

**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 5, 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

| <u>Exhibit</u> | <u>Description</u> |
|----------------------|---|
| 99.1 | Press Release dated August 5, 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: August 5, 2020

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



GENFIT Announces Pivotal Publication of NIS4™ Technology to Identify Patients with At-Risk NASH in *The Lancet Gastroenterology & Hepatology*

Lille (France), Cambridge (Massachusetts, United States), August 05, 2020 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, today announced that pivotal data describing the derivation and validation of NIS4™ has been accepted for publication by *The Lancet Gastroenterology & Hepatology*. NIS4™ is GENFIT’s novel non-invasive, blood-based diagnostic technology, developed to identify patients with non-alcoholic steatohepatitis (NASH) and significant to advanced fibrosis (F_{≥2}), also referred to as at-risk NASH in the published study.

Suneil Hosmane, PhD, Head of Global Diagnostics at GENFIT commented: *“This publication represents a milestone achievement for our NIS4™ technology. The data presented in The Lancet Gastroenterology and Hepatology showcases not only the robust and consistent performance of NIS4™ to identify at-risk NASH, but also the improved performance of NIS4™ relative to other technologies including commonly used liver fibrosis tests. We believe blood-based diagnostic tests powered by NIS4™ technology will play a critical role in the diagnosis and management of patients with NASH. The majority of patients with at-risk NASH, who are at higher risk of progression to severe liver complications, have not been diagnosed and a non-invasive approach to identify them is paramount. The complexity of underlying chronic liver diseases, such as NASH, is that these conditions often do not present with obvious symptoms until the disease is in very advanced stages. Hence, we believe non-invasive testing will continue to gain importance within healthcare systems given the capability to identify those who may require more aggressive medical intervention with a simple blood draw while maintaining high diagnostic accuracy.”*

The NIS4™ technology is an algorithm that incorporates four independent NASH-associated biomarkers – miR-34a-5p, A2M, YKL-40, and HbA1c – to produce a score that can be utilized to identify patients with or without at-risk NASH. This published study details NIS4™ algorithm development and clinical validation against the liver biopsy reference standard in two independent populations comprised of data from over 700 patients. Apart from high overall diagnostic performance, NIS4™ also provided consistent results in critical sub-populations (i.e. diabetic vs. non-diabetic, men vs. women) as compared to other non-invasive tests evaluated in the same individuals.

Prof. Arun Sanyal, MD, Department of Internal Medicine, Virginia Commonwealth University School of Medicine in Richmond, VA, USA, noted: *“There is a major unmet need to establish simple tools that can be used in all patients with risk factors to identify those with non-*



alcoholic steatohepatitis with enough disease activity and fibrosis to be considered for more intense therapies over and above lifestyle changes. The current study is a key step in meeting this unmet need and demonstrates that the NIS4 score can be used to enrich the likelihood of identifying this subpopulation amongst those who are overweight or are obese with or without diabetes. This paves the way for development of patient identification and treatment paradigms that are non-invasive and available to all clinics.”

GENFIT intends to license NIS4™ technology to a major diagnostic partner to enable the development and projected launch of a clinical diagnostic test powered by NIS4™ in the second half of 2020. 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.

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 ($F \geq 2$), 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 plans to initiate a Phase 3 clinical trial of elafibranor in patients with 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, the ability of GENFIT to license the NIS4™ technology to a major diagnostic partner and the timing thereof 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.



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