

**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 3, 2021

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXHIBIT LIST

Exhibit

Description

[99.1](#)

[Press Release dated May 3, 2021](#)

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 3, 2021

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



GENFIT announces the launch by Labcorp of NASHnext® A Novel Noninvasive Diagnostic Test Powered by GENFIT's NIS4™ Technology to Identify Patients with At-Risk NASH

Test Available Exclusively through Labcorp in the U.S. and Canada

Lille, France; Cambridge, MA; May 3, 2021 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced the launch of NASHnext®, a novel, noninvasive diagnostic test for nonalcoholic steatohepatitis (NASH). The test is offered exclusively in the U.S. and Canada through Labcorp, a leading global life sciences company. NASHnext® is powered by NIS4™, GENFIT's proprietary diagnostic technology that uses a novel, blood-based molecular biomarker test to identify NASH and significant fibrosis, also referred to as at-risk NASH, in patients with at least one metabolic risk factor, as published in *The Lancet Gastroenterology and Hepatology*.¹

NASH, the most severe form of nonalcoholic fatty liver disease (NAFLD), is a highly underdiagnosed cause of severe liver complications. NAFLD, a precursor to NASH, is estimated to affect nearly 80 million people in the U.S., but only 5 percent of patients are aware of their liver disease due to its asymptomatic nature and limited availability of tests, with highly invasive liver biopsy being the current clinical standard to diagnose it. Individuals meeting appropriate clinical criteria to support suspected cases of NAFLD or NASH are target populations for NASHnext® testing, one of the first blood-based tests that provides a simple score for the diagnosis of both NASH and significant to advanced liver fibrosis.

"Labcorp supported the research and development of NASHnext® through our Drug Development business, and now through our diagnostics capabilities, we can bring this valuable experience and the test to millions of patients. NASH is a widespread yet underdiagnosed liver disease with very serious consequences including end-stage liver disease and cardiovascular events," said **Brian Caveney, M.D., chief medical officer and president of Labcorp Diagnostics**. *"NASHnext® has the potential to substantially benefit very large patient populations by providing people with essential information regarding their liver health. With a clear diagnosis and the help of their doctors, patients will be able to*

¹ Harrison SA, Ratziu V et al. A blood-based biomarker panel (NIS4) for non-invasive diagnosis of non-alcoholic steatohepatitis and liver fibrosis: a prospective derivation and global validation study. *Lancet Gastroenterol Hepatol*, (in press). Accessed August 3, 2020. [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(20\)30252-1/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(20)30252-1/fulltext)



make informed decisions and implement strategies to monitor or slow the progression of their liver disease.”

In September 2020, GENFIT entered into a licensing agreement with Labcorp for the development and commercialization of a blood-based molecular diagnostic test powered by GENFIT’s NIS4™ technology. Since early 2019, Labcorp Drug Development has been offering the test to global researchers, which has also provided Labcorp with valuable experience in the validation and performance of the test. With the clinical launch of NASHnext®, healthcare providers and patients across the U.S. and Canada now have convenient access to this powerful new tool that provides vital information about a serious health condition that is underdiagnosed.

“The commercialization of NASHnext® by Labcorp is a major milestone for the entire NASH field. We believe that the capabilities and reach of Labcorp, a highly regarded life sciences company, will allow for wide and early availability of the test to help both patients and healthcare professionals manage NASH at scale,” said **Suneil Hosmane, Global Head of Diagnostics at GENFIT.**

GENFIT is a pioneer in NASH diagnostics and is committed to the development of additional diagnostics and therapeutics in chronic liver disease.

Labcorp has been a leader in the development of drugs and diagnostics for more than 50 years and is a recognized global leader in NASH clinical trials. For more information about NASH, visit: <http://www.labcorp.com/NASH>.

Financial terms for this agreement have not been disclosed.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with cholestatic and metabolic chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. GENFIT is currently enrolling in ELATIVE™, a Phase 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC). Elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority. As part of GENFIT’s comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which could enable easier identification of patients with at-risk NASH. NIS4™ technology has been licensed to LabCorp® in the U.S. and Canada for the development and commercialization of a blood-based molecular diagnostic test powered by NIS4™ technology. GENFIT has facilities in Lille and Paris, France, 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). www.genfit.com

ABOUT LABCORP

Labcorp is a leading global life sciences company that provides vital information to help doctors, hospitals, pharmaceutical companies, researchers, and patients make clear and confident decisions. Through our unparalleled diagnostics and drug development capabilities, we provide insights and accelerate innovations to improve health and improve lives. With more than 70,000 employees, we serve clients in more than 100 countries. Labcorp (NYSE: LH) reported revenue of \$14.0 billion in FY2020. Learn more about us at <http://www.Labcorp.com> or follow us on LinkedIn and Twitter @Labcorp.

GENFIT 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, with respect to GENFIT, including statements regarding the potential market size and patient population for NASHNext®, the diagnostic test powered by GENFIT's NIS4® diagnostic technology and developed by its partner Labcorp, the test's and technology's ability to identify NASH with significant fibrosis and its potential to contribute to NASH management and monitoring at a large scale, and Labcorp's capacity to disseminate it on a large scale. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "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, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, exchange rate fluctuations and the Company's continued ability to raise capital to fund its 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 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n°



D.21-0350, 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 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021. 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.

LABCORP CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, including but not limited to statements with respect to Labcorp's (the Company's) future operations, expansion of offerings and capabilities, and opportunities for future growth. Each of the forward-looking statements is subject to change based on various important factors, many of which are beyond the Company's control, including without limitation, the impact of the COVID-19 pandemic on our business and financial condition, as well as on general economic, business, and market conditions, competitive actions and other unforeseen changes and general uncertainties in the marketplace, changes in government regulations, including healthcare reform, customer purchasing decisions, including changes in payer regulations or policies, other adverse actions of governmental and third-party payers, changes in testing guidelines or recommendations, the effect of public opinion on the Company's reputation, adverse results in material litigation matters, failure to maintain or develop customer relationships, our ability to develop or acquire new products and adapt to technological changes, failure in information technology, systems or data security, and employee relations. These factors, in some cases, have affected and in the future (together with other factors) could affect the Company's ability to implement the Company's business strategy, and actual results could differ materially from those suggested by these forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Further information on potential factors, risks, and uncertainties that could affect operating and financial results is included in the Company's most recent Annual Report on Form 10-K and subsequent Forms 10-Q, including in each case under the heading RISK FACTORS, and in the Company's other filings with the SEC.



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