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: September 28, 2020

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 September 28, 2020.

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: September 28, 2020

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

GENFIT and LabCorp Sign Exclusive Agreement to Commercialize a Novel Diagnostic Test for Liver Disease

- **Innovative multi-biomarker blood test based on GENFIT'S NIS4™ technology is specifically designed to identify patients with at-risk non-alcoholic steatohepatitis (NASH)**
- **LabCorp to commercialize the test for clinical care use in U.S. and Canada to help identify the approximately 10 million individuals at risk of progressing to late stage complications due to NASH among the tens of millions of people with metabolic risk factors and suspected disease**
- **The test is expected to be available from LabCorp by early 2021**

Lille, France; Cambridge, MA; *[AND Burlington, N.C.,]* September 28, 2020 GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases**,** and **LabCorp® (NYSE:LH),** a leading global life sciences company that is focused on advancing health and guiding patient care decisions, have agreed to a five-year exclusive licensing agreement for GENFIT's NIS4™ technology to help identify patients with at-risk non-alcoholic steatohepatitis (NASH). As part of the agreement, LabCorp will develop and commercialize a blood-based molecular diagnostic test powered by NIS4™ technology throughout the U.S. and Canada enabling widespread access to healthcare providers.

NASH remains a highly underdiagnosed disease due to its asymptomatic nature and the limitations of existing diagnostic approaches. Liver biopsy, a highly invasive procedure, is the current clinical standard to formally diagnose NASH and to determine the stage of fibrosis. NIS4™ technology, as recently published in *The Lancet Gastroenterology & Hepatology (*available here*),* is a novel, multi-biomarker-based algorithm specifically developed to identify at-risk NASH, defined as the presence of NASH based on a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) ≥4 and significant to advanced fibrosis (F≥2).

Patients with at-risk NASH have an advanced form of the disease and face a greater likelihood of progression to severe complications including liver cancer, cirrhosis and the need for liver transplant, if left untreated. A single test score generated from the integration of four independent biomarkers – miR-34a-5p, alpha-2-macroglobulin, YKL-40, and HbA1c – can be used by a healthcare provider to help inform the best course of intervention.

This agreement with LabCorp will provide broad clinical availability of the test to specialty and primary care physicians across the U.S. and Canada. LabCorp will leverage its deep experience in commercializing innovative diagnostics to educate providers on NASH and the importance of non-invasive testing. The collaboration between the organizations began in early 2019, when LabCorp began offering NIS4™ technology to biopharmaceutical customers for use in clinical studies through Covance, its drug development business.

Marcia Eisenberg, Ph.D., Chief Scientific Officer of LabCorp Diagnostics, stated: "*LabCorp is committed to developing and distributing novel diagnostics to support the diagnosis of patients with NASH, which is one of the fastest growing serious medical conditions in the U.S. GENFIT's NIS4™ is a non-invasive technology specifically designed to identify patients with both NASH and significant to advanced fibrosis, and is an important advance in the ability to identify patients with NASH. We have gained valuable experience with this test since we began performing it in 2019 for clinical studies with biopharmaceutical clients, which will provide insights as we develop and prepare to make it available for use in patient care."*

Suneil Hosmane, Ph.D., Head of Global Diagnostics at GENFIT added: **"***We are pleased to expand our collaboration with LabCorp and are very enthusiastic about the potential impact of this agreement. We strongly believe that this test will help healthcare providers identify the approximately 10 million patients with at-risk NASH and higher risk of progression among the tens of millions with metabolic risk factors, such as type 2 diabetes and obesity, and suspected disease."*

Pascal Prigent, CEO of GENFIT, continued, *"This partnership supports GENFIT's pioneering research efforts in the field of NASH diagnostics that were recently recognized by experts in our most recent Lancet publication. The commercialization of NIS4™ technology by LabCorp is a defining opportunity whereby millions of NASH patients can become aware of, and then begin to take control of their disease."*

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 involved in the development of drugs and diagnostics for more than 50 years and is a recognized global leader in NASH clinical trials.

Specific financial terms for this agreement have not been disclosed.

ABOUT NIS4™

NIS4™ is GENFIT's non-invasive, blood-based diagnostic technology, which was developed to identify patients with non-alcoholic steatohepatitis (NASH) and significant to advanced fibrosis (F≥2), also referred to as at-risk NASH. In January 2019, GENFIT signed a licensing agreement with LabCorp® to make NIS4™ technology available for use in clinical research through their drug development subsidiary, Covance. GENFIT also continues to explore opportunities to obtain formal marketing authorization of an *in vitro diagnostic* (IVD) version of NIS4™ in both the U.S. and European markets. For more information, please visit: https://nis4.com.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and 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 initiated a Phase 3 clinical trial of elafibranor in patients with primary biliary cholangitis (PBC). 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, if approved, could enable easier identification of patients with at-risk NASH. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. 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

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 statements about NIS4™'s performance in identifying patients with at-risk NASH, the performance of NIS4™ relative to other technologies, the potential for diagnostic tests powered by NIS4™ technology to play a critical role in the diagnosis and management of patients with NASH, the potential for non-invasive testing to gain importance, its capability to identify patients who may require medical intervention, the development plans for NIS4™ in the U.S. and in Europe and timing of such development plans, and the potential to obtain formal marketing authorization of an IVD version of NIS4™ in the U.S. and/or European markets. The use of certain words, including "believe," "potential," "expect" 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 related 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 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 French Autorité des marchés financiers ("AMF"), including those listed in Section 2.1 "Main Risks and Uncertainties" of the Company's 2019 Universal Registration Document filed with the AMF on May 27, 2020 under n° D.20-0503, which is available on GENFIT'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 20-F dated May 27, 2020. 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.

ABOUT LABCORP

LabCorp (NYSE: LH), an S&P 500 company, is a leading global life sciences company that is deeply integrated in guiding patient care, providing comprehensive clinical laboratory and end-to-end drug development services. With a mission to improve health and improve lives, LabCorp delivers world-class diagnostics solutions, brings innovative medicines to patients faster, and uses technology to improve the delivery of care. LabCorp reported revenue of more than $11.5 billion in 2019.

To learn more about LabCorp, visit www.LabCorp.com, and to learn more about LabCorp's Covance Drug Development business, visit www.Covance.com.

LABCORP FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, including but not limited to statements with respect to clinical laboratory testing, including a testing in development based on GENFIT's NIS4™ technology, the impact of various factors on operating and financial results, and the

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, 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, the Company's satisfaction of regulatory and other requirements, patient safety issues, changes in testing guidelines or recommendations, 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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