# **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: Friday April 29, 2022

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

Description

<u>99.1</u> <u>Press Release dated April 29, 2022.</u>

### 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.

Date: April 29, 2022

GENFIT S.A.

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT Title: Chief Executive Officer



## GENFIT Announces Publication of the 2021 Universal Registration Document; the 2021 Annual Report on Form 20-F and Availability of Preparatory Documents for the Annual Combined Shareholders Meeting on May 25, 2022

Lille, France; Cambridge, MA; April 29, 2022 - GENFIT (Nasdaq and Euronext: GNFT), a late- stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases, today announced the filing of its 2021 Universal Registration Document with the *Autorité des marchés financiers* (AMF) and its Annual Report on Form 20-F for the year ended December 31, 2021 with the U.S. Securities and Exchange Commission (SEC), as well as the availability of preparatory documents for its annual shareholders meeting on Wednesday May 25, 2022.

These annual reports are available to the public free of charge in accordance with applicable regulations and may be viewed at and downloaded from GENFIT's website at ir.genfit.com. The 2021 Registration Document is also available on the AMF's website: www.amf-france.org and the Annual Report on Form 20-F is available on the website of the SEC (www.sec.gov).

GENFIT's 2021 Universal Registration Document includes, in particular, the annual financial report, the annual Board of Directors' management report, the Board of Directors' report on corporate governance, the Statutory Auditors' reports on the annual and consolidated financial statements and related-party agreements, and the table summarizing the fees paid to the Statutory Auditors.

Documents for the Annual Combined Shareholders Meeting on May 25, 2022 are available to shareholders in accordance with existing regulations, and can be found on the Company's website, in the Investors and Media section (https://ir.genfit.com/financial-information/shareholders- meeting).

### **ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic 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.

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Its R&D is focused on three franchises: cholestatic diseases, Acute on Chronic Liver Failure (ACLF) and NASH diagnostics. In its cholestatic diseases franchise, ELATIVE<sup>TM</sup>, a Phase 3 global trial evaluating elafibranor<sup>1</sup> in patients with Primary Biliary Cholangitis (PBC) is well underway following a successful Phase 2 clinical trial. Topline data is expected to be announced in early 2023. In 2021, GENFIT signed an exclusive licensing agreement with IPSEN to develop, manufacture and commercialize elafibranor in PBC and other indications.<sup>2</sup> GENFIT is also developing GNS5611 in cholangiocarcinoma following the acquisition of exclusive rights in this indication from Genoscience Pharma in 2021<sup>3</sup>. In ACLF, a Phase 1 clinical program with nitazoxanide has been initiated with data expected as early as the third quarter 2022. As part of its diagnostic solutions franchise, the Company entered into an agreement with Labcorp in 2021 to commercialize NASHnext®, powered by GENFIT's proprietary diagnostic technology NIS4® in identifying at-risk NASH.

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). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. www.genfit.com

- <sup>2</sup> With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor
- <sup>3</sup> Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland

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<sup>&</sup>lt;sup>1</sup> Elafibranor and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority



#### 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 its R&D programs and data readout of its clinical trials. 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, 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 AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2021 Universal Registration Document filed with the AMF on 29 April 2022 under n° D.22-0400, 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 2021 Annual Report on Form 20-F filed with the SEC on April 29, 2022. 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.

#### CONTACT

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