketing activity in the United States and France,
- The decrease in reorganization and restructuring charges of €0.1 million (effectively null in 2022), and the decrease of other operating expenses of €0.1 million.

In 2022, GENFIT generated a consolidated operating loss of €27.3 million, compared to an operating income of €31.8 million in 2021.

Financial results

2022 resulted in a financial income of €3.5 million compared to a financial income of €37.7 million in 2021.

In 2022, financial income is due to net foreign exchange gains of €7.1 million, interest income of €0.7 million, offset by interest expense of €4.3 million.

In 2021, financial income was due to net foreign exchange gains of €6.7 million, interest income of €0.3 million, offset by interest expense of €4.9 million. In addition, the company recorded a one time gain of 35.6 million corresponding to a repurchase bonus following the renegotiation of the OCEANEs in January 2021.

The foreign exchange result on cash and cash equivalents was a net gain of €7.1 million in 2022, compared to €6.7 million in 2021. This is notably due to the difference in currency exchange recognized on cash and other current financial assets in US dollars, as GENFIT has decided to keep some of its cash in US dollars. These cash and other current financial assets in US dollars are to be used to pay directly expenses in US dollars (natural currency hedge).

Cash position

As of December 31, 2022, the Company's cash and cash equivalents and current financial assets amounted to €140.6 million compared with €258.8 million as of December 31, 2021.

This is mainly the result of the following, in addition to normal business activity:

- The payment of €24.0 million in January 2022 representing the VAT collected on the initial upfront payment received from Ipsen in December 2021,
- The disbursement of employee participation in the profits of GENFIT SA in May 2022 for a total of €0.6 million for the financial year 2021, and
- The acquisition of Versantis AG totaling €41.5m net of cash acquired.

GENFIT will host a conference call in English and in French on April 14, 2023 at 8.00am ET / 1:00pm GMT / 2:00pm CET

Both the English and French conference calls will be accessible on the investor page of our website, under the 'Events and presentation' section at <https://ir.genfit.com> or by calling 888-394-8218 (toll-free U.S and Canada), 0800-279-0425 (toll-free UK) or 0805 101 219 (toll-free France) five minutes prior to the start time (confirmation code: 8860599). A replay will be available shortly after the call.

APPENDICES

Statement of Operations*

<i>(in € thousands, except earnings per share data)</i>	Year ended	
	31/12/2021	31/12/2022
Revenues and other income		
Revenue	80,069	20,195
Other income	5,510	6,371
Revenues and other income	85,579	26,566
Operating expenses and other operating income (expenses)		
Research and development expenses	(35,166)	(35,818)
General and administrative expenses	(16,153)	(16,405)
Marketing and market access expenses	(1,539)	(992)
Reorganization and restructuring expenses	(142)	11
Other operating income (expenses)	(763)	(652)
Operating income (loss)	31,816	(27,289)
Financial income	44,780	8,212
Financial expenses	(7,122)	(4,758)
Financial profit (loss)	37,658	3,453
Net profit (loss) before tax	69,474	(23,836)
Income tax benefit (expense)	(2,215)	116
Net profit (loss)	67,259	(23,719)
Basic and diluted earnings (loss) per share		
Basic earnings (loss) per share (€/share)	1.51	(0.48)
Diluted earnings (loss) per share (€/share)	1.23	(0.48)

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway.

Appendices

Consolidated Statement of Financial Position*

Assets

<i>(in € thousands)</i>	As of	
	31/12/2021	31/12/2022
Current assets		
Cash and cash equivalents	258,756	136,001
Current trade and others receivables	7,236	15,906
Other current financial assets	0	4,550
Other current assets	2,101	1,998
Inventories	4	4
Total - Current assets	268,097	158,459
Non-current assets		
Intangible assets	174	43,957
Property, plant and equipment	9,015	8,210
Non-current trade and other receivables	3	0
Other non-current financial assets	4,431	4,914
Total - Non-current assets	13,623	57,081
Total - Assets	281,720	215,540

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway.

Appendices

Liabilities

<i>(in € thousands)</i>	As of	
	31/12/2021	31/12/2022
<i>Current liabilities</i>		
Current convertible loans	415	415
Other current loans and borrowings	1,773	4,665
Current trade and other payables	40,988	14,845
Current deferred income and revenue	14,298	14,479
Current provisions	313	61
Other current tax liabilities	5,051	4,906
<i>Total - Current liabilities</i>	62,837	39,370
<i>Non-current liabilities</i>		
Non-current convertible loans	47,682	49,861
Other non-current loans and borrowings	24,365	20,334
Non-current trade and other payables	450	448
Non-current deferred income and revenue	25,821	9,706
Non-current employee benefits	864	782
Deferred tax liabilities	602	510
<i>Total - Non-current liabilities</i>	99,786	81,641
<i>Shareholders' equity</i>		
Share capital	12,454	12,459
Share premium	444,438	444,683
Retained earnings (accumulated deficit)	(405,076)	(337,550)
Currency translation adjustment	22	(1,344)
Net profit (loss)	67,259	(23,719)
<i>Total - Shareholders' equity</i>	119,097	94,528
<i>Total - Shareholders' equity & liabilities</i>	281,720	215,540

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway.

Appendices

Statement of Cash Flows*

<i>(in € thousands)</i>	Year ended 2021/12/31	Year ended 2022/12/31
<i>Cash flows from operating activities</i>		
+ Net profit (loss)	67,259	(23,719)
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Depreciation and amortization on tangible and intangible assets	2,742	1,832
+ Impairment and provision for litigation	(1,996)	(179)
+ Expenses related to share-based compensation	470	245
- Gain on disposal of property, plant and equipment	420	(16)
+ Net finance expenses (revenue)	4,663	2,042
+ Income tax expense (benefit)	2,215	(116)
+ Other non-cash items	(35,538)	2,210
including Income incurred by renegotiating the convertible bond debt		
<i>Operating cash flows before change in working capital</i>	40,235	(17,702)
<i>Change in:</i>		
Decrease (increase) in trade receivables and other assets	4,344	(8,565)
(Decrease) increase in trade payables and other liabilities	55,335	(46,226)
<i>Change in working capital</i>	59,680	(54,791)
Income tax paid	0	(145)
<i>Net cash flows provided by (used in) in operating activities</i>	99,915	(72,638)
<i>Cash flows from investment activities</i>		
- Acquisition net of cash acquired	0	(41,525)
- Acquisition of property, plant and equipment	(537)	251
+ Proceeds from disposal of / reimbursement of property, plant and equipment	309	20
- Acquisition of financial instruments	(3,148)	(5,012)
<i>Net cash flows provided by (used in) investment activities</i>	(3,377)	(46,266)
<i>Cash flows from financing activities</i>		
+ Proceeds from issue of share capital (net)	27,972	5
+ Proceeds from new loans and borrowings net of issue costs	15,270	0
- Repayments of loans and borrowings	(48,436)	(628)
- Payments on lease debts	(1,887)	(1,120)
- Financial interests paid (including finance lease)	(2,109)	(2,180)
+ Financial interests received	274	137
<i>Net cash flows provided by (used in) financing activities</i>	(8,916)	(3,786)
<i>Increase (decrease) in cash and cash equivalents</i>	87,622	(122,690)
Cash and cash equivalents at the beginning of the period	171,029	258,756
Effects of exchange rate changes on cash	105	(65)
<i>Cash and cash equivalents at the end of the period</i>	258,756	136,001

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway.

Appendices

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D pipeline covers six therapeutic areas via six programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorder (UCD), organic acidemia disorder (OAD) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF.

GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) 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). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. www.genfit.com

GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995 in relation to its timelines for topline data readout for our ELATIVE® Phase 3 trial, potential for positive ELATIVE® Phase 3 results, eligibility to meet milestones and receive payments from Ipsen, timelines for data readout in NTZ in ACLF Phase 1 trials, timelines for patient screening and enrollment in our VS-01 ACLF and GNS561 in CCA programs, timelines for the initiation of a Phase 2a proof of concept study evaluating NTZ in patients with ACLF grades 1 and 2, the potential for VS-01-HAC to be a first-line life-saving treatment, the completion of IND enabling nonclinical studies in VS-01-HAC and VS-02-HE, the future of NIS2+™, commercial perspectives for elafibranor and its potential as a therapeutic option for patients, potential market sizes in the disease areas where we develop our product candidates, our ability to qualify for and obtain specific regulatory pathways, our financial outlook including cash flow and cash burn projections and business activity projections for 2023 and beyond. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "targeted", "anticipated", "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, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs and our continued ability to raise capital to fund our 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 2021 Universal Registration Document filed with the AMF on April 29, 2022 under n° D.22-0400, which

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is available on the Company'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 2021 Annual Report on Form 20-F filed with the SEC on April 29, 2022 and the 2022 Half-Year Business and Financial Report. 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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