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**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: October 25, 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 [ X ]    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): \_\_\_\_

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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): \_\_\_\_

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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EXHIBIT LIST

Exhibit	Description
<a href="#">99.1</a>	<a href="#">Press Release dated October 25, 2022.</a>

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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.  
(Registrant)

Date: October 25, 2022

/s/ PASCAL PRIGENT  
Pascal Prigent  
Chief Executive Officer



## **GENFIT Announces Compelling Results for Next-Generation Non- Invasive Diagnostic Technology NIS2+™ in NASH to be Presented at the AASLD Liver Meeting®**

- § **NIS2+™ developed and validated as an optimization of NIS4® technology for the detection of patients with at-risk NASH**
- § **Data demonstrate robust and improved clinical performance of NIS2+™ allowing an efficient identification of at-risk NASH, irrespective of patient characteristics such as age, sex and Type-2 diabetes**
- § **NIS2+™'s analytical improvement allows for larger scale implementation in clinical practice and clinical trials**
- § **Three posters to be presented at AASLD Liver Meeting®**

**Lille (France), Cambridge (Massachusetts, United States), October 25, 2022** – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases, today announced that it has developed NIS2+™, a next-generation technology for the diagnosis of at-risk Non-Alcoholic Steatohepatitis (NASH), and will be presenting results on NIS2+™'s clinical performance in three poster presentations at The Liver Meeting® 2022 organized by the American Association for the Study of Liver Diseases (AASLD).

The first poster highlights NIS2+™ as an optimization of NIS4® technology for identifying at-risk NASH. This next-generation technology addresses the unmet needs for identifying patients with at-risk NASH using non-invasive tests (NITs) that are not impacted by critical patient characteristics. NIS2+™ demonstrated strong clinical performance in detecting at-risk NASH, while its composite scores were not impacted by the status of important subpopulations such as Type-2 diabetes, age and sex. While NIS4®'s performance was compelling, the composite score distributions were significantly impacted in some subpopulations. In addition, the increased robustness and simplicity of NIS2+™ technology (from a 4 to 2-biomarker panel) allows for a wider and easier application in clinical settings.

The second poster demonstrates NIS2+™ as an effective screening tool for the enrollment of patients with at-risk NASH in clinical trials, reducing liver biopsy failure rates and associated costs without inflating the number of patients to screen.

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The data in the third poster puts forward NIS2+™ as a valuable prognostic tool for early detection of fibrosis progression in at-risk NASH patients with significant fibrosis (F2) towards advanced fibrosis (F3) and cirrhosis (F4).

In November 2021, NIS4® technology's utility was validated in a Stage 1 study<sup>1</sup> undertaken by the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) initiative of the Foundation for the National Institutes of Health's Biomarkers Consortium as demonstrating a strong and unique performance in identifying patients with at-risk NASH.<sup>2</sup>

**Dr. Vlad Ratziu, Professor at Sorbonne University and Pitié-Salpêtrière Hospital in Paris, France** commented: *“The timely diagnosis of patients with at-risk NASH constitutes a critical unmet medical need, and therefore we welcome this next-generation diagnostic tool. NIS2+™ simplifies the analytical process with only two biomarkers, is more robust in terms of composite scores across critical subpopulations of interest and can be implemented widely in clinical practice. I anticipate that in clinical practice, NIS2+™ will be a diagnostic test of choice to select NASH patients in need for pharmacotherapy, by bypassing the need for liver biopsy – a real progress for patient management. Moreover, there is a need for non-invasive tests to facilitate enrollment in NASH clinical trials, so that the number of liver biopsies, with their many challenges, can be reduced.”*

#### POSTER PRESENTATIONS

##### Poster Number 1: #2484

**Title:** Derivation and Validation of the NIS2+™ Blood-Based Biomarker Panel, An Improvement of NIS4® Technology for the Identification of At-Risk NASH

**Authors:** Harrison SA, Ratziu V et al.

##### Poster Number 2: #2503

**Title:** NIS2+™ Technology as a Screening Tool for Enrollment of Patient with At-Risk NASH in Clinical Trials

**Authors:** Ratziu V et al.

<sup>1</sup> [https://fnih.org/sites/default/files/2021-11/CWS\\_NIMBLE\\_Abstract.pdf](https://fnih.org/sites/default/files/2021-11/CWS_NIMBLE_Abstract.pdf)

<sup>2</sup> <https://ir.genfit.com/news-releases/news-release-details/genfit-fnih-nimble-study-demonstrates-nis4r-technologys-unique>



**Poster Number 3: #2522**

**Title:** NIS2+™, an Improvement of NIS4® Technology for Early Detection of Fibrosis Progression in Patients with Liver Biopsy-Proven At-Risk NASH and F2

**Authors:** Ratziu V et al.

#### **ABOUT THE LIVER MEETING®**

The Liver Meeting® organized by the AASLD 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. The Liver Meeting® 2022 will be held from November 04-08, 2022 at the Walter E. Washington Convention Center in Washington DC.

#### **ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in the research and development of therapeutic and diagnostic solutions in liver diseases, 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 is focused on three franchises: cholestatic diseases, Acute on Chronic Liver Failure (ACLF) and NASH diagnostics. In its cholestatic diseases franchise, ELATIVE™, a Phase 3 global trial evaluating elafibranol<sup>3</sup> in patients with Primary Biliary Cholangitis (PBC) is well underway following a successful Phase 2 clinical trial. Topline data is expected to be announced in the second quarter 2023. In 2021, GENFIT signed an exclusive licensing agreement with IPSEN to develop, manufacture and commercialize elafibranol in PBC and other indications.<sup>4</sup> GENFIT is also developing GNS561<sup>1</sup> in cholangiocarcinoma following the acquisition of exclusive rights in this indication from Genoscience Pharma in 2021<sup>5</sup>. In ACLF, a Phase 1 clinical program with nitazoxanide has been

<sup>3</sup> Elafibranol and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority

<sup>4</sup> With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranol

<sup>5</sup> Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland



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initiated in 2021, and GENFIT further expanded its ACLF pipeline in 2022 via the acquisition of Swiss-based clinical-stage company Versantis, with a Phase 2 ready program evaluating liposomes technology and a preclinical stage small molecule. As part of its diagnostic solutions franchise, the Company entered into an agreement with Labcorp in 2021 to commercialize NASHnext<sup>®</sup>, powered by GENFIT's proprietary diagnostic technology NIS4<sup>®</sup>, and recently developed NIS2+<sup>™</sup>, an evolutionary and optimized diagnostic tool in identifying at-risk NASH.

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). 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)

### ABOUT NIS2+<sup>™</sup>

NIS2+<sup>™</sup> is a blood-based diagnostic test specifically designed to detect at-risk NASH among patients with metabolic risk factors based on an independent 2-biomarker panel. It was developed and validated by GENFIT as a robust NIT across characteristics of interest such as Type-2 diabetes, age and sex, allowing large-scale implementation in clinical practice.

### 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 clinical performance of NIS2+<sup>™</sup> and its ability to be used as a prognostic assessment of fibrosis progression. 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, the impact of the COVID-19 pandemic,



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exchange rate fluctuations 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 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.

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