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: March 31, 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 March 31, 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: March 31, 2020

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

EXHIBIT 99.1

GENFIT: Update on Regulatory and Clinical Activities Amid the COVID-19 Pandemic

Lille (France), Cambridge (Massachusetts, United States), March 31, 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 reported an update on its regulatory and clinical activities in the context of the COVID-19 pandemic.

The unprecedented spread of COVID-19 is impacting the global health and business ecosystem, GENFIT included. During this crisis, our priorities are to ensure the safety and well-being of our employees, of the patients and healthcare professionals involved in our clinical trials, as well as the integrity of our ongoing clinical trials.

GENFIT is therefore monitoring the situation closely and, in light of our priorities and in accordance with the recently issued guidance documents of the U.S. Food and Drug Administration (FDA) and European Medicines Agency, we have worked with our contract research organizations, trial sites and investigators to critically reassess all our existing programs.

RESOLVE-IT Phase 3 trial in NASH with fibrosis continues

As announced previously, the first ~1000 patients required to support regulatory approval have completed their final visits and the database related to that cohort was locked at the end of February, as planned. The un-blinding of the study and subsequent announcement of interim results will take place after receipt and incorporation of insight from the FDA. We do not currently anticipate that the COVID-19 situation will significantly delay receipt of this feedback.

After careful consideration of the potential benefits to NASH patients in continuing treatment, we have also decided to continue the extension phase of RESOLVE-IT. Working with our contract research organization, we have implemented appropriate measures to ensure the safety of patients who are already participating in the study: virtual clinic visits, local laboratory assessment, home delivery of study drug, and halting the screening of new patients. Additional measures may be implemented, as required by the evolving COVID-19 situation.

Other trials are paused

Following guidance from regulatory authority recommendations and prioritizing the safety of our clinical trial participants, all phase 1 trials – which include pharmacokinetic, food effect and bioequivalence studies – have been put on hold. These studies are necessary to support the elafibranor NDA submission for NASH.

Enrollment of patients in the PK/PD trial in pediatric patients with NASH as well as the Phase 2 study addressing liver fat have also been paused.

While our NASH combination and PBC programs both continue with several work streams still being executed, we have decided to put on hold the initiation of the Phase 2 combination study, as well as that of the Phase 3 study in patients with PBC.

All supporting activities pertaining to continuation of ongoing studies or the initiation of new studies will continue in order to minimize potential delays when the pandemic crisis subsides.

NIS4 Diagnostic

Our diagnostic solution continues to be deployed in the clinical research field through our commercial partner Covance, a subsidiary of diagnostics leader LabCorp. While interest in NIS4 is high, there may be some limits in test utilization due to delays potentially experienced by some NIS4 clients as the result of the current COVID-19 situation.

GENFIT teams are progressing the in-vitro diagnostic (IVD) aspect of the program in parallel.

Supply chain update

Although the COVID-19 pandemic is rapidly evolving, and our plans may change accordingly, at this stage we do not anticipate any supply disruption for any of our current or planned studies. We have on hand sufficient supply of elafibranor for all our clinical studies up to mid-2021, and we do not foresee any issues with supply of raw materials and production of commercial batches. Likewise, our partners and the GENFIT teams have put in place contingency plans to manage the operational aspects of our ongoing and planned trials, even under the current conditions.

Employee update

Our employees are fully committed and are doing their best to ensure business continuity during this crisis. The measures we have deployed are fully aligned with governmental measures recommended for impacted countries and will be adjusted as the situation evolves. These measures enable GENFIT to pursue the vast majority of our activities, while abiding by health authorities' sanitary recommendations: remote work has been enacted for all compatible positions, social distancing measures are applied for employees still working in the office, safety protection procedures are enforced, and business travel is strictly limited to that which is considered absolutely critical for the Company's operations.

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. Elafibranor was granted a Breakthrough Therapy Designation by FDA in this indication.

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 PBC

Primary biliary cholangitis (PBC) is a chronic, autoimmune 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.

ABOUT NIS4

GENFIT is developing NIS4, a blood-based diagnostic test to identify patients with NASH and fibrosis ($F \geq 2$, $NAS \geq 4$), who are the focus of current NASH clinical trials. The NIS4 program is based on the in-house discovery of a 4-biomarker algorithm, and GENFIT is currently pursuing commercialization of this test, which aims to be a validated alternative to the liver biopsy. In January 2019, GENFIT signed a licensing agreement with LabCorp® to make the NIS4 diagnostic kit available in the clinical research field, and GENFIT plans to file an application with the FDA for approval of NIS4 as an *in vitro* diagnostic (IVD) .

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. 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 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 timing of anticipated receipt of FDA insights regarding elafibranor in NASH and incorporation of such insight, appropriateness of safety measures in the continuing RESOLVE-IT Phase 3 clinical trial, ability to continue supporting activities and to minimize potential delays once the COVID-19 pandemic subsides, potential for supply disruptions for our ongoing and planned clinical studies and impact of the COVID-19 pandemic on our operations and timelines. 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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Attachment

- GENFIT: Update on Regulatory and Clinical Activities Amid the COVID-19 Pandemic (https://ml-eu.globenewswire.com/Resource/Download/2a09d057-a288-4371-9a35-d6f380dabc6b)