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: December 6, 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 December 6, 2023.

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: December 6, 2023

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

GENFIT Announces Publication in the *Journal of Hepatology* on the Accurate Performance of NIS2+™ as a Screening Tool for the Enrollment of Patients in MASH Clinical Trials

- **The paper published in *Journal of Hepatology* demonstrates that NIS2+™ technology could significantly reduce liver biopsy failure rate and maximizes accuracy of patient selection for MASH[1] clinical trials**
- **Growing body of clinical evidence: this is the third paper on NIS2+™ that has been published in a leading medical journal in 2023**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), December 6, 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 publication in the *Journal of Hepatology*[2] of a paper on the performance of NIS2+™ as a screening tool for the enrollment of patients in Metabolic Dysfunction–Associated Steatohepatitis (MASH) clinical trials.

The study highlights NIS2+™'s potential effectiveness to significantly reduce the number of liver biopsies required for the enrollment of patients in MASH clinical trials. The study demonstrates that, for 1,000 inclusions in a trial, NIS2+™ could significantly reduce the number of unnecessary liver biopsies being performed (632 vs 1,522; -58%). The data taken from this study indicate that NIS2+™ may reduce liver biopsy failure rate to <30% and that NIS2+™ alone performs better than FIB-4 alone (a non-invasive test for fibrosis detection) or combined with FIB-4.

In MASH clinical trials, patients are referred to liver biopsy for potential enrollment based on clinical and biological features that are neither sensitive nor specific, leading to unacceptably high (>60%) liver biopsy failure rates. Reducing liver biopsy failure rates using non-invasive tests represents a high unmet need and an important step towards accelerating recruitment at optimized cost in future MASH clinical trials.

Dr. Vlad Ratziu, Professor at Sorbonne University and Pitié-Salpêtrière Hospital in Paris, France, stated: *"Most late-stage MASH trials do not have a well-defined, non-invasive strategy for referring patients to liver biopsy. There is a real need to maximize the accuracy of the patient selection process by using better non-invasive predictors of at-risk MASH. NIS2+™ has the potential to become an*

[1] At the EASL Congress in June 2023, it was announced that non-alcoholic steatohepatitis (NASH) would now be referred to as Metabolic dysfunction-associated steatohepatitis (MASH).
[2] https://doi.org/10.1016/j.jhep.2023.10.038

accessible and rapid screening tool that could have a major impact on the feasibility of MASH clinical trials, including the speed of enrollment."

Dr. Stephen Harrison, Chairman and Founder for Pinnacle Clinical Research, Chairman and Co-Founder of Summit Clinical Research, USA and Visiting Professor of Hepatology at the Radcliffe Department of Medicine, University of Oxford, UK, commented: *"Screening patients with NIS2+™ would potentially prevent unnecessary liver biopsies, reducing the likelihood of study related complications and improve patient satisfaction. It would also lead to a liver biopsy failure rate decrease, maintaining timely and cost-efficient completion of MASH clinical trials – a prerequisite for the testing of the numerous molecules currently in development."*

A total of three papers on NIS2+™ technology have been published in leading medical journals this year. Six posters and two oral presentations featuring complementary data on the performance of NIS2+™ were also presented this year at key scientific conferences: NASH-TAG, EASL[3], Paris-NASH and AASLD[4] TLM.

ABOUT MASH

MASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with an increased risk of cardiovascular disease along with long-term risk for progression to cirrhosis, leading to liver insufficiency and potential progression to liver cancer. MASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for liver transplant. The prevalence of MASH is rapidly increasing as a result of the growing obesity and diabetes epidemics and is believed to affect as much as 12 percent of people in the U.S. and six percent worldwide.

ABOUT NIS2+™

NIS2+™ is a blood-based diagnostic technology specifically designed to detect at-risk MASH among patients with metabolic risk factors based on an independent 2-biomarker panel. It is an optimization of the NIS4® technology and was developed and validated by GENFIT as a robust technology across characteristics of interest such as type-2 diabetes, age and sex, allowing large- scale implementation in clinical practice. GENFIT continues to explore the possibility of obtaining regulatory approval and CE Certificates of Conformity, for the widespread use an IVD test powered by NIS2+™ technology in both the United States and Europe.

ABOUT GENFIT

[3] European Association for the Study of the Liver
[4] American Association for the Study of Liver Diseases

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 the ability of NIS2+™ to reduce the number of liver biopsies required to complete patient enrollment in MASH clinical trials, liver biopsy failure, maximize accuracy of patient selection and lower costs of MASH clinical trials, as well as reduce likelihood of study- related complications and improve patient satisfaction. 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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