

**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 16, 2020**

**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 November 16, 2020.](#)

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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.

Date: November 16, 2020

**GENFIT S.A.**

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



**GENFIT: New Data Presented at AASLD The Liver Meeting Digital Experience™**

- **New clinical data on the identification of at-risk NASH using NIS4™ technology alone or in combination with other non-invasive tests**
- **New clinical data on NIS4™ technology as a prognostic biomarker to identify patients with higher likelihood of disease progression**
- **Late breaker abstract on the detection of immune cells in liver tissue based on a combination of handcrafted and deep-learning approach**
- **Other new NASH data including clinical data supporting the correlation of NASH activity scores with fibrosis and markers of glucose metabolism, and late breaker abstract presenting final results of the RESOLVE-IT™ interim surrogate efficacy analysis**

**Lille (France), Cambridge (Massachusetts, United States), November 16, 2020** – GENFIT (Nasdaq and Euronext: GNFT) a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, today announced that data on NIS4™ technology and the complete RESOLVE-IT Phase 3 NASH clinical trial were among those highlighted in five posters at *The Liver Meeting Digital Experience™* (TLMdX), the annual scientific congress of the American Association for the Study of Liver Diseases (AASLD), that was held virtually from November 13 to November 16, 2020.

**Posters and Presentations**

**Title:** *Identification of patients with at-risk NASH or advanced fibrosis using NIS4™ alone or in combination as compared with other testing strategies*

**Poster:** # 1519

**Author/s:** Q. M. Anstee et al.

**Title:** *Baseline levels of NIS4™ and other fibrosis biomarkers and prediction of histological progression to advanced fibrosis in NASH*

**Poster:** # 1484

**Author/s:** S. A. Harrison et al.



## PRESS RELEASE

**Title:** *Automated detection of immune cells in liver tissue based on a combination of handcrafted and deep-learning approach*  
**Poster:** #LP35  
**Author/s:** B. Allaert et al.

**Title:** *RESOLVE-IT™ Phase 3 trial of elafibranor in NASH: final results of the week 72 interim surrogate efficacy analysis*  
**Poster:** #LP23  
**Author/s:** S. A. Harrison et al.

**Title:** *One-year changes in histological NASH activity scores are correlated with changes in fibrosis and glucose metabolism markers*  
**Poster:** # 1538  
**Author/s:** V. Ratziu et al.

The Liver Meeting® is one of the most important hepatology congresses for the medical and scientific community. It brings together more than 10,000 scientists, gastroenterologists and hepatologists from around the world. Due to the COVID-19 pandemic, the 2020 edition of the Liver Meeting has become The Liver Meeting Digital Experience™ (TLMdX), an online forum for the exchange of groundbreaking ideas and findings in basic, translational, and clinical research in diseases of the liver and biliary tract, and in liver transplantation.

### ABOUT NIS4™

NIS4™ is GENFIT's non-invasive, blood-based diagnostic technology, developed to identify patients with non-alcoholic steatohepatitis (NASH) and significant to advanced fibrosis ( $F \geq 2$ ), also referred to as at-risk NASH. In January 2019, GENFIT signed a licensing agreement with LabCorp® to make NIS4™ technology available for use in clinical research through their drug development subsidiary, Covance. In September 2020, GENFIT expanded the agreement to enable LabCorp to develop and commercialize a test based on NIS4™ technology for use as a clinical diagnostic across different practice settings throughout the US and Canada. The test is anticipated to be commercially available in early 2021. GENFIT continues to explore opportunities to obtain formal marketing authorization of an *in vitro diagnostic* (IVD) version of NIS4™ in the U.S. and European markets. For more information, please visit: <https://nis4.com>.



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## PRESS RELEASE

### ABOUT NASH

NASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. NASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for liver transplant. The prevalence of NASH is rapidly increasing as a result of the growing obesity and diabetes epidemics and is believed to affect as much as 12 percent of people in the U.S. and six percent worldwide. Because of its asymptomatic nature, NASH is often undiagnosed, and can only be confirmed through an invasive biopsy. GENFIT is developing an effective non-invasive diagnostic technology that could help diagnose patients non-invasively and on a large scale.

### 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 a Phase 3 clinical trial evaluating elafibranor in patients with primary biliary cholangitis (PBC). As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company is also developing 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. 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)

### 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 statements regarding the commercial availability of Labcorp's diagnostic test using NIS4 technology. The use of certain words, including "believe," "potential," "expect" 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 related 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 and the Company's 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 French Autorité des marchés financiers ("AMF"), including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2019 Universal Registration Document filed with the AMF on May 27, 2020 under n° D.20-0503, which is available on GENFIT'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 20-F dated May 27, 2020. 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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