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: December 17, 2021

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 December 17, 2021.

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: December 17, 2021

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

GENFIT: Ipsen and GENFIT enter into exclusive licensing agreement for elafibranor, a Phase III asset evaluated in Primary Biliary Cholangitis, as part of a long-term global partnership

IPSEN
Innovation for patient care

- **Agreement gives Ipsen global* rights to develop and commercialize GENFIT's late- stage, first-in-class PPAR alpha and delta agonist elafibranor in Primary Biliary Cholangitis (PBC)**
- **Investigational treatment elafibranor being evaluated in the global Phase III trial, ELATIVE™, with topline data expected early 2023**
- **GENFIT receives €120m upfront and is eligible to receive up to €360m in milestone payments as well as tiered double-digit royalties of up to 20%**
- **Ipsen becomes 8% shareholder of GENFIT via an equity investment of €28m**

Paris (France); December 17, 2021, **Ipsen (Euronext: IPN; ADR: IPSEY) and GENFIT (Nasdaq and Euronext: GNFT)**, have entered into a long-term strategic partnership for global collaboration between the two companies. The agreement gives Ipsen exclusive worldwide* license to develop, manufacture and commercialize GENFIT's investigational treatment elafibranor, for people living with Primary Biliary Cholangitis (PBC). The partnership also gives Ipsen access to future clinical programs led by GENFIT and combines GENFIT's scientific expertise and proprietary technologies in liver disease with Ipsen's development and commercialization capabilities. To underscore the long-term commitment represented by this partnership, Ipsen will also purchase newly issued GENFIT equity representing 8% post-issuance through a €28m investment in GENFIT, becoming one of the largest shareholders.

The ongoing, pivotal Phase III global trial, ELATIVE™,[i] is evaluating the safety and efficacy of elafibranor in 150 people living with PBC who have an inadequate response or intolerance to ursodeoxycholic acid (UDCA). Global recruitment is well underway. There is significant unmet medical need for people with PBC and, following positive Phase II data,[ii] elafibranor was granted Breakthrough Therapy Designation by the U.S Food and Drug Administration (FDA) and Orphan Drug Designation by the U.S. FDA and European Medicines Agency (EMA).[iii,iv] Results from the Phase II randomized double-blind, placebo controlled trial found that after 12 weeks of dosing with elafibranor, patients with PBC unresponsive to UDCA experienced significantly reduced levels of

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* With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor.

disease-activity markers including alkaline phosphatase (ALP) and composite endpoints with bilirubin as well as other markers of disease activity when compared to placebo.[ii]

David Loew, Chief Executive Officer, Ipsen, said "*Today's announcement marks an exciting new stage in Ipsen's ambitions to expand our portfolio to support more people living with rare diseases around the world. We are excited by elafibranor's data package, demonstrating the potential benefit of this first-in-class, innovative treatment option to help the PBC community. We look forward to the results of the ongoing Phase III program and regulatory submissions around the world to bring this potential new treatment option to patients. Ipsen is pleased to partner with GENFIT, a company that shares our common values and goals of bringing to market first-in-class treatments to improve the lives of people living with rare conditions like PBC.*"

Pascal Prigent, Chief Executive Officer of GENFIT, added: "*We are excited to partner with Ipsen and launch this long-term strategic collaboration, with the goal to accelerate our growth and generate value for our shareholders. Ipsen's world-class development capabilities, well-established global commercial footprint and excellent track record in delivering therapies to patient populations with unmet medical need makes it the ideal partner for GENFIT. Today's landmark agreement demonstrates our ability to advance highly promising assets into late-stage development in-house and derive significant value. While we hope, above all, that this partnership with Ipsen will be a significant step towards having a positive impact on the lives of millions of patients suffering from life-threatening liver diseases, we also believe our shareholders will recognize the benefit offered by this collaboration model. The transaction proceeds indeed reinforce GENFIT's long-term financial visibility, including further funding for GENFIT to expand its pipeline, and they also provide opportunities for targeted business development, as exemplified by today's other announcement regarding our in-licensing of a new molecule.*"

PBC is a rare, progressive, chronic autoimmune disease of the liver.[v] Bile is a liquid produced inside the liver that is used to help digest fats and remove waste products from the body.[vi] PBC leads to a slow, progressive destruction of the small bile ducts of the liver, causing bile and other toxins to build up in the liver (known as cholestasis).[v] Further damage can lead to scarring, fibrosis and eventually cirrhosis of the liver.[v] Common symptoms of PBC include fatigue and pruritus (itching) which can be debilitating and, in more advanced cases, jaundice.[v] Untreated, PBC can lead to liver failure, or in some cases death. PBC is more common in women with nine women diagnosed for every man; it is also a leading cause of liver transplantation.[v]

GENFIT remains responsible for the Phase III ELATIVE™ trial until the completion of the double- blind period. Ipsen will assume responsibility for all additional clinical development, including completion of the long-term extension period of the ELATIVE™ trial, and global* commercialization. This newly established strategic partnership will also provide Ipsen with access to GENFIT's research capabilities and other clinical programs through rights to first negotiation.

Under the agreement, Ipsen will pay GENFIT up to €480m, comprising upfront cash payment of €120m, as well as regulatory, commercial, and sales-based milestone payments up to €360m, plus tiered double-digit royalties of up to 20%. Ipsen also becomes a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28m investment. The new shares will be issued pursuant to the twentieth resolution of GENFIT's 30 June 2021 shareholders' meeting and will be subject, upon issuance, to a lock-up period ending, in the event of positive ELATIVE ™ results, on the earlier of the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorisation of elafibranor in PBC or the date on which the U.S. FDA grants approval of elafibranor in PBC. Issuance of the new shares is expected to take place on or about December 22, 2021. In addition, the Board of Directors of GENFIT will propose at the next shareholders' meeting that Ipsen becomes a board member.

The transaction is expected to be dilutive to Ipsen's profitability over the near term, primarily reflecting R&D and launch-preparation expenses. This is in line with Ipsen's medium-term outlook regarding its strategic focus on building a high-value and sustainable pipeline through external innovation.

GENFIT will host a conference call on December 17, 2021 at 7:45am ET / 12:45pm GMT / 1:45pm 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 800-289-0438 (toll-free U.S. and Canada), 0800 358 6377 (toll-free UK) or 0805 101 219 (France) five minutes prior to the start time (confirmation code: 9932717). A replay will be available shortly after the call.

Primary Biliary Cholangitis

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. PBC is a disease with high unmet medical needs, with many patients unable to benefit from existing therapies. The prevalence of people living with PBC in the US is estimated to be between 23.9-39.2 per 100,000.[vii,viii]

Elafibranor

Elafibranor, GENFIT's lead therapeutic candidate, is currently under evaluation in ELATIVE™, a Phase III clinical trial to evaluate its efficacy and safety in patients with PBC. Elafibranor is an oral, once-daily, first-in-class drug candidate acting via dual agonism of peroxisome proliferator- activated alpha/delta receptors. Datafrom a Phase II clinical trial demonstrated elafibranor has the potential to become an efficacious treatment in PBC, a rare liver disease. It was granted a

Breakthrough Therapy designation by the FDA in this indication. Elafibranor is an investigational compound that has not been reviewed nor received approval by a regulatory authority.

ELATIVE™ Program

ELATIVE™ is a Phase III clinical trial evaluating the safety and efficacy of elafibranor 80mg versus placebo in 150 patients with Primary Biliary Cholangitis (PBC) with an inadequate response to ursodeoxycholic acid (UDCA), which is the existing first line therapy for PBC. ELATIVE™ is a multicenter, randomized, double blind study to evaluate the efficacy and safety of elafibranor versus placebo. Treatment durationuntil interim analysis for accelerated approval is 52 weeks. Top line data is expected in between the end of the first quarter and the middle of the second quarter 2023.

Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established Consumer Healthcare business. With Total Sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. 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 c.5,700 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.

GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. Today, GENFIT has a robust and diversified pipeline, using different compounds and technologies evaluated at different development stages and in different liver diseases. Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and Acute on Chronic Liver Failure (ACLF): two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ Phase III clinical trial evaluating elafibranor (elafibranor is an investigational compound that has not been reviewed nor been approved by a regulatory authority) in patients with Primary Biliary Cholangitis (PBC). A Phase I clinical program with nitazoxanide in ACLF has been initiated. GENFIT has facilities in Lille and Paris, France, 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). www.genfit.com

IPSEN CONTACT

Investors

Craig Marks
Vice President, Investor Relations
+44 7584 349 193

Adrien Dupin de Saint-Cyr
Investor Relations Manager
+33 6 64 26 17 49

Media

Jess Smith
Senior Director, Head of Global Communications
R&D and Business Development
+44 7557 267 634

Fanny Allaire
Global Communications Director
+ 33 6 08 91 92 55

GENFIT CONTACT

GENFIT | Investors
Tel: +33 3 2016 4000 | investors@genfit.com

PRESS RELATIONS | Media
Stephanie Boyer – Press relations | Tel: +333 2016 4000 | stephanie.boyer@genfit.com

References

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[iii] GENFIT Press Release. 2019 https://www.genfit.com/press-release/genfit-announces-fda-grant-of-breakthrough-therapy-designation-to-elafibranor-for-the-treatment-of-pbc/

[iv] European Medicines Agency. 2019. https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3192182

[v] Kimagi T, Heathcote EJ. Orphanet *J Rare Dis*. 2008; 3:1

[vi] NHS. Primary Biliary Cirrhosis. https://www.nhs.uk/conditions/primary-biliary-cirrhosis-pbc/

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

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