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: November 16, 2023

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

EXHIBIT LIST

Exhibit	Description
99.1	Press Release dated November 16.

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: November 16, 2023

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

GENFIT Highlights ACLF Development Strategy at "ACLF Day" during AASLD The Liver Meeting® 2023

- **GENFIT highlighted new focus and development strategy in Acute On-Chronic Liver Failure (ACLF)**
- **ACLF is a very serious condition affecting ~294,000[1] [2] patients with chronic liver diseases in the USA and Europe every year and is associated with multi-organ failure and high short-term mortality**
- **It is an underserved medical condition with currently no approved treatment and few programs under development globally**
- **GENFIT has developed a unique pipeline of 5 different drug candidates targeting key pathophysiological pathways of ACLF**
- **Phase 2 interim data readout from lead program VS-01 in ACLF targeted for 2Q24**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), November 16, 2023 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced the highlights from its "ACLF Day" held on November 11, 2023 during AASLD The Liver Meeting ® in Boston, MA (USA).

GENFIT is now mainly focused on the development of therapies for ACLF which is an area of very high unmet medical need. ACLF is a potentially deadly, but reversible, condition in patients with chronic liver diseases, which is associated with multi-organ failure and high short-term mortality. There is currently no approved treatment for ACLF. The presentation from the event is available on the company website in the investors section.

The development of the company's new, expanded and diversified pipeline targeting rare and life- threatening liver diseases with high unmet medical needs will be supported by potential milestone payments and royalties deriving from the licensing of elafibranor[3] to its partner, Ipsen. At AASLD, Ipsen presented additional data from the ELATIVE® Phase 3 study in primary biliary cholangitis (PBC) and announced its publication in the prestigious *New England Journal of Medicine* (November 2023)[4].

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[1] Source: Moreau, R., et al., (2013) Supplemental Table 10)

[2] Therapies targeting ACLF are eligible for Orphan Drug Designation given low prevalence and lack of therapies

[3] Elafibranor's rights have been licensed to Ipsen in December 2021 and to Terns Pharmaceuticals in June 2019 for China, Hong Kong and Macau

[4] https://www.nejm.org/doi/full/10.1056/NEJMoa2306185

Data from ELATIVE® are being used to support Ipsen's submissions for elafibranor as a treatment for PBC with regulatory authorities in the US and EU[5].

Pascal Prigent, CEO of GENFIT, commented: *"During AASLD we were excited to further discuss our development strategy around our new pipeline focused on ACLF, where we believe multiple programs have the potential to transform the treatment paradigm for these patients. It was also great to see more data presented by our partner Ipsen on PBC, which confirm that elafibranor has a competitive profile and a great potential to help patients with this disease. This AASLD meeting reinforced our conviction that Ipsen, as it works through the approval process with regulatory authorities in the US and EU, is committed to getting elafibranor to patients as quickly and efficiently as possible. For GENFIT this could mean significant revenues that will fund the development of a truly unique portfolio aiming at providing solutions for healthcare professionals treating patients suffering from a very challenging condition for which there is currently no approved options. We look forward to presenting preliminary data from our lead ACLF program, VS-01, as early as next year."*

ACLF: high short-term mortality, no approved treatment

ACLF is a serious, but potentially reversible, condition in patients with chronic liver disease and cirrhosis, which is associated with multiple organ failure, and a 23% to 74% mortality at 28 days[6] depending on grade severity. As part of the "ACLF Day" event during AASLD, the critical need for treatment has been highlighted by leading experts in ACLF.

Dr Jennifer C. Lai, MD, MBA, Transplant Hepatologist, Endowed Professor of Liver Health & Transplantation, University of California, San Francisco (UCSF) said: *"ACLF is a terrifying condition for patients and their caregivers, but it's equally terrifying for clinicians, because we know our patients are in grave and immediate danger, and we have no approved treatment to help them. It is very frustrating and therefore it is critical that therapies are developed, ideally to reverse the course of the disease or at least to give the patient more time to get a potentially life-saving transplantation. This is an area of huge unmet medical need and I welcome new efforts to develop potentially helpful therapies."*

GENFIT's pipeline in ACLF: targeted to address the unmet need

GENFIT's ACLF therapeutic candidates have been strategically selected based on the pathophysiology of ACLF – as defined by liver experts and consortiums such as EF-CLIF (European Foundation for the study of Chronic Liver Failure) – to address the most relevant pathways.

[5] https://www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2023/08/11114914/Ipsen-investorpresentation- September-2023.pdf (slide 9)

[6] Arroyo V et al., Nat. Rev. Dis. Primers 2 (2016)

Considerations about the limitations in current standard of care have also been taken into account. Among the pathways identified, priority is given to systemic inflammation, cell death and microbiota.

Dean Hum, PhD, Chief Scientific Officer of GENFIT, commented: "*Our R&D strategy is centered on understanding the pathophysiology of ACLF and selecting molecules that we believe are best positioned to impact specific relevant pathways. This multi-factorial approach will allow us greater chances of success as well as leveraging potential synergies via combinations. It also offers the possibility to apply key learnings across all ACLF programs, to accelerate overall execution.*"

The ACLF pipeline overview:

- **VS-01 –** Phase 2 initiated (interim data readout targeted for the end of 2Q24): VS-01 is a liposomal-based technology designed to remove ammonia and other ACLF toxins from the blood (peritoneal route of administration)
- **NTZ –** Reformulation and Phase 2 under preparation (proof-of-concept study initiation targeted for the first half of 2025): NTZ is an anti-inflammatory and anti-bacterial agent aiming to reduce systemic inflammation, and impede release of PAMPs[7] and bacterial translocation (oral route of administration)
- **SRT-015 –** First-in-Human study under preparation (expected to be initiated 2H24): SRT-015 is an ASK1 inhibitor, liver-centric, aimed at inhibiting cell death, inflammation and fibrosis (injectable route of administration)
- **CLM-022 –** Preclinical proof of concept under preparation (expected to start 2024): CLM-022 is an NLRP3 inflammasome inhibitor aimed at inhibiting systemic inflammation and cell death (pyroptosis)
- **VS-02-HE –** Completion of IND enabling studies expected in 2025: VS-02-HE aims at reducing hyperammonemia, stabilizing blood ammonia and preventing hepatic encephalopathy (oral route of administration)

Inaugural *Patient Advocacy Council* organized by GENFIT

Patients are at the heart of what GENFIT does. As we embark on a major new R&D initiative, it was important to integrate the patient voice very early in the process. This is why we hosted two *Patient Advocacy Council* sessions at AASLD. GENFIT's ambition is to co-design initiatives with patient representatives and leading clinicians in order to better understand patients' and caregivers' information needs, gather their insights and perspective in the context of clinical trial design, and facilitate access to innovative medicine through clinical trials.

[7] Pathogen-associated molecular patterns

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening 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. Today, GENFIT has a growing and diversified pipeline with programs at various development stages. The Company's area of focus is Acute on Chronic Liver Failure (ACLF). Its ACLF franchise consists of five assets in development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE. These are all based on differentiated mechanisms of action leveraging complementary pathways. Other assets target other life-threatening disease indications such as cholangiocarcinoma (CCA) and Urea Cycle Disorders (UCD)/Organic Acidemias (OA). GENFIT's track record in bringing early-stage assets with high potential to late development and pre- commercialization stages is highlighted in the successful 52-week Phase 3 ELATIVE® trial evaluating elafibranor in PBC. Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on Metabolic dysfunction-associated steatohepatitis (MASH) (previously known as nonalcoholic steatohepatitis – NASH) and ammonia. 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. For more information, visit 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 expectations for availability of clinical data in the evaluation of VS-01 in ACLF, Ipsen's ability to obtain quickly and efficiently, marketing authorization for elafibranor in PBC, GENFIT's ability to receive milestones and royalties under the collaboration and licensing agreement with Ipsen with respect to PBC and the use of those potential revenues to fund GENFIT's further R&D and start dates of clinical and pre-clinical development phases for GENFIT's other pipeline programs. The use of certain words, including "believe", "potential," "expect", "target", "may" and "will" 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 other things, 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, potential commercial success of elafibranor if approved, exchange rate fluctuations, 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 2022 Universal Registration Document filed with the AMF on April 18, 2023, which 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 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023 and subsequent filings and reports filed with the AMF or SEC, including the Half-Year Business and Financial Report at June 30, 2023 or otherwise made public, by the Company. 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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