

**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: 13 November 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

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be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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

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EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated 13 November 2024.</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: 13 November 2024

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

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## GENFIT Announces Corporate Updates and Upcoming Participation at The Liver Meeting® 2024

- **PBC program (licensed to Ipsen):**
  - Ipsen to present new data on elafibranor at The Liver Meeting® 2024
  - Launch of Iqirvo® (elafibranor)<sup>1</sup> on track with expectations; encouraging feedback from healthcare providers and payers in the U.S.
  - UK NICE reimbursement approved and first reimbursed sales in Germany in October 2024
  - Next €26.5M milestone payment by Ipsen pending a third pricing and reimbursement approval in Europe
- Scientific progress in ACLF to be featured at The Liver Meeting® 2024, with 4 posters presenting new preclinical data, and 3 events bringing together key ACLF stakeholders
- Results from UNVEIL-IT® Phase 2 trial evaluating VS-01 in ACLF now expected in 2H25; protocol modified to improve recruitment and trial design
- New insights and emerging scientific trends incorporated into our ACLF development plan, with data readout from 4 clinical trials anticipated by the end of 2025, including data from 3 new clinical trials to be launched in 1H25, in addition to UNVEIL-IT®

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), November 13, 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 provided a corporate update ahead of The Liver Meeting 2024®<sup>2</sup>.

**Pascal Prigent, CEO of GENFIT** said: “We are thrilled to see that Ipsen continues to execute as planned and make great progress with elafibranor, on both commercial and regulatory fronts in the U.S. and Europe, further enhancing our financial outlook for the rest of this year and beyond. We continue to build on our momentum in Acute on-Chronic Liver Failure (ACLF), where we plan to initiate multiple clinical studies in 2025 and report Phase 2 UNVEIL-IT® data from our VS-01 program. We recently updated the Phase 2 UNVEIL-IT® study protocol to improve trial enrollment and worked with centers to address logistical hurdles associated with the use of new technology. We are very confident that with these changes, along with supporting several exciting initiatives that will help better identify patients that are particularly at risk, we have taken the right steps to put GENFIT in a strong position to advance this program forward for patients.”

<sup>1</sup> Elafibranor is marketed and commercialized by Ipsen under the trademark Iqirvo®

<sup>2</sup> The Liver Meeting 2024® is a registered trademark of the American Association for the Study of Liver Diseases



## I. Positive momentum for the Primary Biliary Cholangitis (PBC) program

Ipsen recently reported positive commercial and regulatory developments with Iqirvo<sup>®3</sup> in the U.S. and Europe<sup>4 5</sup>:

- U.S. launch progress is on-track after June 10, 2024 U.S. Food and Drug Administration approval following priority review<sup>6</sup>
- Ipsen received EMA<sup>7</sup> approval on September 20, 2024 and the UK MHRA<sup>8</sup> approval on October 9, 2024 followed by UK NICE<sup>9</sup> approval on October 22, 2024
- Recent reimbursement in Germany and the UK brings GENFIT closer to a €26.5M milestone payment, pending a third pricing and reimbursement approval in a major European country

## II. Strategic developments across the ACLF franchise

### GENFIT at The Liver Meeting 2024

GENFIT will present pre-clinical data as part of its ACLF franchise with the following posters:

- **VS-01**: Effect of VS-01 on Acute-on-Chronic Liver failure-related toxins such as lipopolysaccharide and hydrophobic bile acids in vitro (poster #1603)
- **SRT-015**: Intravenous administration with the ASK1 inhibitor SRT-015 alleviates liver injury and systemic inflammation in disease models of liver failure (poster #1597)
- **CLM-022**: Investigational drug CLM-022, a potent inhibitor of NLRP3 inflammasome-mediated pyroptosis, as a potential treatment for acute and chronic inflammatory liver diseases (poster #2232)

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<sup>3</sup> Iqirvo®, NIS2+® and UNVEIL-IT® are registered trademarks of GENFIT SA

<sup>4</sup> [https://www.ipsen.com/websites/ipsen\\_com\\_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf](https://www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf)

<sup>5</sup> [https://www.ipsen.com/websites/ipsen\\_com\\_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf](https://www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf)

<sup>6</sup> [https://www.ipsen.com/websites/ipsen\\_com\\_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf](https://www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2024/10/24164500/Ipsen-YTD-2024-sales-presentation-1.pdf)

<sup>7</sup> European Medicines Agency

<sup>8</sup> Medicines and Healthcare products Regulatory Agency

<sup>9</sup> UK National Institute for Health and Care Excellence



- **NTZ:** Efficacy of Nitazoxanide (NTZ) in Pathogen-Associated Molecular Patterns (PAMPs)-induced disease models (poster #2222)

GENFIT will also lead 3 key events on ACLF:

- **ACLF KOL Advisory Board** (November 14, 2024), bringing together 9 leading experts from Europe and the United States
- **ACLF Patient Advocacy Council** (November 16, 2024), with the participation of Professor Debbie Shawcross, MBBS PhD FRCP, Professor of Hepatology and Chronic Liver Failure, Institute of Liver Studies King's College London, UK and EASL Vice-Secretary), the Global Liver Institute (GLI), the European Liver Patients' Association (ELPA), and real-life patients and caregivers
- **ACLF Morning Insights** session (November 17, 2024), focused on addressing unmet needs, diagnostics, and guidelines for ACLF, with Dr. Jasmohan Bajaj, Professor of Medicine in the Division of Gastroenterology, Hepatology and Nutrition at Virginia Commonwealth University and Richmond VA Medical Center in Richmond, Virginia, USA. The event will also offer an intensivist's perspective with Dr. William Bernal, Professor of Liver Critical Care Medicine in the Liver Intensive Therapy Unit at the Institute of Liver Studies at King's College Hospital, London and Member of the EASL-CLIF Consortium Steering Committee. It will also outline GENFIT's clinical roadmap and highlight the patient and caregiver experience, via GLI and ELPA.

Key strategic insights and emerging trends uncovered through unique sources and channels

Over the last 12 months, GENFIT has made strides in understanding the ACLF continuum, enriching our body of knowledge compared to the knowledge available in the field at the time of our pivot to ACLF.

Key takeaways derived from these workstreams will inform the design of on-going and upcoming trials evaluating VS-01, NTZ and SRT-015. These insights will also help further strategize the research and clinical development of CLM-022 and VS-02-HE.

- **UNVEIL-IT@3 clinical and operational improvements:** As announced in September 2024<sup>10</sup>, lower than expected trial enrollment prompted a protocol amendment to better accommodate patient care logistics and comorbidities. These recent modifications require time before they can be implemented in every investigational site and before they can significantly impact the enrollment curve. Therefore, we are now guiding 2H25 for UNVEIL-IT results. The two main points of focus for our improvement efforts have been:

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<sup>10</sup> <https://ir.genfit.com/news-releases/news-release-details/genfit-reports-first-half-year-2024-financial-results-and>



- o Inclusion and exclusion criteria were overly restrictive for a patient population with multiple co-morbidities. As we accumulated data to better characterize these patients, we collaborated with investigators and KOLs to modify the protocol and better address the targeted population.
  - o Logistical challenges are inherent to the introduction of any new technology. In the case of VS-01 the necessary steps in the reconstitution process, and the limitation of a clinical trial setting, had previously restricted patient enrollment windows. By generating additional stability data, we now offer enhanced storage flexibility for study material, enabling clinical trial centers to use VS-01 more frequently. Additionally, we have been working on the development of an innovative medical device which should be available next year and will further streamline the reconstitution process.
- **Cutting-edge processing of Real-World Evidence:** An in-depth analysis of medical claims data – leveraged through advanced A.I. and machine learning techniques from a targeted U.S. population of over 270,000 patients – provided pivotal insights into risk profiles within specific patient sub-populations of the ACLF continuum, as well as differences in referral dynamics, patient journeys and clinical management practices compared to Europe. Applying sophisticated algorithms uncovered epidemiological patterns and trends within this substantial dataset, generating actionable intelligence that enhances our understanding and supports more precise, data-driven decisions across our portfolio.
  - **Preclinical research:** New preclinical models have been established with leading experts, serving as key enablers to deliver valuable data aimed at improving our understanding of our portfolio potential. To date, the data already generated encompasses a range of disease models and various formulations. This approach is designed to optimize asset positioning and refine population targeting, ultimately supporting strategic decision-making and maximizing impact across our therapeutic landscape.
  - **Collaboration with learned societies:** Strategic partnerships, including with the European Foundation for the Study of Chronic Liver Failure (EF CLIF) and engagement with U.S. KOLs from NACSELD <sup>11</sup>, offered important insights through unique data sources encompassing several observational studies, while also accelerating and expanding discussions with key leaders in the field. This type of collaboration places GENFIT at the forefront of international research, advancing the understanding of ACLF pathophysiology and uncovering novel approaches for the treatment of this syndrome.

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<sup>11</sup> North American Consortium for the Study of End-Stage Liver Disease



## PRESS RELEASE

### Data readout from 4 clinical trials anticipated by the end of 2025

Building on insights from the upcoming KOL Advisory Board and additional real-world evidence anticipated by late November 2024, GENFIT will finalize the design of two new proof-of-concept studies evaluating VS- 01 and NTZ, alongside a First-in-Human study for SRT-015 with GENFIT's formulation. These trials are expected to launch in the first half of 2025, with data readouts expected by year-end.

With Phase 2 data for UNVEIL-IT trial also anticipated by the close of 2025, GENFIT will deliver four clinical data sets in 2025, advancing three clinical-stage assets of our ACLF pipeline in parallel.

### Preclinical assets

- **CLM-022**: Preclinical Proof of Concept expected to be obtained by end of 2024
- **VS-02-HE**: Completion of Investigational New Drug (IND) enabling studies expected in 2025

### III.GNS561 in KRAS-mutated cholangiocarcinoma

The phase 1b/2a clinical trial is currently ongoing and preliminary data from Phase 1b is targeted by the end of 2024. Final data is expected by the end of 2025.

### IV.NIS2+® in MASH

During The Liver Meeting 2024, GENFIT will also present new data on NIS2+<sup>®</sup>s<sup>3</sup> efficacy as a monitoring tool for patients with MASH<sup>12</sup> with the following posters:

- NIS2+, an effective monitoring tool for tracking disease evolution in patients with fibrotic MASH (poster #2062)
- NIS2+, an effective tool for monitoring MASH resolution and fibrosis improvement in patients with at-risk MASH (poster #2063)

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<sup>12</sup> Metabolic dysfunction-associated steatohepatitis



## PRESS RELEASE

· Detecting MASH resolution and fibrosis improvement with NIS2+ in patients with at-risk MASH (poster #2067)

Significant progress has been made since the recognition of NIS2+ as a key tool for detecting at-risk MASH in June 2024<sup>13</sup>, as our technology is now also covering screening and monitoring needs, and not just diagnostics needs. With more than 20 clinical MASH trials using our technology, more publications are referring to it, highlighting the relevance of our solution. In March 2024, Rezdiffra™ (resmetirom) was the first drug approved in MASH in the United States. As a reminder, GENFIT signed a commercial agreement with Labcorp in 2021 to provide broad clinical availability of the test to specialty and primary care physicians across the U.S. and Canada. Our business goal is now to develop an IVD version of the test, either in collaboration with a commercial partner or by ourselves.

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorder (UCD) and organic acidemia (OA). GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated in the accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration, the European Medicines Agency and the Medicines and Healthcare Regulatory Agency in the UK for Primary Biliary Cholangitis (PBC). Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. [www.genfit.com](http://www.genfit.com)

<sup>13</sup> <https://ir.genfit.com/news-releases/news-release-details/genfit-new-easl-easd-easo-clinical-practice-guidelines-masld>



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## PRESS RELEASE

### 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 ability to receive upcoming milestone payments from Ipsen pursuant to our Licensing and Collaboration agreement and the effect of Ipsen commercial performance on our financial outlook, availability and timing of results of our UNVEIL-IT clinical trial in ACLF as well as four additional clinical programs, and the impact of changes to the UNVEIL-IT clinical trial protocol on improving trial enrollment and the timing and impact of development of a new medical device for VS-01 reconstitution. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" 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 others, 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, and 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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) with the *Autorité des marchés financiers* ("AMF"), which is available on GENFIT's website ([www.genfit.fr](http://www.genfit.fr)) and the AMF's website ([www.amf.org](http://www.amf.org)), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024 and subsequent filings and reports filed with the AMF or SEC or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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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