

**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 10, 2019**

**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 10, 2019.](#)

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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: **November 10, 2019**

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer

## GENFIT Announces Results of NIS4, an Investigational Non-Invasive NASH Diagnostic, at AASLD 2019

- NIS4 is GENFIT's innovative non-invasive in vitro diagnostic test, or IVD, to identify patients with NASH who may be appropriate candidates for drug therapy
- Program is based on the in-house discovery of a 4-biomarker algorithm potentially replacing biopsy with a single blood test
- Study finds patients living with type 2 diabetes are at increased risk of being diagnosed with NASH

Lille (France), Cambridge (Massachusetts, United States), November 10, 2019 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced results from a study demonstrating NIS4, an innovative non-invasive diagnostic blood test designed to diagnose nonalcoholic steatohepatitis (NASH), outperformed other non-invasive diagnostics in identifying NASH in people with type 2 diabetes. These data will be presented at AASLD The Liver Meeting® 2019 in Boston today, November 10 from 12:30PM-1:30PM (Poster #1757).

The study titled, “*Type 2 diabetes as a risk factor for NASH and fibrosis in a cohort of 2363 patients with suspicion of NAFLD: use of NIS4 for identification of at-risk NASH in diabetic patients*” explores how type 2 diabetes is a risk-factor for NASH and liver fibrosis, and also compares the diagnostic performance of NIS4 vs other non-invasive blood marker-based scores in a population of patients with type 2 diabetes. Cohort 1 (N=820) assessed the influence of type 2 diabetes status and anti-diabetic treatment on the prevalence of  $NAS \geq 4$  and  $F \geq 2$ , while cohort 2 (N=275) assessed the diagnostic performance of NIS4 in patients with type 2 diabetes.

The data show that of the patients in Cohort 1, the presence of type 2 diabetes is associated with increased prevalence of active NASH ( $NAS \geq 4$ ) and significant fibrosis ( $F \geq 2$ ), i.e. at risk of progression to serious liver outcomes. The probability of having  $NAS \geq 4$  with  $F \geq 2$  increases with the number of additional anti-diabetic therapies taken by patients to control their glycemia, irrespective of the antidiabetic drug classes used, whether insulin or non-insulin drugs. The data accentuate the need for active surveillance of liver injury in patients with type 2 diabetes, in order to identify those at need of intervention to prevent evolution to clinically relevant hepatic outcomes.

The data from cohort 2 also show that NIS4 significantly outperformed existing non-invasive diagnostic tests in accurately identifying NASH ( $NAS \geq 4$ ) and significant fibrosis ( $F \geq 2$ ) in patients with type 2 diabetes. Specifically, NIS4 had an area under receiver operating characteristic (AUROC) performance of 0.801 [0.748; 0.854] ( $p < 0.01$ ) that is statistically superior compared to FIB4<sup>1</sup> (0.704 [0.641; 0.767]), NFS<sup>2</sup> (0.597; [0.527; 0.667]), ELF<sup>3</sup> (0.704. [0.642; 0.766]) and Fibrometer (0.678, [0.613; 0.743]). Therefore, NIS4 can demonstrate good diagnostic performance and accurately identify NASH ( $NAS \geq 4$ ) and significant fibrosis ( $F \geq 2$ ) in patients with type 2 diabetes.

“*These results reiterate the potential superiority of NIS4, our in-house developed four biomarker panel, to statistically identify NASH and fibrosis with superior sensitivity and specificity also observed in patients with type 2 diabetes,*” said **Suneil Hosmane, Ph.D., Head of Global Diagnostics at GENFIT**. “*Our ongoing research in this area underscores our commitment to improving diagnosis and treatment experiences for patients with NASH, a potentially life-threatening disease that is on the rise, yet significantly underdiagnosed.*”

“*The findings presented today are great news for researchers, clinicians and people who are at-risk for NASH. This simple blood test will be instrumental in the NASH patient journey and provide physicians with the tool to identify patients in need of therapeutic intervention,*” said **Stephen Harrison, study author and Medical Director of Pinnacle Clinical Research**. “*While liver biopsy is the current clinical reference standard for diagnosis, it is a costly, invasive procedure that can cause pain and discomfort for patients, and can even have serious, life-threatening complications. Currently there are no minimally-invasive tests approved specifically for NASH, which is expected to soon be the primary cause of liver transplant.*”

### ABOUT NIS4

GENFIT is developing an *in vitro* diagnostic (IVD) test to identify patients with NASH and fibrosis ( $F \geq 2$ ,  $NAS \geq 4$ ), who are the focus of current NASH clinical trials. The NIS4 program is based on the in-house discovery of a 4-biomarker algorithm and is currently pursuing commercialization of this test which aims to be a validated alternative to the liver biopsy. In January, 2019, GENFIT signed a licensing agreement with LabCorp® to roll out the diagnostic kit in the clinical research field, and plans to file NIS4 for formal marketing approval with the FDA in 2020.

### ABOUT NASH

NASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also potential progression to liver cancer. NASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, liver transplant and cardiovascular disease. 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.

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial (“RESOLVE-IT”) as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC next year following its positive Phase 2 results. As part of GENFIT’s comprehensive approach to clinical management of patients with NASH, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. GENFIT is a publically traded company listed on the Nasdaq Global Select Market and in 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 about the Company's expectations for NIS4 regulatory filing submission, the potential of NIS4 to provide a simple, non-invasive and cost-effective diagnostic tool to all healthcare providers involved in the clinical management of NASH patients and the initiation of a Phase 3 trial in PBC. 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 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, 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 final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. 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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<sup>1</sup> Fibrosis-4

<sup>2</sup> NAFLD Fibrosis Score

<sup>3</sup> Enhanced Liver Fibrosis

## **Attachment**

- GENFIT Announces Results of NIS4, an Investigational Non-Invasive NASH Diagnostic, at AASLD 2019 (<https://ml-eu.globenewswire.com/Resource/Download/e1106d2d-347f-439a-a555-0612e1bca0ac>)