

---

**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: November 17, 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 LIST

| <b>Exhibit</b>       | <b>Description</b>                                     |
|----------------------|--|
| <a href="#">99.1</a> | <a href="#">Press Release dated November 17, 2022.</a> |

---

## 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: November 17, 2022

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



### GENFIT Pipeline Day Highlights Diverse Product Portfolio in Underserved Liver Diseases

- Phase 3 data for elafibranor in primary biliary cholangitis (PBC) expected in 2Q23
- Expanded pipeline now covers five therapeutic areas with high unmet medical need via six independent programs exploring the potential of differentiated mechanisms of action
- A regular stream of new clinical data expected over the next few years across the spectrum of development stages (Phase 1, Phase 2, Phase 3)
- Aggregated global market size potential >\$15bn<sup>1</sup>, distributed among acute on- chronic liver failure (ACLF) with ~\$6bn, hepatic encephalopathy (HE) with ~\$4bn, cholangiocarcinoma (CCA) with ~\$3bn, urea cycle disorder (UCD)/organic acidemia disorder (OAD) with ~\$1.5bn and PBC with ~\$1.5bn
- Targeted indications include four orphan indications offering valuable incentives and optionality for accelerated market access
- Replay of event now available on Investors & Media section of GENFIT website

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland) November 17, 2022 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with liver diseases characterized by high unmet medical needs, today announced the highlights from its Pipeline Day events reviewing the Company's clinical progress and recent strategic updates.

A video replay of the Pipeline Day events which took place in Paris (on October 5, 2022) and New York (on October 19, 2022) is now available and can be accessed from the "Events & Presentations" page under the "Investors & Media" section of the GENFIT website.

#### Pipeline and R&D strategy

Over the last 12 months, GENFIT has successfully executed its strategic plan.

In December 2021, GENFIT signed a licensing and collaboration agreement with Ipsen for the elafibranor program, which consolidated GENFIT's financial situation (€120M upfront payment,



## PRESS RELEASE

€28M equity investment with a significant premium, up to €360M milestones and tiered double-digit royalties up to 20%).

GENFIT also secured patient recruitment for the ELATIVE® Phase 3 trial in PBC, successfully completing this activity in June 2022 despite challenges faced with the COVID pandemic. Topline data are expected in the next few months.

GENFIT then strengthened, diversified and expanded our Research and Development pipeline with the goal to capitalize on our expertise in bringing early stage assets up to pre-commercialization stages in liver diseases. Its new R&D strategy now focuses exclusively on liver diseases with high unmet medical need and significant market potential, with the in-licensing of the rights for a novel asset initially developed by Genoscience Pharma in CCA in December 2021, followed by the acquisition of the Swiss-based clinical-stage biopharmaceutical company Versantis in September 2022, adding three additional assets positioned in ACLF, in HE and in UCD/OAD.

**Pascal Prigent, Chief Executive Officer of GENFIT** commented: *"GENFIT's perspectives have dramatically evolved over the last two years. Although the outcome was not what we had hoped for, GENFIT has greatly benefited from its work in NASH. We have acquired great know-how in liver disease specific research, from target identification to proprietary models. We also developed expertise in clinical development and regulatory affairs in emerging diseases. We have built solid networks with experts, academic institutions, patient associations, etc. It is this accumulated experience and established infrastructure that we are able to leverage now. The clinical development of elafibranor in PBC is nearing completion with high level results expected in Q2 next year. We see the signature of the related strategic partnership with Ipsen at the end of 2021 as further reason to be optimistic about elafibranor's commercial outlook. The deal with Ipsen also gave us the financial means to make significant progress on our pipeline over the past nine months, as we executed two other deals with Genoscience and Versantis, continuing to execute our strategic roadmap. During our Pipeline Day, we were excited to host a deep dive into the new programs recently integrated into our pipeline and hear from leading experts, who provided valuable insights into the unmet medical needs of patients, as well as potential market opportunities. These presentations also outlined what we believe has been a transformative year for GENFIT, as we work with increased momentum to diversify our pipeline with innovative therapeutic opportunities for rare liver diseases."*

### Key Expert Speakers included:

- Jennifer C. Lai, MD, MBA – Transplant Hepatologist, University of California, UCSF, USA
- Jonel Trebicka, MD, PhD, Professor of Medicine, Chair of Department of Internal Medicine, UKM Uniklinikum Muenster, Germany
- Mark Yarchoan, MD, Associate Professor of Oncology at John Hopkins Medicine, Baltimore, USA



- Angela Lamarca, MD – Medical Oncology, Fundacion Jimenez Diaz University Hospital, Madrid, Spain

Back Bay Life Science Advisors also shared the results of a market study conducted in 2021 in ACLF. This study was based on an extensive review of published literature as well as in-depth discussions with Key Opinion Leaders (KOLs) managing ACLF patients, with hospital pharmacists, hospital administrators, and managed care organizations (payers) in the US.

### **Pipeline Program Highlights**

#### **NTZ and VS-01-ACLF for acute on-chronic liver failure (ACLF)**

- ACLF is a syndrome that is characterized by an abrupt life-threatening worsening of a pre-existing advanced chronic liver disease resulting in acute liver decompensation, liver failure and extrahepatic organ failure (brain, kidneys, cardiovascular and respiratory). ACLF is an underserved medical condition associated with short-term mortality (23% to 74% mortality at 28 days, depending on severity grade) and a significant cost of care for healthcare systems. No drugs have been approved in this indication so far. Conservative estimates lead to a current total addressable population of ~215,000 patients with ACLF across the US and EU5, a number expected to grow up to ~300,000 patients by 2036. The ACLF market size is estimated to be as high as \$6bn (US and EU) by 2030<sup>2</sup>.
- GENFIT is currently developing two programs in ACLF. The first one aims at evaluating the potential of the molecule nitazoxanide (NTZ). Preclinical data generated via several disease models highlighted the potential of NTZ with regards to inflammation, liver and kidney function, brain edema and survival in sepsis, and as such supported further clinical development. Phase 1 results in patients with hepatic impairment as well as patients with renal impairment will be disclosed in the coming months. The second program aims at evaluating VS-01-ACLF, a first-in-class innovative liposomal-based therapeutic product candidate for potential first-line therapy. A Phase 1 trial highlighted the favorable safety and tolerability profile of VS-01 and provided encouraging preliminary efficacy results, with >80% of treated patients improving or stabilizing their disease (Child-Pugh Score assessment). A Phase 2 Proof-of-concept study is expected to launch as early as 4Q22 (a 60-patient, randomized and controlled trial). VS-01-ACLF has been granted Orphan Drug Designation (ODD) in ACLF by the US Food and Drug Administration (FDA).

#### **VS-02-HE for hepatic encephalopathy (HE)**

- HE is a nervous system disorder brought on by advanced chronic liver disease. It is one of the major complications of advanced liver disease and portal hypertension. 30%-40% of



## PRESS RELEASE

patients with cirrhosis will experience at least one episode of HE. The hepatic failure leads to the accumulation of the neurotoxin ammonia in the blood stream, ultimately leading to abnormally functioning neurons, and often coma. HE is associated with increased hospitalizations, recurrences, healthcare costs and mortality. It is a largely underdiagnosed and undertreated condition and is associated with poor quality of life. In the US only, 2 million patients are believed to be at risk of developing HE and 200,000 patients are hospitalized yearly<sup>3</sup>. In Europe, incidence is close to 1 million patients. Standard of care with current treatments is associated with side effects and moderate efficacy. The estimated annual economic burden associated with HE in the US was \$7.2bn in 2009 and around \$12bn in 2014<sup>4</sup>. Estimates for global market size are as high as \$4.1bn in 2026<sup>5</sup>.

- GENFIT is developing VS-02, a urease inhibitor currently in preclinical stage. It will be developed as a unique oral and colon-active formulation designed to minimize systemic absorption of ammonia and to act where ammonia is primarily produced, while reducing glutamine levels in the brain. The treatment goal is to reduce/stabilize the accumulation of ammonia in the blood and prevent rehospitalization. Investigational New Drug-enabling<sup>6</sup> nonclinical studies are targeted for completion in 2025.

### **GNS561 for cholangiocarcinoma (CCA)**

- CCA is a type of cancer that forms in the bile ducts that carry the digestive fluid bile and is the second most common primary hepatic malignancy accounting for approximately 15% of all primary liver tumors. Cases of CCA are usually asymptomatic in early stages and are therefore often diagnosed when the disease is already in advanced stages. The silent presentation of these tumors combined with their highly aggressive nature and being refractory to chemotherapy contribute to poor prognosis and high mortality, representing ~2% of all cancer-related deaths worldwide yearly. Although CCA is a rare cancer, its incidence (0.3–6 per 100,000 inhabitants per year) and mortality (1–6 per 100,000 inhabitants per year), have been increasing in the past few decades worldwide, representing a global health problem. Although surgery is a potential curative option for CCA, most patients are diagnosed at late stages due to lack of specific symptoms. The majority of patients with CCA have metastatic or locally advanced (i.e. unresectable) disease at presentation, and only ~25% are eligible for resection. When disease is unresectable, the current first-line treatment is chemotherapy. After progression on first-line chemotherapy, second-line treatments exist but despite the options presently available, the unmet need remains high due to limited benefits on survival. 9,000 new patients are diagnosed every year in the US, and 10,000 in EU<sup>7</sup>. Based on available data, the global market size is evaluated at \$1.2bn in 2021 and, with the Compound Annual Growth Rate (CAGR) at 12.5%, it is expected to reach \$3.2bn in 2030<sup>8</sup>.



---

## PRESS RELEASE

- GENFIT is developing GNS561, a small molecule PPT1 inhibitor that blocks cancer cell proliferation by inhibiting late stage autophagy leading to cell death<sup>9</sup>. It received ODD from the FDA in September 2022, confirming its potential in this disease area. First-In-Human effects of PPT1 inhibition following GNS561 administration in patients with primary and secondary liver cancers have been observed. The safety profile, exposure, and preliminary signal of activity support the investigation of GNS561 in combination. A Phase 1b/2 study is expected to be launched with a mitogen-activated protein kinase (MEK) inhibitor in the near future in patients with KRAS (Kirsten rat sarcoma viral oncogene homolog) mutated cholangiocarcinoma who have failed treatment with first line treatment and who do not have an actionable mutation.

### **VS-01-UCD for urea cycle disorder (UCD)/organic acidemia disorder (OAD)**

- Patients suffering from UCD and OAD, which are two different groups of congenital metabolic diseases, have difficulties to metabolize ammonia. This is due to a deficiency in one of the six enzymes involved in the urea cycle, creating a situation where ammonia is not eliminated in the urine, ultimately leading to hyperammonemia attacks. Patients are usually diagnosed after they are born, via universal newborn screening tests. While these conditions are ultra-rare with 1,900 acute hyperammonemic crises in the US and EU5 per year<sup>10</sup>, the mortality is very high as 75% will die after 5 years, and survivors will often have severe brain injuries. There is no acute treatment available for early onset crises, and neonatal hemodialysis is risky, highly invasive and widely unavailable. 45% of UCD patients remain untreated and no drug is currently approved for treatment of OAD. Based on available data, global market size in UCD and OAD is evaluated at \$1.5bn in 2021, based on two drugs that have been approved in UCD but not in acute hyperammonemia<sup>11</sup>.
- GENFIT is developing VS-01-UCD, a potential first-line lifesaving treatment for acute hyperammonemic crises. As the peritoneal route of administration is well adapted to pediatric patients, this treatment should be feasible in all hospitals and should be quickly implemented. This is a tremendous improvement over neonatal hemodialysis, which is only possible in specialized centers and is a long and complex procedure. ODD and Rare Pediatric Disease designation (RPDD) have been granted to VS-01 by the FDA for this indication. GENFIT is also potentially eligible to a Priority Review Voucher upon approval.





---

## PRESS RELEASE

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with 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 pipeline covers five therapeutic areas via six independent programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorder (UCD)/organic acidemia disorder (OAD) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF.

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. [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, in relation to expected availability of ongoing or upcoming clinical data over the coming months and years, specifically data from the Phase 3 ELATIVE® clinical trial, launch of a Phase 1b/2 study of GNS561 in CCA, anticipated market potential in each of the disease areas that GENFIT is investigating, development costs and timelines for development of our pipeline. 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



## PRESS RELEASE

ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, the impact of the COVID-19 pandemic, exchange rate fluctuations, potential synergies related to the acquisition of Versantis and our capacity to integrate Versantis and to develop its programs and our 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 April 29 2022 under n° D.22-0400, 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 2021 Annual Report on Form 20-F filed with the SEC on April 29, 2022 and the 2022 Half-Year Business and Financial Report. 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

**GENFIT** | Investors

Tel: +33 3 2016 4000 | [investors@genfit.com](mailto:investors@genfit.com)

**PRESS RELATIONS** | Media

Stephanie Boyer – Press relations | Tel: +333 2016 4000 | [stephanie.boyer@genfit.com](mailto:stephanie.boyer@genfit.com)

<sup>1</sup> Based on actual figures as well as preliminary market studies derived from different sources

<sup>2</sup> Extrapolated from 'Time trend in the healthcare burden and mortality of ACLF in the US' – Hepatology 2016

<sup>3</sup> Potnis et al., International Journal of Hepatology 2021

<sup>4</sup> Stepanova et al., Clin Gast Hep 2012

<sup>5</sup> Hepatic Encephalopathy Market Report by Coherent Market Insights

<sup>6</sup> The purpose of IND-enabling studies is to secure approval to conduct the first-in-human clinical trials with a new drug (IND stands for Investigational New Drug)

<sup>7</sup> IQVIA derived data

<sup>8</sup> Olympus Research Global

<sup>9</sup> Harding JJ, Awada A, Roth G, Decaens T, Merle P, Kotecki N, Dreyer C, Ansaldi C, Rachid M, Mezouar S, Menut A, Bestion EN, Paradis V, Halfon P, Abou-Alfa GK, Raymond E. First-In-Human Effects of PPT1 Inhibition Using the Oral Treatment with GNS561/Ezurpimtrostat in Patients with Primary and Secondary Liver Cancers. Liver Cancer. 2022 Feb 15;11(3): 268-277. doi: 10.1159/000522418

<sup>10</sup> Summar et al., 2013 | Martin-Hernandez et al., 2014 | Nettesheim et al., 2017

<sup>11</sup> 2021 assessment from longitudinal and real-world data reference publications (no projections nor modelling)