

**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: 29 February 2024

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be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated 29 February 2024.

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: 29 February 2024

GENFIT S.A.

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



GENFIT Announces Revenues and Cash Position as of December 31, 2023

- **Cash and cash equivalents totaled €77.8 million as of December 31, 2023**
- **Revenues amounted to €28.6 million as of December 31, 2023 including a milestone payment of €13.3 million**
- **Upcoming FDA PDUFA action date for elafibranor in PBC: June 10, 2024**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), February 29, 2024 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced its cash position as of December 31, 2023 and revenues for 2023.

Cash Position

As of December 31, 2023, the Company's cash and cash equivalents amounted to €77.8 million compared with €140.2 million as of December 31, 2022. As of September 30, 2023, cash and cash equivalents totaled €93.9 million.

This amount does not include the receipt in February 2024 of a €13.3 million milestone payment from Ipsen, which was invoiced in December 2023, triggered by the acceptance of the New Drug Application (NDA) filing by the US Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for accelerated approval of elafibranor in Primary Biliary Cholangitis (PBC) in December 2023.

As previously indicated in past communications¹, in 2024 GENFIT expects to receive total milestone payments of approximately €89 million (including the €13.3 milestone already received in February 2024), subject to the approval and commercialization of elafibranor in PBC.

The decrease in cash and cash equivalents between September 30, 2023, and December 31, 2023, takes into account our continued research and development efforts, notably for:

- UNVEIL-IT™, our Phase 2 clinical trial evaluating VS-01 in Acute-on-Chronic Liver Failure (ACLF);
- our cholangiocarcinoma program evaluating GNS561;

¹ GENFIT Updates 2024 Outlook Following Acceptance of Elafibranor Filings in Primary Biliary Cholangitis (PBC)



- our ACLF program evaluating NTZ;
- our non-clinical trial of SRT-015 in ACLF; and
- ELATIVE®, specifically the portion of the Phase 3 clinical trial evaluating elafibranor in PBC that has not yet been transferred to Ipsen.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until approximately the fourth quarter of 2025. This is based on current assumptions and programs, and does not include exceptional events. This estimation includes our expectations to receive future milestone revenue in 2024, subject to approval by applicable regulatory authorities and US and European commercial launches of elafibranor in PBC by Ipsen, representing a total of approximately €75.2 million.

Revenues

Revenues for 2023 amounted to €28.6 million compared to €20.2 million for the same period in 2022.

Of the €28.6 million, €13.3 million was attributable to a milestone payment invoiced to Ipsen in December 2023 in accordance with the Collaboration and Licensing agreement signed in December 2021. This milestone payment was earned following the NDA filing acceptance by the FDA and MAA filing acceptance by the EMA for accelerated approval of elafibranor. €8.7 million in revenue was attributable to the partial recognition of the €40.0 million deferred income as described below. €6.5 million in revenue was generated from the services rendered under the Transition Services Agreement and Part B Transition Services Agreement, signed in April 2022 and September 2023 respectively by GENFIT and Ipsen, in order to facilitate the transition of certain services related to the Phase 3 ELATIVE® clinical trial until the complete transfer of the responsibility of the trial to Ipsen. €0.1 million was attributable to other ancillary activities.

Of the €20.2 million in revenues for 2022, €15.9 million was attributable to the partial recognition of the €40.0 million deferred income per IFRS² 15 in accordance with the Collaboration and Licensing Agreement signed with Ipsen in 2021. €1.0 million in revenue was generated from services rendered by GENFIT to Ipsen in accordance with the Transition Services Agreement signed in 2022. €3.3 million was recognized as revenue in accordance with the Inventory Purchase Agreement signed with Ipsen in 2022, under which the Company sold almost all of its remaining stock of elafibranor's active ingredient and drug products for the ELATIVE® Phase 3 clinical trial to Ipsen.

² International Financial Reporting Standards



Upcoming FDA PDUFA³ Action Date for Elafibranor in PBC: June 10, 2024

Regulatory filing acceptance has been obtained in the US, Europe and the United Kingdom⁴ and a Priority Review has been granted for an NDA by the FDA for elafibranor in PBC with a PDUFA target action date of June 10, 2024.

Upcoming Financial Communications

The Company will release its full-year 2023 financial results on April 4, 2024. The 2023 Universal Registration Document, the 2023 Annual Financial Report (included in the 2023 Universal Registration Document), and the Annual Report on Form 20-F will be published by the end of April 2024.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening 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. Today, GENFIT has a growing and diversified pipeline with programs at various development stages. The Company's area of focus is Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise consists of five assets in development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE. These are all based on differentiated mechanisms of action leveraging complementary pathways. Other assets target other life-threatening disease indications such as cholangiocarcinoma (CCA) and Urea Cycle Disorders (UCD)/Organic Acidemias (OA). GENFIT's track record in bringing early-stage assets with high potential to late development and pre-commercialization stages is highlighted in the successful 52-week Phase 3 ELATIVE® trial evaluating elafibranor in PBC. Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on Metabolic dysfunction-associated steatohepatitis (MASH) previously known as nonalcoholic steatohepatitis (NASH) and ammonia. 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

³ Prescription Drug User Fee Act

⁴ Ipsen confirms U.S. FDA grants priority review for New Drug Application for elafibranor for the treatment of rare cholestatic liver disease, PBC



FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about the Company's eligibility to receive future milestone payments from Ipsen relating to the development and commercial launch of elafibranor in PBC, approval of elafibranor in PBC and potential commercialization as early as 2024, and expected cash runway. The use of certain words, including "believe", "potential," "expect", "target", "may" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable 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 of drug candidates, cost of, progression of, and results from, our 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, 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 and subsequent filings and reports filed with the AMF or SEC, including the Half- Year Business and Financial Report at June 30, 2023 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.



PRESS RELEASE

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