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GENFIT Reports Third Quarter 2026 Financial Information and Provides Corporate Update

- **Cash and cash equivalents of €95.6 million as of September 30, 2026; expected to fund the Company beyond 2028, with continued revenue growth and disciplined spending thereafter expected to drive GENFIT toward profitability**
- **€36.3 million in revenue for the first nine months of 2026 from royalties on Ipsen's sales of Iqirvo® (elafibranor), an increase of 188% year-over-year**
- **PBC: Ipsen reported €283m in Iqirvo® net sales in the first nine months of 2026, up 170.8% year-over-year, supporting GENFIT's expectation that a new commercial sales milestone could be reached based on full-year 2026 net sales**
- **MASH: NIS™ Technology gaining momentum following Medicare reimbursement for Labcorp's NASHnext® in August**
- **Clinical pipeline: Three Phase 2 clinical trials advancing in ACLF and CCA, with data readouts targeted for 2027**

Lille (France); Cambridge, (Massachusetts, United States); November 5, 2026 - GENFIT (Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announces its third quarter 2026 financial results[1] and provides a corporate update.

Cash and Revenue

Cash position

As of September 30, 2026, the Company's cash and cash equivalents amounted to €95.6 million compared with €113.8 million as of June 30, 2026, and €101.1 million as of December 31, 2025.

In 2026, cash consumption was primarily driven by research and development activities across our Acute-on-Chronic Liver Failure (ACLF) franchise programs, notably NTZ/G1090N, SRT-015, CLM-022 and VS-02 HE, as well as our GNS561 program in cholangiocarcinoma (CCA). Cash consumption was partially offset by two significant cash inflows during the first half of 2026: (i) the second €30.0 million tranche received under the royalty financing agreement and (ii) the receipt of the first commercial milestone from Ipsen totaling €17.0 million ($20.0 million), which had been recognized in 2025 and was received in cash in 2026.

Cash runway

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 R&D pipeline and support general corporate purposes. Beyond this period, as sales of elafibranor increase, we expect related cash flows to become an increasingly important source of funding, with the objective of ultimately financing our operations and future development through cash generated by the business. This is based on current assumptions

[1] Unaudited financial information under IFRS



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and programs and does not include exceptional events. In particular, this assumes (i) the continued commercial performance of Iqirvo® (elafibranor) and resulting royalties, (ii) the expectation to receive significant commercial milestones under the Ipsen Agreement, (iii) maintaining operating expenses at levels broadly consistent with current expectations, (iv) the development of revenues from our diagnostic activities, and (v) the possibility to draw down, if needed, the third and final installment of the Royalty Financing agreement.

Revenue

Revenue	Nine-months ended	
(In € thousands)	30/09/2025	30/09/2026
Royalty revenue	12,596	36,308
Milestone revenue	26,556	0
Other revenue	81	125
Total	39,233	36,433

Royalty revenue

Virtually all royalty revenue is derived from worldwide sales of Ipsen's Iqirvo[2] (elafibranor) under the Ipsen Agreement. These are utilized to repay the Group's Royalty Financing agreement. Year-over-year growth for the periods presented was 188%, reflecting accelerating U.S. sales and strong performance across Europe and other markets.

Milestone revenue

On May 20, 2025, GENFIT announced that Ipsen's Iqirvo (elafibranor) was granted pricing and reimbursement in Italy for Primary Biliary Cholangitis (PBC), the third major European country to do so in addition to the UK and Germany. This third approval triggered a milestone payment of €26.5 million under GENFIT's Licensing and Collaboration Agreement with Ipsen, due upon pricing and reimbursement of Iqirvo (elafibranor) in three major European markets.

Year-over-year revenue comparisons should consider the timing of milestone payments. Revenue for the nine months ended September 30, 2025 included a milestone payment, while no milestone revenue was recognized in the nine months ended September 30, 2026. Additional milestone revenue may however be recognized in future periods.

Corporate update

Elafibranor in cholestatic liver diseases

Primary Biliary Cholangitis (PBC) - Iqirvo net sales reached €109.4 million in Q3 2026, compared with €48.6 million in Q3 2025, representing 125.4% year-over-year growth at constant exchange rates (CER). For the first nine months of 2026, net sales reached €282.6 million, versus €107.4 million over the same period in 2025, representing 170.8% growth at CER.[3] Iqirvo is leading growth within Rare Disease, Ipsen's fastest-growing franchise. Earlier in July, Ipsen upgraded its peak sales estimates from €500 million to €1 billion in PBC. This

[2] Iqirvo® and NASHnext® are registered trademarks of GENFIT SA

[3] Ipsen press release - 22 October 2026



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revision followed Ipsen's announcement on July 13, 2026[4], that the primary endpoint of alkaline phosphatase (ALP) normalization had been achieved in 85% of patients treated with Iqirvo (elafibranor), compared with 23% of patients receiving placebo at Week 52, in the Phase 3 ELSPIRE study.

- **Next steps:** Following positive results of the ELSPIRE study, regulatory submission is underway for PBC label update. Ipsen intends to publish its full-year results and fourth-quarter sales on February 11, 2027.

Primary Sclerosing Cholangitis (PSC) - Phase 3 ELASCOPE study launched early 2026 is still ongoing. The market opportunity in PSC is estimated to be comparable in size to the second-line PBC market. Subject to successful development and regulatory approval of elafibranor in this indication, GENFIT would be eligible to receive additional milestone payments as well as incremental double-digit royalties.

- **Next steps**: Data readout expected around 2031.

Non-invasive diagnostic technology in Metabolic dysfunction-Associated SteatoHepatitis (MASH)

Medicare reimbursement for Labcorp's NASHnext®[2] test (based on GENFIT's NIS™ technology) became effective in August 2026 (under the Clinical Laboratory Fee Schedule) for patients meeting coverage criteria. GENFIT believes broader reimbursement by private payers, if obtained, could support accelerated adoption of its technology over time. Further market expansion could also be supported by a potential future In Vitro Diagnostics (IVD) launch, which may facilitate deployment across a wider range of healthcare settings.

In September, based on intention-to-diagnose data collected across key specialties, increasing disease prevalence, and a staged commercialization strategy spanning Laboratory Developed Tests (LDT) and IVD, IQVIA estimated that U.S. peak annual sales of products using GENFIT's technology could exceed $1.5 billion by 2033, with annual testing volume in the U.S. reaching more than 7 million tests.[5]

GENFIT is engaging with stakeholders at AASLD The Liver Meeting® 2026 (November 5-9) to raise awareness of the evolving evidence supporting non-invasive approaches to identifying patients with at-risk MASH, including its NIS™ Technology.

- **Next steps**: GENFIT intends to outline its industrial strategy for the development and large-scale commercialization of an IVD kit based on its NIS™ Technology toward year-end. Subject to successful development, regulatory approval, partner execution and market adoption, GENFIT believes a potential commercial launch from 2028 could contribute to a meaningful acceleration in NIS™-related revenues over time.

R&D pipeline

Nangibotide to be evaluated in Phase 2 in ACLF - In summer 2026, GENFIT acquired the nangibotide program, a differentiated late-stage asset targeting the TREM-1 pathway. Phase 2 development is supported by efficacy signals observed across three prior Phase 2 clinical trials in septic shock and Covid19, including statistically significant improvements in mortality and SOFA score in selected analyses, together with a favorable safety and tolerability profile across more than 400 exposed subjects.

- **Next steps:** Nangibotide is expected to enter a Phase 2 study in ACLF by year-end, with data readout targeted in the second half of 2027.

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[4] Ipsen press release - 13 July 2026

[5] Regulatory authorization through the applicable local approval process is required for IVD products and has not yet been obtained.



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Nitazoxanide to be evaluated in Phase 2 in ACLF – Positive Phase 1 data reported in early 2026 confirmed the favorable safety profile of NTZ and demonstrated multi-modal biological activity, supporting its continued clinical development across the ACLF disease continuum. In March 2026, FDA granted Orphan Drug Designation for NTZ for the treatment of ACLF.

- **Next steps:** The proof-of-concept study initiated in the third quarter of 2026 is expected to deliver data in mid-2027.

GNS561 to be evaluated in Phase 2 in combination, in KRAS mutated CCA – Encouraging preliminary data from the ongoing Phase 1b study evaluating GNS561 in combination with a MEK inhibitor in KRAS-mutated CCA were disclosed in December 2025 and June 2026, leading to the expansion of the study into additional cohorts.

- **Next steps:** Additional Phase 1b data expected by year-end; Phase 2 initiation on track by year-end, with data readout targeted for the second half of 2027.

Research programs in ACLF and CCA – GENFIT is directing its capital and development resources towards the programs with the strongest translational rationale and clinical potential.

- **Next steps:** Further details will be provided as and when these programs advance into clinical development.

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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 second-line 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, a BCorp™ certified company since 2025, is headquartered in Lille, France and has offices in Paris (France) and Cambridge, MA (USA). The Company is listed on the Euronext regulated market in Paris, Compartment B (Euronext: GNFT) and joined the CAC Mid 60 and SBF 120 indices on September 18, 2026. In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including, but not limited to, statements regarding the Company's cash runway, revenue growth, spending and path to profitability; potential royalties, milestone payments and additional royalty financing; the development, regulatory prospects and commercial potential of elafibranor; the development, reimbursement, adoption and commercialization of products based on NIS™ Technology, related market projections and GENFIT's revenue potential; and the advancement of its R&D programs, including anticipated clinical trial initiation and data readout timelines. 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 the Company's ability to advance its therapeutic programs and initiate and complete clinical trials; uncertainties relating to regulatory requirements and decisions, patient enrollment, clinical trial execution, safety findings, manufacturing and clinical supply; the possibility that findings from prior studies in other indications, preclinical research or ex vivo assays may not predict safety, efficacy or clinical benefit in patients with ACLF; uncertainties relating to the clinical utility, further validation, adoption and use of non-invasive MASH diagnostics, including for disease or treatment- response monitoring; changes in clinical practice, treatment uptake, reimbursement, access and applicable regulatory requirements; and the Company's dependence on partners and other third parties whose plans and activities may change. Those risks and uncertainties also include those 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 2025 Universal Registration Document filed on April 3, 2026 (no. 26-0221) 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 reports filed with the AMF or otherwise made public, by the Company, including the Half-Year 2026 Business and Financial Report. 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

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



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otherwise. Links to third-party websites and materials, in particular those of Ipsen, are provided for convenience only. GENFIT is not responsible for the content of such materials and does not endorse or adopt any forward-looking statements contained therein.



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