

**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 11, 2021**

**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 May 11, 2021](#)

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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: May 11, 2021

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



## GENFIT Provides Pipeline Update and Launch of New Clinical Programs

- **R&D effort refocused on two therapeutic areas with significant unmet medical needs: ACLF and cholestatic diseases**
- **GENFIT well positioned to leverage its experience from discovery to late development stages in these severe liver diseases**
- **These two new franchises will focus on developing NTZ, elafibranor and GFT1575 drug- candidates**
- **Three new clinical trials to be launched in 4Q21 in ACLE, PSC and PBC, with data expected in 2022**

**Lille, France; Cambridge, MA; May 11, 2021** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced a refocus of its R&D on acute on chronic liver failure (ACLF) and cholestatic diseases.

### **ACLF**

Acute on Chronic Liver Failure (ACLF), a syndrome in patients with chronic liver disease and cirrhosis characterized by acute hepatic decompensation resulting in liver failure and/or one or more extrahepatic organ failures, is associated with increased risk for short-term mortality. There are no approved drugs to treat patients and therefore a need exists for a therapy that helps them to survive without transplantation.

GENFIT is launching a clinical program with nitazoxanide (NTZ) in this disease. A Phase 1 study to evaluate pharmacokinetics and pharmacodynamics in patients with varying degrees of hepatic impairment is expected to start in 4Q21 with clinical data expected end of 2022. GENFIT will also explore the potential of proprietary compounds elafibranor and GFT1575 in ACLF.

### **Cholestatic diseases**

Chronic cholestatic diseases are characterized by defective bile acid transport from the liver to the intestine, which is caused by primary damage to the biliary epithelium in most cases<sup>1</sup>. GENFIT is already present in this therapeutic area with ELATIVETM, its Phase 3 clinical trial evaluating the potential of its lead drug-candidate elafibranor in Primary Biliary Cholangitis (PBC).

<sup>1</sup> Poupon R. et al. J of Hepatol, Volume 32, SUPPLEMENT 1, 129-140, January 01, 2000



In 2021, GENFIT also plans to initiate an exploratory study to evaluate the potential benefit of elafibranor in newly diagnosed patients with PBC, with data expected end of 2022. Given that patients with PBC have significant unmet needs as it pertains to quality of life and fatigue, this study will evaluate biochemical markers of PBC along with indices of quality of life, including sleep data collection. In the fourth quarter 2021, GENFIT also plans to launch a Phase 2 proof of concept study to evaluate elafibranor in Primary Sclerosing Cholangitis (PSC), with clinical data expected end of 2022. Lastly, a preclinical research program has been initiated to evaluate potential candidates for other rare cholestatic pediatric diseases.

**Pascal Prigent, CEO of GENFIT**, commented *“We are excited to announce new developments in our pipeline and look forward to moving some programs into the clinic as early as the fourth quarter of 2021. With these novel programs our goal is to take a first step aimed at bringing to the market new therapeutic options that may help patients suffering from the debilitating consequences of ACLF and cholestatic diseases. This represents some hope for patients as there are currently no treatment options for these life-threatening diseases”*.

**Dr. Jonel Trebicka, MD, PhD, Professor for Translational Hepatology at Goethe University of Frankfurt (Germany)**, added: *“The science continues to emerge regarding ACLF and the potential mechanisms that contribute to the underlying pathophysiology of this condition for which mortality rates are very high and for which treatment options are limited to supportive care and/or, in a minority, liver transplant. It is clear, however, that systemic inflammation is a major driver for poor outcomes, which supports the clinical evaluation of development candidates such as NTZ, which has demonstrated notable anti-inflammatory effects in a pre-clinical model of ACLF.”*

**Dr. Kris V. Kowdley, Director, Liver Institute Northwest, Clinical Professor Elson S. Floyd College of Medicine, Washington State University**, added: *“Progress continues to be made in identifying new therapies for the treatment of cholestatic liver diseases, however considerable unmet needs remain, especially for patients with PSC for whom there are currently no approved therapies. There is solid scientific rationale to support the evaluation of elafibranor in PSC, given its mechanism of action as a PPAR $\alpha$ / $\delta$  agonist and the anti-cholestatic effects that were observed in a Phase 2 trial of patients with PBC, which are now being further assessed in a Phase 3 pivotal trial.”*

As previously announced, GENFIT will organize two conference calls:

**In English on May 11, 2021 at 4:15pm EDT / 22:15 CEST  
In French on May 12, 2021 at 1:30am EDT / 07:30 CEST**



Both conference calls will be accessible on the investor page of our website, under the events section at [ir.genfit.com](http://ir.genfit.com) or by calling +1 877-407-9167 (toll-free) five minutes prior to the start time (no passcode needed). A replay will be available shortly after the call.

#### **ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with cholestatic and metabolic chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. GENFIT is currently enrolling in ELATIVE™, a Phase 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC). Elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority. As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company has also developed NIS4®, a new, non-invasive blood-based diagnostic technology which could enable easier identification of patients with at-risk NASH. NIS4® technology has been licensed to LabCorp® in the U.S. and Canada for the development and commercialization of a blood-based molecular diagnostic test powered by NIS4® technology. Since April 2021, NASHnext® powered by NIS4™ is offered exclusively in the U.S. and Canada through Labcorp, a leading global life sciences company. 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). [www.genfit.com](http://www.genfit.com)

#### **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, with respect to GENFIT, including statements regarding our expected future performance, business prospects, financial perspective, corporate strategy, events and plans, including the timing of our data read out in our ELATIVE™ phase 3 program in PBC, projections regarding our cash consumption over the next two years, our ability to move our ACLF and cholestatic disease programs into the clinical stage and expected timing for data readout, our continued ability to fund our R&D and clinical programs, the market opportunities for ACLF and cholestatic diseases. . 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, fluctuations in exchange rates and the Company's continued ability to raise capital or find other financial resources 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 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. 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**

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