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: June 30, 2023

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

INCORPORATION BY REFERENCE

The contents of this report on Form 6-K (including Exhibit 99.1) are hereby incorporated by reference into the registrant's registration statement on Form F-3 (File No. 333-271312) and registration statement on Form S-8 (File No. 333-271311) and related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Information contained on, or that can be accessed through, any website included in Exhibit 99.1 is expressly not incorporated by reference.

EXHIBIT LIST

Exhibit	Description
99.1	Press Release dated June 30, 2023.

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: June 30, 2023

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

Ipsen and GENFIT Announce Positive Results from Phase III ELATIVE® trial of elafibranor in patients with primary biliary cholangitis, a rare cholestatic liver disease

- **Trial met primary endpoint with a statistically significant higher percentage of patients achieving a clinically meaningful cholestasis response compared to placebo**
- **Elafibranor was well tolerated with a safety profile consistent with previous studies**
- **Results position elafibranor as a potentially important new treatment option, where there is still high unmet need**
- **Ipsen intends to submit regulatory applications for elafibranor following discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)**
- **GENFIT conference call (English and French) on June 30 at 8am ET / 1pm GMT / 2pm CET**

Paris (France); June 30, 2023 - Ipsen (Euronext: IPN; ADR: IPSEY) and GENFIT (Nasdaq and Euronext: GNFT) today announced positive topline data from the pivotal ELATIVE® Phase III trial. In the trial the efficacy and safety of elafibranor, an investigational dual α,δ PPAR agonist, is being
assessed for the treatment of patients with the rare cholestatic liver disease, primary biliary cholangitis (PBC), who have an inadequate response or intolerance to the current standard of care therapy, ursodeoxycholic acid (UDCA).

The trial met its primary composite endpoint, with 51% of patients on elafibranor 80mg achieving a cholestasis response compared with 4% on placebo ($p<0.0001$). Cholestasis response is defined in the trial as alkaline phosphatase (ALP) <1.67 x upper limit of normal (ULN), an ALP decrease ≥ 15 percent and total bilirubin (TB) ≤ ULN at 52 weeks. ALP and bilirubin are important predictors of disease progression. Reductions in levels of both can indicate reduced cholestatic injury and improved liver function.

The first secondary endpoint, normalization of ALP at Week 52, was also met with statistically significant improvements for investigational elafibranor compared with placebo. For the other secondary endpoint, a trend for pruritus improvement was observed with a greater decrease from baseline in the PBC Worst Itch NRS score for patients on elafibranor compared to placebo, which

did not reach statistical significance. In the study, elafibranor was generally well tolerated with a safety profile consistent with that observed in previously reported studies.

"*These are encouraging results that suggest elafibranor could be an effective treatment to prevent progression of PBC in patients who have received UDCA. It has a good safety profile and was well- tolerated, and could provide an important new therapeutic option for long-term treatment of patients with this debilitating condition*," said **Howard Mayer, Executive Vice President and Head of Research and Development for Ipsen**. "*PBC is a serious condition which, if not treated properly, can lead to progression of liver disease and ultimately liver failure. We are excited about the potential of this investigational treatment and Ipsen now intends to discuss these results with regulatory agencies and plans to move forward with regulatory submissions to the U.S. Food and Drug Administration and the European Medicines Agency*."

"*We are pleased by these results because PBC remains a disease where significant unmet medical needs exist*", added **Pascal Prigent, Chief Executive Officer of GENFIT**. "*This long-awaited trial outcome is therefore good news for patients and for healthcare professionals who need more options to improve the clinical management of patients with PBC. It is also a gratifying recognition of the quality of our team's work and of GENFIT's ability to innovate and deliver tangible results.*"

PBC is a rare, progressive, autoimmune cholestatic liver disease[1] 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.[1] Common symptoms of PBC include fatigue and pruritus (itch), which can be severely debilitating.[1] Untreated, PBC can lead to liver failure, or in some cases death. It is also a leading cause of liver transplantation. It primarily affects middle-aged women, with nine women diagnosed for every man. It is a disease where a significant proportion of patients are unable to benefit from existing therapies. The prevalence of people living with PBC is estimated to be between 23.9-39.2 per 100,000 in the U. S[2] [3] and 22.27 per 100,000 in Europe.[4]

ELATIVE® is a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial, with an open-label long-term extension (NCT03124108). ELATIVE® is evaluating the efficacy and safety of elafibranor 80mg once daily versus placebo for the treatment of patients with PBC with an inadequate response or intolerance to UDCA, the existing first-line therapy for PBC. The trial enrolled 161 patients who were randomized 2:1 to receive elafibranor 80mg once daily or placebo.

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[1] Kimagi T, et al.. Orphanet J Rare Dis. 2008; 3:1

[2] Lu et al. Clinical Gastro and Hepatol 2018; 16:1342-1350

[3] Galoosian et al. Journal of Clinical and Transplantation Hepatology 2020; 8:49-60

[4] Gazda J, et al. Can J GastroenterolHepatol. 2021 ; 915 -1525

Patients with an inadequate response to UDCA would continue to receive UDCA in combination with elafibranor or placebo, while patients unable to tolerate UDCA would receive only elafibranor or placebo.

Full data from the ELATIVE® trial will be presented at a future scientific congress.

GENFIT will host a conference call on June 30, 2023 at 8:00am ET / 1:00pm GMT / 2:00pm CET in English and in French

Both the English and French conference calls will be accessible on the investor page of our website, under the events section at https://ir.genfit.com/ or by calling 888-394-8218 (toll-free U.S. and Canada), 0800 279 0425 (toll-free UK) or 0805 101 219 (France) five minutes prior to the start time (confirmation code: 6752821). A replay will be available shortly after the call.

ABOUT ELAFIBRANOR

Elafibranor is a novel, oral, once-daily, dual peroxisome activated receptor (PPAR) alpha/delta (α,δ) agonist, currently under investigation as a treatment for patients with PBC, a rare liver disease. In 2019, it was granted a Breakthrough Therapy designation by the FDA in adults with PBC who have an inadequate response to ursodeoxycholic acid (UDCA). Elafibranor has not received approval by regulatory authorities anywhere in the world.

ABOUT IPSEN

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With total sales of €3.0bn in FY 2022, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, the Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has around 5,400 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions. Its R&D pipeline covers six therapeutic areas via seven programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorders (UCD), organic acidemias (OA) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF. GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). 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). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. For more information, visit www.genfit.com

IPSEN FORWARD LOOKING STATEMENTS

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in

which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's latest Universal Registration Document, available on ipsen.com.

GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995 in relation to the clinical performance of elafibranor in the ELATIVE® Phase 3 clinical trial in PBC, plans to move forward with regulatory authorities for potential approval of elafibranor in PBC and our ability to accelerate our development. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "targeted", "anticipated", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the

negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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 in relation to safety, biomarkers, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs and our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, which is available on the Company'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 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023. 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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