UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of report: February 6, 2025

Commission File Number: 001-38844

GENFIT S.A.

(Translation of registrant's name into English)

Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

☒ Form 20-F ☐ Form 40-F

INCORPORATION BY REFERENCE

The contents of this report on Form 6-K (including Exhibit 99.1) are hereby incorporated by reference into the registrant's registration statement on Form F-3 (File No. 333-271312) and registration statement on Form S-8 (File No. 333-271311) and related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Information contained on, or that can be accessed through, any website included in Exhibit 99.1 is expressly not incorporated by reference.

EXHIBIT LIST

Exhibit	Description
99.1	Press Release dated February 6, 2025.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENFIT S.A.

Date: February 6, 2025

By: /s/ Pascal PRIGENT
Name: Pascal PRIGENT
Title: Chief Executive Officer

GENFIT Outlines Anticipated New Clinical Trial Initiations, Development Milestones and Data Readouts in 2025

- **2 new ACLF clinical trials expected to initiate in 1Q25**
- **3 clinical data readouts expected by year-end 2025 across the ACLF pipeline, including on- going UNVEIL-IT® Phase 2 trial**
- **Data of on-going Phase 1b also expected by year-end 2025 for GNS561/trametinib in KRAS- mutated cholangiocarcinoma, to support dose selection for Phase 2**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), February 6, 2025 - GENFIT (Nasdaq and Euronext: GNFT) , a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today outlines the design of new clinical trials within its Acute on-Chronic Liver Failure (ACLF) pipeline, with several clinical data readouts by end of 2025.

Pascal Prigent, CEO of GENFIT, commented: "*Throughout 2024, our work in ACLF with leading academic partners and real-world evidence from a dataset of over 270,000 U.S. patients provided valuable insights. This effort informed the design of two new trials which are expected to initiate in the first quarter with VS-01 and G1090N, the new formulation of NTZ. We believe these designs will streamline execution and enable faster patient recruitment. With the UNVEIL-IT®1 Phase 2 readout in ACLF and the GNS561 Phase 1b readout in cholangiocarcinoma, we anticipate four clinical data readouts by year-end, positioning 2025 as a pivotal year for GENFIT. Combined with our strengthened financial outlook, announced last week and pending OCEANE bondholders' approval, GENFIT is well-positioned to operate on strong foundations for the coming years.*"

Evidence Supporting ACLF Pipeline Strategic Development

New trials, set to launch, build on key 2024 findings from complementary workstreams that provided a holistic understanding of the ACLF continuum, including:

§ Advanced Real-World Evidence analysis: AI-driven evaluation of medical claims data from over 270,000 U.S. patients, uncovering ACLF risk profiles, referral dynamics, and management practices, including patients with acute decompensation of cirrhosis (AD)
§ KOL insights: Key perspectives from the ACLF KOL Advisory Board held during the November 2024 Liver Meeting2 in San Diego, including both U.S. and European perspectives, with both NACSELD3 and EF CLIF4 stakeholders

[1] Iqirvo®, NIS2+® and UNVEIL-IT® are registered trademarks of GENFIT SA
[2] The Liver Meeting 2024® is a registered trademark of the American Association for the Study of Liver Diseases
[3] North American Consortium for the Study of End-Stage Liver Disease
[4] European Foundation for the Study of Chronic Liver Failure

§ EF CLIF collaboration: Ongoing engagement with our academic partner EF CLIF, providing strategic insights into clinical management practices and needs
§ Learnings from UNVEIL-IT®: Feedback from investigators on challenges and opportunities

This integrated approach ensures a comprehensive foundation to advance our ACLF pipeline. Notably, it has provided the rationale for including a subset of patients with AD at a high-risk of progressing to ACLF in our target population for the new trials. Broadening inclusion criteria to cover the ACLF continuum creates opportunities to address both stages of the disease. With easier and faster identification, it will also enable a rapid assessment of drug-candidates' therapeutic potential, supporting data-driven prioritization and minimizing the risk of engaging into larger-scale investments.

Dr. Jonel Trebicka, MD, PHD, Head of Department and Professor of Medicine, University of Münster, Germany , commented: "*It makes sense for GENFIT to evaluate its assets in a subset of patients with AD having specific comorbidities that contribute to a particularly poor prognosis. This category of high-risk patients should be included in clinical trials given that patients with AD transition rapidly to ACLF, and vice versa. AD and ACLF are very dynamic syndromes sharing key pathophysiological mechanisms.*"

Dr. Jacqueline O'Leary, Chief of Hepatology at the Dallas VA Medical Center and Professor of Medicine at UTSW, USA , added: "*ACLF should be viewed as a continuum. Real-world evidence showed that some patients with acute decompensation face a high risk of mortality. Therefore, it is crucial to include this specific patient group when evaluating drug candidates.*"

2025 New Clinical Trial Initiations and Readouts

The first trial to be launched is a proof-of-concept study that underscores GENFIT's commitment to VS-01:

§ Target population: patients with AD or ACLF grade 1 having overt Hepatic Encephalopathy (HE) grades 2, 3 or 4, and ascites as a prerequisite for drug administration
§ Number of patients: 21

§ Treatment duration: up to 4 days
§ Primary endpoint: Time to improvement in overt HE
§ Secondary endpoints: Safety and tolerability, pharmacokinetic and pharmacodynamic parameters
§ Exploratory endpoints will include blood ammonia, inflammatory and other clinical markers or outcomes

The second proof-of concept trial confirms GENFIT's commitment to NTZ, with G1090N, its new formulation developed in 2024:

§ Target population: Patients with AD who are at risk of progression to ACLF or ACLF grade 1
§ Number of patients: 21

§ Treatment duration: 7 days
§ Primary endpoint: Safety and tolerability
§ Secondary endpoint: Pharmacokinetic and pharmacodynamic parameters
§ Exploratory endpoints will include inflammatory and clinical markers or outcomes

By design, these two new trials are not expected to compete with the recruitment of patients for UNVEIL-IT®.

A third study, a First-in-Human trial with a new formulation of SRT-015, is set to launch following final analyses of preclinical data expected in 1Q25. Pending positive analysis, pharmacokinetic and pharmacodynamic assessments will be conducted in healthy volunteers, with clinical data readout anticipated by late 2025.

With the readout of UNVEIL-IT® Phase 2, which evaluates VS-01, also targeted in the second half of 2025, up to 4 clinical datasets are expected to be released by GENFIT before the end of this year within our ACLF pipeline.

In addition, final data of the Phase 1b evaluating GNS561 in combination with trametinib in patients with KRAS-mutated cholangiocarcinoma, is also expected by year-end and is aimed to support dose selection for Phase 2. Preliminary safety data analyzed end of 2024 from the patients treated in the first cohort of Phase 1b with the combination of GNS561 and trametinib are supportive of the completion of the first cohort and of the continuation of the study.

END

ABOUT GENFIT

GENFIT is a late-stage 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 has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ aka G1090N, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Additional assets target other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorder (UCD) and organic acidemia (OA). GENFIT's expertise in the development of high- potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated in the accelerated approval of Iqirvo® (elafibranor[5]) by the U.S. Food and Drug Administration, the

[5] Elafibranor is marketed and commercialized in the U.S by Ipsen under the trademark Iqirvo®.

European Medicines Agency and the Medicines and Healthcare Regulatory Agency in the UK for Primary Biliary Cholangitis (PBC). Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. 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 on 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 expected timelines for research and development programs, impact of program designs on ability and speed of recruiting patients into trials and assessing potential of drug candidates therapeutic potential, expectations regarding financial outlook. 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 safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, 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 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) 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 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024, the Half-Year Business and Financial Report dated September 19, 2024 and subsequent filings and reports filed with the AMF or SEC 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 inwhich 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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