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: August 10, 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 August 10, 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: August 10, 2023

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

GENFIT Announces the Publication of New Data on the Clinical Performance of NIS2+™ in Older Patients in *Hepatology Communications*

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); August 10, 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 new data on the clinical performance of NIS2+™ in older patients, for the detection of at-risk nonalcoholic steatohepatitis (NASH) in *Hepatology Communications*[1].

In conjunction with Labcorp, a global leader of innovative and comprehensive laboratory services, data reported in the manuscript is the first to show and compare the clinical performance of NIS4® and its recently developed and improved upgrade NIS2+™ in a population of older adults (≥65 years of age) with well-established biomarker panels: FIB-4, NFS, ELF and ALT.

While previously published data showed that NIS2+™ had a high overall clinical performance for the detection of at-risk NASH achieving an AUROC[2] of 0.81 in a large study population, the Centers for Medicare & Medicaid Services (CMS) in the US requires peer-reviewed, published data showing that tests, that will be used for patient management, have high assay performance in patients who are ≥65 years of age. Results of this study showed the clinical performance of NIS2+™ was superior to other tests for the diagnosis of at-risk NASH in patients ≥65 years of age, greatly assisting with CMS reimbursement efforts. These data support the clinical value of this blood-based test for the diagnosis of at-risk NASH in older adults who would benefit from intensive lifestyle or therapeutic interventions.

Arun J Sanyal, MD, FAASLD, commented: "*I am delighted to see this work published. At-risk NASH is a serious condition that is commonly present in those 65 years or older and can progress silently to cirrhosis. This study demonstrates that the NIS2+™ test can be used to identify this population, and provides clinicians a tool that can be used in primary care settings to identify patients with this condition, so that they can engage in more aggressive management strategies or triage them for tertiary care. Such simple, yet validated, tools are not widely available, and they represent an important addition to the diagnostic armamentarium for metabolic dysfunction-associated steatotic liver disease.*"

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[1] https://www.doi.org/10.1097/HC9.0000000000000223

[2] Area Under the Receiver Operating Characteristics

ABOUT NIS2+™

NIS2+™ is a blood-based diagnostic test specifically designed to detect at-risk NASH among patients with metabolic risk factors based on an independent 2-biomarker panel. It was developed and validated by GENFIT as a robust Non-Invasive Test (NIT) across characteristics of interest such as type-2 diabetes, age and sex, allowing large-scale implementation in clinical practice.

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 of a successful Phase III trial (ELATIVE®) evaluating elafibranor in Primary Biliary Cholangitis (PBC) and a growing and diversified pipeline of innovative therapeutic and diagnostic solutions. Its R&D pipeline covers six therapeutic areas via seven 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 disorders (UCD), organic acidemias (OA) and 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. For more information, visit 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 of NIS2+™ in NASH and its reimbursement by the Centers for Medicare & Medicaid Services (CMS) in the US. 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.

CONTACT

GENFIT | Investors

Tel: +33 3 2016 4000 | investors@genfit.com

GENFIT | Press relations

Stephanie Boyer | Tel: +333 2016 4000 | stephanie.boyer@genfit.com