

**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):

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EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated December 17, 2021.</a>

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**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



**On heels of global strategic partnership announced today, GENFIT acquires rights to novel asset**

- *Exclusive rights for a novel early-stage asset acquired from Genoscience Pharma in cholangiocarcinoma in the United States, Canada and Europe*
- *Phase 2 clinical program expected to start in 1H 2022*
- *Agreement comes on the heels of today's other announcement of a long-term global strategic partnership with Ipsen including an exclusive licensing agreement for elafibranor, a Phase 3 asset currently evaluated in Primary Biliary Cholangitis*

**Lille, France; Cambridge, MA; December 17, 2021** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, is pleased to announce the strengthening of its cholestatic disease franchise through the acquisition of exclusive rights from Genoscience Pharma to develop and commercialize the investigational treatment GNS561 in cholangiocarcinoma in the United States, Canada and Europe, including the United Kingdom and Switzerland. This announcement comes on the heels of today's other announcement on our global strategic pharma partnership.

GNS561 is a novel clinical-stage autophagy/PPT1 inhibitor developed by Genoscience Pharma and cholangiocarcinoma is an orphan disease. It has completed pre-clinical studies and a Phase 1b trial confirming the rationale for targeting cholangiocarcinoma, a rare liver malignancy with high mortality and with limited treatment options.

Under the agreement, Genoscience Pharma is eligible for clinical and regulatory milestone payments and tiered royalties. The first payable milestone is contingent on positive Phase 2 clinical trial results. GENFIT is also committed to take a €3 million equity stake in Genoscience Pharma through the subscription of new ordinary shares.

**Pascal Prigent, CEO of GENFIT**, stated: *“This licensing agreement with Genoscience Pharma comes as an immediate follow-up to the global strategic partnership announced today. Proceeds from this strategic agreement will strengthen the trajectory of our long-term growth and pipeline expansion, which is exemplified by the acquisition of GNS561's rights in cholangiocarcinoma. This decision fully aligns with our strategic roadmap by broadening our asset portfolio within our cholestatic disease franchise through*



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*the addition of an innovative drug candidate, with the potential to address considerable unmet needs for patients. The scientific rationale, together with preclinical and clinical evidence, support further development of the asset, and our plan is to start a Phase 2 program in the first half of 2022. We believe that GNS561's mechanism of action is very promising. Given the current landscape, standard of care, lack of marketed options and, based on KOL opinions, we will interact with regulatory agencies to investigate accelerated paths to approval, post Phase 2."*

**Philippe Halfon, CEO of Genoscience Pharma**, added: *"This is a great step for the development of GNS561 as a new potential treatment option in liver cancer, as it offers an innovative mechanism of action for patients with high unmet needs. We believe that GENFIT is a highly qualified partner for the development of GNS561 in cholangiocarcinoma and we will provide GENFIT with our expertise to support their development plan. On our side, we will pursue, at Genoscience Pharma, the development of GNS561 in other oncology indications as well as research in other therapeutic areas."*

**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.

### **ABOUT CHOLANGIOCARCINOMA**

Cholangiocarcinoma is a type of cancer that forms in the slender tubes (bile ducts) that carry the digestive fluid bile. Cholangiocarcinoma occurs mostly in people over the age of 50. Cholangiocarcinoma is divided into intrahepatic and extrahepatic types based on where the disease occurs in the bile ducts. Cholangiocarcinoma is often diagnosed when it is advanced, making successful treatment difficult to achieve. Several risk factors of chronic inflammatory damage and increased cellular turnover have been established, such as primary sclerosing cholangitis (a cholestatic liver disease), liver flukes, biliary tract cysts, hepatolithiasis and toxins. Treatment options for Cholangiocarcinoma are limited and associated with high rates of tumor recurrence, and short survival times.

### **ABOUT GNS561**

GNS561 is a PPT-1 (Palmitoyl Protein Thioesterase-1) inhibitor that blocks autophagy. Autophagy is activated in tumor cells in response to certain conditions, due to a tumor cell growth in



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advanced cancers. One of the key organs implicated in the autophagy process is the lysosome. By entering the lysosomes and binding to its target, GNS561 has an important inhibiting activity on late-stage autophagy, which leads to tumor cell death. GNS561 is an investigational compound and has not been registered by any regulatory authority.

### ABOUT GENOSCIENCE PHARMA

Genoscience Pharma is a French clinical-stage biotechnology company developing novel lysosomotropic therapeutics to establish a new standard of care against cancer, autoimmune and infectious diseases. Its lead candidate GNS561 is a Phase 2 ready best-in-class drug candidate, tackling cancer cells through autophagy modulation. Genoscience Pharma is also entering a Phase 2 trial in hepatocarcinoma with GNS561. [www.genosciencepharma.com](http://www.genosciencepharma.com)

### ABOUT 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 3 clinical trial is 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) following a successful Phase 2 clinical trial. Patient enrolment is anticipated to be completed in the first quarter of 2022 and topline data is expected to be announced between the end of the first quarter and the end of the second quarter 2023. In ACLF, a Phase 1 clinical program with nitazoxanide 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](http://www.genfit.com)



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### 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, including statements regarding timelines to commence a Phase 2 study of GNS561 in cholangiocarcinoma, the probability of success of GNS561's mechanism of action to address the unmet medical need related to cholangiocarcinoma and the potential for the path to regulatory approval to be shortened. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "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, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, impact of the ongoing COVID-19 pandemic, exchange rate fluctuations 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 Chapter 2 "Main Risks and Uncertainties" of the Company's 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, which is available on the Company's website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)), and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC") including the Company's 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021 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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