

**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: May 31, 2023

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be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 31, 2023.

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: May 31, 2023

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



PRESS RELEASE

GENFIT Further Strengthens its ACLF Franchise with a Third Clinical-Stage Asset

- § Exclusive worldwide rights licensed from Seal Rock Therapeutics for injectable formulation of ASK1 Inhibitor SRT-015 in acute liver disease
- § Preclinical and clinical evidence support ASK1 inhibition as a relevant therapeutic strategy in multi-system disorders such as Acute-on-Chronic Liver Failure (ACLF)
- § First-in-Human study planned in the second half of 2024 to support a Proof-of-Concept study in ACLF patients as early as 2025
- § No material impact on previously guided cash runway: company funding remains secured until the fourth quarter of 2024¹
- § GENFIT's ACLF franchise now comprises 3 assets (VS-01, NTZ, SRT-015) based on differentiated mechanisms of action leveraging complementary pathways

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); May 31, 2023 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs, today announced it has licensed the exclusive worldwide rights of ASK1 Inhibitor SRT-015 (injectable formulation in acute liver disease²) from Seal Rock Therapeutics, a Seattle, Washington (USA) based clinical stage company developing first-in-class and best-in-class kinase inhibitors.

ASK1 inhibition: a therapeutic strategy with multi-system benefits

ASK1 inhibition has shown several potentially beneficial effects that may be relevant in ACLF, such as blocking LPS (lipopolysaccharide) associated hyperinflammatory response, reducing the ROS (Reactive Oxygen Species)-related immune response, reducing apoptosis, reducing release of the proinflammatory cytokines, reducing fibrosis, and protecting macrophage mitochondrial function.

Multi-organ benefits have been observed in several animal models and clinical trials³:

¹ Based on current assumptions, excluding exceptional events and in particular, potential milestone payments, which GENFIT would receive, should the ELATIVE® study be successful

² GENFIT acquired the rights of SRT-015 for use in liver disease in which injectable therapy is intended to be administered for a period of 21 consecutive days or less, including the management of ACLF during such a period

³ ASK1 inhibition: a therapeutic strategy with multi-system benefits: *Journal of Molecular Medicine* (2020)



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- In kidney diseases, ASK1 modulation limits renal inflammation, apoptosis and fibrosis
- In liver diseases, ASK1 modulation prevents hepatocyte death, inflammation and fibrosis
- In brain disorders, ASK1 modulation limits neurodegeneration
- In inflammatory diseases, ASK1 modulation limits damaging immune responses, and
- In cardiopulmonary disease, ASK1 modulation slows the onset of heart failure.

Pascal Prigent, CEO of GENFIT commented: *“We are excited to be announcing this licensing deal which marks an additional milestone in the execution of our development strategy in liver diseases with high unmet medical needs. ACLF is a complex disorder that will likely require the combination of different approaches and with this acquisition, we continue to strengthen our leadership in this indication. We now have a unique portfolio of three differentiated clinical stage programs in ACLF. Considering its liver-centric activity, the potential for multi-organ benefits and the breadth of evidence supporting further development in ACLF, we strongly believe in the potential of SRT-015.”*

Under the agreement, Seal Rock Therapeutics is eligible for payments up to €100 million, including regulatory, clinical, and commercial milestone payments, plus tiered royalties.

Other assets in GENFIT’s ACLF franchise

In ACLF, whose market size has been estimated by IQVIA to reach almost \$4 billion in the US and in the five main European countries by 2030, GENFIT is developing two other assets: VS-01 and NTZ.

- VS-01

VS-01 is currently being evaluated in the international UNVEIL-IT™ Phase 2, open-label, randomized, controlled, multi-center, proof of concept study to assess its efficacy, safety, and tolerability in addition to standard of care (SOC), compared to SOC alone, in adult patients with ACLF grades 1 and 2 and ascites.

IND (Investigational New Drug) was in effect as of April 17, 2023, and the first patient is expected to be screened and enrolled in the Phase 2 trial in the coming days. It is planned that approximately 60 adult patients with ACLF grades 1 and 2 will be enrolled in this trial. Patients will be randomized in a 1:1 ratio to receive either daily intraperitoneal administration of VS-01 over 4 days on top of SOC (active treatment group) or SOC alone (control group).



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The primary objective of the study is to measure efficacy using the Chronic Liver Failure Consortium (CLIF-C) ACLF⁴ score at day 7.

Data expected to be available in the first half of 2024 should support preparation of further testing of efficacy. Given the high unmet need in this indication and the Orphan Drug Designation obtained from the US Food and Drug Administration for VS-01, it is expected that the program qualifies for some of the expedited regulatory pathways provided by health authorities.

- NTZ

Preliminary data from two Phase 1 studies recently conducted in subjects with renal impairment and subjects with hepatic impairment supported a favorable safety and tolerability profile. Taken together, safety and pharmacokinetic results, as well as exploratory pharmacodynamic data, support further clinical development of NTZ in patients with ACLF, and a Phase 2a proof of concept study with NTZ in patients with ACLF grades 1 and 2 is currently under discussion with the FDA.

ABOUT ACLF

Acute-on-Chronic Liver Failure is a rare, life-threatening, but potentially reversible condition of varied etiology. ACLF is recognized clinically as a syndrome, globally defined by multi-organ dysfunction and failure in patients with chronic liver disease or liver cirrhosis and high short-term mortality within a period of 28 to 90 days.

Patients with cirrhosis may initially be compensated. With progression, many patients will go on to have acute decompensation of cirrhosis characterized by the rapid development of complications such as ascites, hepatic encephalopathy (HE), gastrointestinal hemorrhage, or bacterial infection, which are very common causes of hospitalization. On admission, approximately 30% of these

⁴ The EASL-CLIF Consortium is a network of more than a hundred of European University Hospitals which carry out clinical investigations of the EASL-CLIF Chair aimed at performing large observational, pathophysiological and therapeutic studies to increase our understanding of Chronic Liver Failure and to improve the management of patients with cirrhosis.



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patients will develop liver and/or other organ failure(s) (i.e. brain, kidneys, cardiovascular and respiratory) and will be considered as having ACLF.^{5 6 7 8 9}

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 six therapeutic areas via seven programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorders (UCD), organic acidemias (OA) 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

ABOUT SEAL ROCK THERAPEUTICS

Seal Rock Therapeutics is a privately held, clinical stage company based in Seattle focused on developing first-in-class and best-in-class treatments for severe diseases with limited or no available therapies. Seal Rock is led by an experienced management team with a track record of successful drug discovery, development, and commercialization. The company's clinical-stage lead

⁵ Arroyo V et al., *J Hepatol*, 2015, 62(1 Suppl), S131 -S143

⁶ Malik R et al., *J Hepatol*, 2009, 51(3), 426 -9

⁷ Olson JC et al., *Hepatology*, 2011, 54(5), 1864 -72

⁸ Jalan R et al., *J Hepatol*, 2012, 57(6), 1336 -48

⁹ Wlodzimirow KA et al., *Liver International*, 2013, 33(1), 40 -42



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product candidate, SRT-015, is a highly optimized, first-in-class ASK1 inhibitor. Seal Rock is also developing preclinical-stage brain-penetrant ASK1/LRRK2 dual kinase inhibitors for the treatment of neurodegenerative conditions such as Parkinson’s disease and ALS.

GENFIT 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 the potential, efficacy, safety, tolerability, regulatory milestones and development and data timelines for SRT-015, VS-01 and NTZ, and the overall market size and prevalence of ACLF. The use of certain words, including “consider”, “contemplate”, “think”, “aim”, “expect”, “understand”, “should”, “aspire”, “estimate”, “targeted”, “anticipated”, “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, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs 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 “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. 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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