

**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: February 20, 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 February 20, 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: February 20, 2020

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



GENFIT: Unblinding of Phase 3 RESOLVE-IT Data Deferred

Lille (France), Cambridge (Massachusetts, United States), February 20, 2020 – 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 that unblinding of the Phase 3 RESOLVE-IT data will be delayed to incorporate the latest FDA insights expected by the end of March. Topline interim results will be announced in the weeks following receipt of FDA insight.

This decision has been taken to ensure that the latest thinking in the NASH field is properly captured so the Company can optimize elafibranor’s NDA dossier at the time of submission.

At this stage the trial remains unblinded, meaning this delay is not related to:

- concerns about elafibranor’s efficacy;
- safety or tolerability issues with elafibranor;
- corporate, legal, strategic or financial matters.

The final visit of the last patient for the interim cohort to support accelerated marketing approval has been completed on time, and the Phase 3 clinical trial RESOLVE-IT database will be locked as planned, before the end of February.

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 ELAFIBRANOR

Elafibranor, GENFIT’s lead pipeline therapeutic candidate, has been developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation by FDA. Elafibranor is an oral, once-daily, first-in-class drug acting via dual agonism of peroxisome proliferator-activated alpha/delta receptors.



PRESS RELEASE

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 an increased risk of cardiovascular disease along with long-term risk for progression to cirrhosis, leading to liver insufficiency and potential progression to liver cancer. NASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for liver transplant. The prevalence of NASH is rapidly increasing as a result of the growing obesity and diabetes epidemics and is believed to affect as much as 12 percent of people in the U.S. and six percent worldwide.

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 of elafibranor in PBC in 2020, following its positive Phase 2 results. As part of GENFIT’s comprehensive approach to clinical management of patients with NASH, the company is also developing a new, non-invasive blood-based diagnostic test, NIS4, which, if approved, could enable easier identification of patients with 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

PRESS RELEASE

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 elafibranor’s potential to treat NASH and PBC, elafibranor’s security and tolerability profile, Phase 3 RESOLVE-IT clinical trial top line data publication calendar, GENFIT’s ability to file and optimize an NDA dossier with regulatory authorities, elafibranor’s potential to become the first approved drug for NASH resolution without worsening of fibrosis, and the continuation of GENFIT’s other therapeutic programs. The use of certain words, including “believe,” “potential,” “expect” and “will”, “provisional” 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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