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: May 11, 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 May 11, 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: May 11, 2020

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

GENFIT: Announces Results from Interim Analysis of RESOLVE-IT Phase 3 Trial of Elafibranor in Adults with NASH and Fibrosis

- **Elafibranor did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis**
- **GENFIT will engage with regulatory authorities to determine next steps regarding the extension phase evaluating the effect of elafibranor on clinical outcomes**
- **Safety and tolerability of elafibranor was consistent with previously conducted studies**
- **GENFIT to host investor calls in English on May 11, 2020 at 4:30pm EDT / 10:30pm CEST, and in French on May 12, 2020 at 1:30am EDT / 7:30am CEST**

Lille (France), Cambridge (Massachusetts, United States), May 11, 2020 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced results from an interim analysis of the RESOLVE-IT Phase 3 trial evaluating once-daily, 120mg of elafibranor in adults with non-alcoholic steatohepatitis (NASH).

The trial did not meet the predefined primary endpoint of NASH resolution without worsening of fibrosis in the ITT population of 1,070 patients. The response rate in the 717 patients enrolled on study drug was 19.2% for patients who received elafibranor 120mg compared to 14.7% for patients in the placebo arm. On the fibrosis key secondary endpoint, 24.5% of patients who received elafibranor 120mg achieved fibrosis improvement of at least one stage compared to 22.4% in the placebo arm. The other key secondary endpoint related to metabolic parameters did not achieve statistical significance.

Pascal Prigent, CEO of GENFIT, stated: "*These results are highly disappointing, not only for the GENFIT team, but also for patients and healthcare providers as there continues to be considerable unmet medical need in the NASH space. The GENFIT team is actively reviewing the full interim dataset and will be conducting additional analyses, to gain a clearer understanding of the higher than anticipated response rates in the placebo arm. We plan to share these detailed findings with the regulatory authorities in the coming months and with their guidance, determine a final decision regarding the continuation of the RESOLVE-IT trial. In parallel, we continue as planned with our NIS4™ and Phase 3 PBC (primary biliary cholangitis) programs, which are independent of our NASH program with elafibranor. We will provide updated guidance on our global corporate strategy later in the year, once we have more clarity on the regulatory implications of the RESOLVE-IT interim readout, as well as more visibility on the evolution of the impact of the worldwide pandemic on our ongoing studies.*"

Dr. Stephen Harrison, MD, Hepatologist, Medical Director of Pinnacle Clinical Research, San Antonio, TX, (USA) commented: "*NASH is a complicated, heterogeneous disease, and the results of the RESOLVE-IT Phase 3 study of elafibranor in NASH demonstrate this significant hurdle. Placebo response was higher compared to some other late phase trials, and it will be important for the field to understand variations across all trials.*"

INTERIM RESULTS

The RESOLVE-IT Phase 3 trial evaluated the effect of elafibranor compared to placebo in 1,070 patients (ITT population) with biopsy proven NASH as defined by NAS greater than or equal to 4, fibrosis stage 2 or 3. Patients were randomized 2:1 to receive elafibranor 120mg or placebo once daily, with a follow-up liver biopsy at week 72 to evaluate histologic endpoints (resolution of NASH without worsening of fibrosis or fibrosis improvement of at least one stage). Patients with no biopsy results at week 72 were considered as non-responders in the efficacy analysis.

The full dataset will be presented at one of the international hepatology congresses that will take place in the second half of 2020.

Baseline characteristics

		Statistics	Elafibranor	Placebo	Overall
ITT Set (F2-F3)		N	717	353	1070
Age (Years)		Mean (SD)	54.35 (12.06)	55.04 (11.10)	54.58 (11.75)
Sex	Female	N(%)	283 (39.5)	137 (38.8)	420 (39.3)
	Male	N(%)	434 (60.5)	216 (61.2)	650 (60.7)
Fibrosis Stage	Stage 2	N (%)	338 (47.1)	167 (47.3)	505 (47.2)
	Stage 3	N (%)	379 (52.9)	186 (52.7)	565 (52.8)
Type 2 Diabetes	No	N (%)	361 (50.3)	178 (50.4)	539 (50.4)
	Yes	N (%)	356 (49.7)	175 (49.6)	531 (49.6)
NAS	4	N (%)	104 (14.5)	45 (12.7)	149 (13.9)
	5	N (%)	209 (29.1)	90 (25.5)	299 (27.9)
	6	N (%)	239 (33.3)	120 (34.0)	359 (33.6)
	7	N (%)	146 (20.4)	92 (26.1)	238 (22.2)
	8	N (%)	19 (2.6)	6 (1.7)	25 (2.3)

Interim efficacy results at week 72

ITT (missing biopsy = non-responder)		Elafibranor 120mg		*Placebo*		*P-Value*
		N	%	N	%	
Primary Endpoint	NASH Resolution without worsening of fibrosis	138/717	19.2	52/353	14.7	0.0659
Key secondary Endpoint	Fibrosis improvement of at least one stage	176/717	24.5	79/353	22.4	0.4457

No significant differences as compared to placebo were achieved on the key secondary endpoints, including fibrosis improvement of at least one stage and changes in metabolic parameters (triglycerides, Non-HDL Cholesterol, HDL Cholesterol, LDL Cholesterol, HOMA-IR in non diabetic patients, and HbA1c in diabetic patients).

Safety and tolerability results

The safety and tolerability profile of elafibranor was similar to what has been observed in our previously conducted trials.

Conference Call in English on May 11, 2020 at 4:30pm EDT /10:30pm CEST, and in French on May 12, 2020 at 1:30am EDT / 7:30am CEST. GENFIT will host a conference call to discuss the results of the Phase 3 RESOLVE-IT clinical trial.

The English conference call will be accessible from the investor page of our website, in the events section at https://ir.genfit.com/, or by calling 877-407-9167 (toll-free U.S. and Canada), 201-493-6754 (international) or 0 800 912 848 (France) ten minutes prior to the start time (no passcode needed). A replay will be available shortly after the call.

The French conference call will be accessible from the investor page of our website, in the events section at https://ir.genfit.com/, or by calling 0805639972 (toll-free), or +33170709502 (toll/local) ten minutes prior to the start time (passcode required: 53637769#). A replay will be available shortly after the call.

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 more than 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 patients with 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 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 our expected future performance, business prospects, events and plans, including timing of further analyses and the publication of the full dataset of interim results of our Phase 3 RESOLVE-IT clinical trial, our expected clinical and regulatory strategy for elafibranor, timing of clinical and regulatory milestones in our PBC and NIS4™ programs, our financial perspective, and our ability to continue supporting activities and to minimize potential delays on our business once the COVID-19 pandemic subsides. 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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