

**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: February 28, 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):

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EXHIBIT LIST

Exhibit

Description

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[99.1](#)

[Press Release dated February 28, 2022.](#)

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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: February 28, 2022

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer

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## GENFIT Announces Solid Revenues and Cash Position as of December 31, 2021

§ **Cash and cash equivalents totaled €258.8 million as of December 31, 2021, which includes the €120 million upfront payment and a €28 million equity investment pursuant to the licensing agreement signed in December 2021 with Ipsen**

**Lille, France; Cambridge, MA; February 28, 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 its cash position as of December 31, 2021 and revenues for 2021<sup>1</sup>.

### Financials

As of December 31, 2021, the Company's cash and cash equivalents amounted to €258.8 million compared with €171.0 million, as of December 31, 2020. This amount includes:

- A €120 million non-refundable upfront payment from Ipsen received in December 2021, as well as €24 million in VAT collected on that amount
- A €28 million equity investment from Ipsen in December 2021
- A €7.9 million Research Tax Credit 2020 reimbursement received in October 2021
- A €2.25 million subsidized loan from Bpifrance in November 2021 in addition to the State Guaranteed Loans received in June and July 2021

As of June 30, 2021, cash and cash equivalents amounted to €104.4 million.

The solid cash position as of December 31, 2021 takes into account the collaboration and license agreement signed with Ipsen in December 2021 which gives Ipsen exclusive worldwide<sup>2</sup> license to develop, manufacture and commercialize GENFIT's investigational treatment elafibranor for people living with Primary Biliary Cholangitis (PBC), in return for a €120 million upfront payment. In addition to the upfront payment GENFIT is eligible to receive up to €360 million in milestone payments as well as tiered double-digit royalties of up to 20%. To underscore the long-term commitment represented by this partnership, Ipsen also purchased newly issued GENFIT equity representing 8% post-issuance through a €28 million investment in GENFIT, becoming one of the largest shareholders.

<sup>1</sup> Unaudited financial information under IFRS

<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



**Pascal Prigent, CEO of GENFIT**, commented: *“This breakthrough strategic partnership with Ipsen marks the beginning of a new chapter for GENFIT. With a considerably improved financial situation, we’re now in a good position to accelerate our development.”*

### Revenues<sup>3</sup>

Revenues for 2021 were €80.06 million compared to €0.76 million for 2020. This mainly results from the receipt of the €120 million upfront payment from Ipsen, out of which €80 million is recognized as 2021 revenue, after deduction of €40 million deferred revenue, which will gradually be recognized as revenue following the completion of the ELATIVE™ double-blind study, in accordance with the IFRS 15 norms.

As a comparison, revenues for 2020 mainly resulted from the licensing agreements with Labcorp to roll out the NIS4® diagnostic technology in NASH and the sale of goods and services provided pursuant to the collaboration and license agreement with Terns Pharmaceuticals.

### A note about the COVID-19 pandemic and its potential consequences on our business

During this evolving crisis, our priorities continue to be to ensure the safety and well-being of our employees, of the patients and healthcare professionals involved in our clinical trials, as well as the integrity of our ongoing clinical trials. We remain committed to ensuring business continuity and have been monitoring the situation closely.

We have worked with our contract research organizations (CRO), trial sites and investigators to regularly revise our program execution estimations to take into account the evolution of the pandemic situation and its impact on our activities.

As a result of measures implemented in consultation with our CRO we were able to minimize disruption to our ELATIVE™ Phase 3 clinical trial of elafibranor in PBC, which enrolled its first patient in September 2020. At the start of the trial, and considering the pandemic situation, we had estimated that enrollment in the ELATIVE™ study would take approximately 18 months and so far, we have been broadly in-line with this estimate. However, the recent rapid expansion of the highly contagious Omicron strain of COVID has created additional complications for us in enrolling patients and in clinical trial operations generally. The rate of infection, as well as the containment measures put in place to control its growth have led to patients postponing site visits or having to be re-screened because they had fallen outside the screening window. This recent worsening of the COVID pandemic has also created significant additional administrative backlogs at sites and regulatory agencies, due to the combination of continued high volume of trials and staffing shortages. This has disproportionately impacted regions where there were already significant delays, such as Latin America. Although we currently do not anticipate these recent complexities to substantially change the guidance related to availability of the ELATIVE™ top line results, we are currently assessing with our CRO the extent of impact on enrollment timelines. We will provide an update during our next webcast scheduled for April 7, 2022.

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<sup>3</sup> Revenues recognized under IFRS 15



### Upcoming Financial Communications

The Company will release its full-year 2021 financial results on April 7, 2022. The 2021 Universal Registration Document, the 2021 Annual Financial Report (included in the 2021 Universal Registration Document), and the Annual Report on Form 20-F will be published by the end of April 2022.

### 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.

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™, a Phase 3 global trial evaluating elafibranol<sup>4</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 elafibranol in PBC and other indications.<sup>5</sup> GENFIT is also developing GNS561<sup>4</sup> in cholangiocarcinoma following the acquisition of exclusive rights in this indication from Genoscience Pharma in 2021<sup>6</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.

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<sup>4</sup> *Elafibranol and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority*

<sup>5</sup> *With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranol*

<sup>6</sup> *Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland*



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](http://www.genfit.com)

## 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, and statements regarding the Company's cash position and revenues and the impact of the COVID-19 pandemic on our activities including the impact on timelines for patient enrollment in the ELATIVE™ study and availability of ELATIVE™ top-line results. 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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