

PRESS RELEASE

GENFIT Reports Third Quarter 2025 Financial Information and Provides a Corporate Update

- Cash and cash equivalents totaled €119.0 million as of September 30, 2025
- €39.2 million in revenues for the nine months ended September 30, 2025, including the €26.5 million milestone payment following pricing and reimbursement approval of Iqirvo® (elafibranor) in three major European markets

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), November 20, 2025 - **GENFIT (Nasdaq and Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced its third quarter 2025 financial results¹ and provided a corporate update.

Cash Position

As of September 30, 2025, the Company's cash and cash equivalents amounted to €119.0 million compared with €107.5 million as of June 30, 2025, and €81.8 million as of December 31, 2024.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements beyond the end of 2028, enabling the Company to further develop its pipeline focused on Acute on-Chronic Liver Failure (ACLF) and support general corporate purposes. This is based on current assumptions and programs and does not include exceptional events. This estimation assumes (i) our expectation to receive significant future commercial milestone revenue pursuant to the license agreement with Ipsen and Ipsen meeting its sales-based thresholds and (ii) drawing down all additional installments under the Royalty Financing agreement with HCRx.

In the first nine months of 2025, cash utilization is mainly the result of our research and development efforts in our pipeline focused on ACLF (notably VS-01, G1090N², SRT-015, CLM-022, and VS-02 HE), as well as GNS561 in cholangiocarcinoma (CCA). Cash utilization was notably offset by a €26.5 million milestone payment received in July 2025 under the Licensing and Collaboration Agreement with Ipsen, following pricing and reimbursement approvals for Iqirvo® (elafibranor) in three major European markets³.

Revenue

Revenue⁴ for the first nine months of 2025 amounted to €39.2 million compared to €59.7 million for the same period in 2024.

¹ Unaudited financial information under IFRS

² Novel formulation of NTZ being developed internally

³ Iqirvo® (elafibranor) has been granted pricing and reimbursement in the UK, Germany and Italy

⁴ Revenue recognized under IFRS 15

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Revenue for the first nine months of 2025 was primarily driven by the Licensing and Collaboration Agreement with Ipsen, including (i) royalty revenue from worldwide sales (excluding Greater China) of Ipsen's Iqirvo® (elafibranor) totaling €12.6 million and (ii) milestone revenue from pricing and reimbursement approval of Iqirvo® (elafibranor) in three major European countries³ totaling €26.5 million.

Program highlights

ACLF pipeline

G1090N² – A Phase 1 First-in-Human study in healthy volunteers is currently underway with safety data expected at the end of this year. Early signals of efficacy from ex-vivo functional assays are also expected at the same time.

SRT-015 – Current work on an improved formulation aims at increasing exposure. Pending positive development, the launch of a first-in-human trial could be initiated as early as the second half of 2026.

CLM-022 – Current experiments aim at confirming therapeutic efficacy using different disease models relevant for AD and ACLF as well as starting formulation development and first toxicological studies in 2025. Pending further positive developments, a first-in-human trial could be initiated in the first half of 2027.

VS-02-HE – We intend to develop VS-02-HE as a unique oral formulation designed to act in the gut where ammonia is primarily produced, minimizing systemic absorption of ammonia while reducing glutamine levels in the brain. Completion of Investigational New Drug-enabling nonclinical studies and formulation development are expected by the end of 2025. A first-in-human trial could be initiated in the second half of 2027.

Other life-threatening diseases

GNS561 in CCA – Data readout from the ongoing Phase 1b clinical trial are expected by the end of 2025.

VS-01-HAC in Urea Cycle Disorders & Organic Acidemias (pediatric indication) – Data from the pivotal juvenile toxicology study in Göttingen Minipigs are expected before the end of 2025. Following discontinuation of VS-01 in ACLF, additional preclinical work will be conducted before moving into the clinic. Update on the ongoing preclinical work and potential clinical development is expected before the end of 2025.

Primary Biliary Cholangitis (PBC)

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As reported in Ipsen's third quarter financial results⁵, Iqirvo® (elafibranor) continues to show solid growth across both the U.S. and European markets in PBC.

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ABOUT GENFIT

GENFIT is a biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades.

Today, GENFIT focuses on Acute on-chronic Liver Failure (ACLF) and associated conditions such as acute decompensation (AD) and hepatic encephalopathy (HE). It develops therapeutic assets which have complementary mechanisms of action, selected to address key pathophysiological pathways. GENFIT also targets other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorders (UCD) and organic acidemia (OA). Its R&D portfolio, covering several stages of development, ensures a constant news flow.

GENFIT's expertise in developing high-potential molecules – from early to advanced pre-commercialization stages – culminated in 2024 with the accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for the treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.⁶

Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® for the detection of Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis).

GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about our achievement of key milestones enabling us to receive payments

⁵ [Ipsen delivers strong sales in the first nine months of 2025 and further upgrades its full-year guidance](#)

⁶ Elafibranor is marketed and commercialized, notably in the U.S and Europe, by Ipsen under the trademark Iqirvo®.

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under our license agreement with Ipsen, the successful commercialization of Iqirvo® (elafibranor), our achievement of the necessary objectives to obtain the future €55 million in additional payments under the royalty financing agreement signed with HCRx, anticipated timing for study data readouts, in particular regarding our development programs for G1090N in the prevention and/or treatment of ACLF and for GNS561 in CCA, and development plans for our other pipeline programs and our financial outlook including cash flow and cash burn projections. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among others, the uncertainties inherent in research and development, including in relation to non-clinical and pre-clinical programs, reproducibility of preclinical results, the translation of animal model data to human biology, in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, patient recruitment, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, pricing, approval and commercial success of elafibranor in the relevant jurisdictions, exchange rate fluctuations, 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 "Risk Factors and Internal Control" of the Company's 2024 Universal Registration Document filed on April 29, 2025 (no. 25-0331) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2024 Annual Report on Form 20-F filed with the SEC on April 29, 2025 and subsequent filings and reports filed with the AMF or SEC including the Half-Year Business and Financial Report at June 30, 2025 or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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 press release. 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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