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 26, 2019

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):

<u>99.1</u>

Press Release dated September 26, 2019.

Description

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 27, 2019

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT Title: Chief Executive Officer

GENFIT Reinforces Corporate Leadership in the U.S.

Lille (France), Cambridge (Massachusetts, United States), September 26, 2019 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced Dr. Dean Hum's appointment as President of GENFIT Corp. and Dr. Suneil Hosmane as Head of Global Diagnostics.

Dr. Hum, who joined GENFIT in 2000 as Chief Scientific Officer will be relocating to the United States and will be based at the Cambridge, M.A. office. He will continue to serve as Chief Operating Officer. Dean will ensure that the U.S. subsidy's growth is steady and in alignment with the global corporate strategy. Dr. Suneil Hosmane, who is currently based at the Cambridge, M.A. office, is promoted to Head of Global Diagnostics, and becomes a member of the Executive Committee. Suneil, who joined GENFIT Corp. in 2018 as Executive Vice President of Strategic Development, will manage the development and marketing activities related to NIS4, GENFIT's proprietary blood test designed to identify NASH patients eligible for treatment. Beyond NIS4, Suneil will also be spearheading the in-house biomarker discovery program and designing additional non-invasive diagnostic solutions for metabolic and liver diseases.

Pascal Prigent, Chief Executive Officer of GENFIT, commented: "Dean has been instrumental in growing GENFIT over the last 20 years, ranging from corporate strategy, operational management, and scientific research and now leverages his experience for the talented U.S. team. As an active member of the Liver Forum, he's extremely well connected to the key stakeholders in the NASH space, is recognized for his broad scientific expertise, and long tenure in the field. His presence in the United States will greatly contribute to accelerating GENFIT's objectives of U.S. expansion and increasing corporate visibility."

ABOUT NASH

"NASH" is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.

ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product candidate. Elafibranor is an oral, once-daily, first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation. GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

ABOUT RESOLVE-IT

RESOLVE-IT is a phase 3 study evaluating the efficacy and safety of elafibranor 120mg versus placebo in patients with nonalcoholic steatohepatitis (NASH) and fibrosis. It is a multicenter, randomized, double-blind, placebo-controlled study with 2 arms. It is conducted under Subpart H (FDA) and conditional approval (EMA). Treatment duration until interim analysis for accelerated approval is 72 weeks.

ABOUT NIS4

GENFIT is developing an *in vitro* diagnostic (IVD) test to identify and monitor patients eligible for therapeutic intervention. This program is based on the in-house discovery of a 4-biomarker algorithm potentially replacing biopsy with a single blood test. In January, 2019, GENFIT signed a licensing agreement with Labcorp® to roll out the diagnostic kit in the clinical research field, and plans to file for regulatory submission for NIS4 as early as 2020.

ABOUT PBC

"PBC" is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC later this year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro*

diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 160 employees. GENFIT is a public company listed on the Nasdaq Global Select Market and in 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 the company's growth, the commercialization of NIS4, the potential for NIS4 to identify and monitor NASH patients eligible for treatment, and the design of new non-invasive solutions for metabolic and liver diseases. 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 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, 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 final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. 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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Attachment

• 2019.09.26 - GENFIT PR - DH President GNFT Corp (https://ml-eu.globenewswire.com/Resource/Download/b1e60985-445b-474e-b13b-153928a7884e)