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: May 23, 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 May 23, 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: May 23, 2023

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

Exhibit 99.1

GENFIT Announces Publication of the Development and Validation of NIS2+™ in the *Journal of Hepatology*

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); May 23, 2023- **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases, today announced the publication of the development and validation of NIS2+™ in the *Journal of Hepatology*.[1]

NIS2+™ is a next-generation technology for the diagnosis of at-risk Non-Alcoholic Steatohepatitis (NASH). It is a non-invasive diagnostic technology designed as an optimization of NIS4® technology, a blood-based panel currently used to detect at-risk NASH.

In November 2021, NIS4® was recognized by the NIMBLE[2] Initiative of the FNIH's[3] Biomarkers Consortium as showing a unique performance in identifying patients with at-risk NASH.

Data presented at the AASLD [4] Liver Meeting® in October 2022 demonstrated the robust and improved clinical performance of NIS2+™ allowing an efficient identification of at-risk NASH, irrespective of patient characteristics such as age, sex and type 2 diabetes. It was also demonstrated that NIS2+™ is an effective screening tool for the enrollment of patients with at-risk NASH in clinical trials, reducing liver biopsy failure rates and associated costs without inflating the number of patients to screen.

There is currently a high unmet medical need for an In Vitro Diagnostic (IVD) test to enable a non- invasive, accessible and rapid diagnostic that is an alternative to liver biopsy, improving overall clinical care and greatly reducing barriers to entry for innovative therapies. NIS2+™ is the only blood-based technology developed for the identification of at-risk NASH allowing it to be applied for large-scale use in clinical practice.

Dr. Vlad Ratziu, Professor at Sorbonne University and Pitié-Salpêtrière Hospital in Paris, France commented:
"*With NASH drugs potentially coming on the market in the very near future, there is an increasing and urgent need for patients and the healthcare system for a NASH diagnostic that is non-invasive, robust and cost-effective. By having both a diagnostic and therapeutic solution, physicians will be able to efficiently manage patients with progressive forms of NASH.*"

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[1] https://doi.org/10.1016/j.jhep.2023.04.031

[2] Non-Invasive Biomarkers of Metabolic Liver Disease

[3] Foundation for the National Institutes of Health

[4] American Association for the Study of Liver Diseases

Stephen A. 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:
"*We are excited that the development and validation of NIS2+™ have been recognized by one of the leading medical journals. Thanks to such progression in patient management with the development of this next-generation technology, physicians can offer satisfactory solutions to patients suffering from at- risk NASH*."

GENFIT continues to explore the possibility of obtaining regulatory approval and CE Certificates of Conformity, alone or with a development and commercial partner, to release an IVD test powered by NIS2+™ technology on the US and European markets.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe 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. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D pipeline covers six therapeutic areas via six programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorder (UCD), organic acidemias (OA) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF.

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. www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995 in relation to the clinical performance and future of NIS2+™ and the possibility of obtaining authorization for commercialization from the relevant health authorities. The use of certain words, including “consider”, “contemplate”, “think”, “aim”, “expect”, “understand”, “should”, “aspire”, “estimate”, “targeted”, “anticipated”, “believe”, “wish”, “may”, “could”, “allow”, “seek”, “encourage” or “have confidence” or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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, biomarkers, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs 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 “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. 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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