

**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: September 2, 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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- |                      |                                                                    |
|----------------------|--------------------------------------------------------------------|
| <a href="#">99.1</a> | <a href="#">Press Release dated September 2, 2019.</a>             |
| <a href="#">99.2</a> | <a href="#">Letter to the Shareholders dated September 2, 2019</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.**

Date: September 3, 2019

By: /s/ Jean-François Mouney

Name: Jean-François Mouney

Title: Chairman and Chief Executive Officer

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## GENFIT: Board of Directors, Represented by Chairman Jean-François Mouney, Appoints Pascal Prigent as New CEO

**Lille (France), Cambridge (Massachusetts, United States), September 2, 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 that its board of directors has appointed Pascal Prigent, GENFIT's Executive Vice President of Marketing and Commercial Development, as Chief Executive Officer, following the recommendation of Jean-François Mouney, who will remain Chairman of the Board.

As the Company celebrates its 20th anniversary, co-founder Jean-François Mouney has decided to focus exclusively on his role as Chairman of the Board starting September 16, 2019. At his recommendation, Pascal Prigent, currently the EVP of Marketing and Commercial Development, has been appointed as CEO by the Board.

Pascal joined GENFIT in May 2018 and has worked closely with Jean-François and Dean Hum, GENFIT's COO and CSO, since his arrival. A key member of GENFIT's Executive Committee, Pascal is instrumental in establishing a global team of high profile collaborators and consultants with the objective to prepare for the potential commercialization of elafibranor and NIS4. Prior to GENFIT, Pascal had over 20 years of experience in the pharmaceutical industry, including international management roles with Eli Lilly and GlaxoSmithKline.

**Jean-François Mouney, Co-founder, Chairman & CEO of GENFIT**, commented: *“It’s a personal decision taken after thoughtful consideration, following two decades of intensive work dedicated to developing GENFIT. I’ve asked Pascal to accept the CEO position because I’m convinced he is best positioned to oversee our future corporate growth. Pascal has the right experience, the right skills, the right mindset and the right personality to help build GENFIT for success in the years to come. I look forward to continuing my leadership as Chairman of the Board, including potentially recruiting new board members with international and diverse experience to best prepare us for the exciting years ahead.”*

**Pascal Prigent, future Chief Executive Officer of GENFIT**, added: *“I am honored to take on the role of GENFIT’s CEO and look forward to working with Jean-François and the Board, as well as Dean and the highly skilled teams at GENFIT. Jean-François’ success over the last 20 years, from entrepreneur to CEO of a U.S.-listed company recognized as a global leader in NASH, is the result of his unyielding commitment and expertise. In the coming months, our Phase 3 RESOLVE-IT trial will have an interim read-out, and elafibranor could potentially become the first and only therapy to address NASH resolution without worsening of fibrosis. With our recent expansion into the United States and a solid cash position, we are preparing the company’s future as a commercial organization, to create long term value for our employees and shareholders, and for the NASH field overall, especially the patients”*

**Xavier Guille des Buttes, Vice-Chairman of the Board of Directors of GENFIT**, added: *“The Board has unanimously approved Pascal’s nomination. In the time since he has joined GENFIT Pascal has made significant contributions and has demonstrated to us that his skill set, personality and track-record will be valuable tools in the pivotal period our Company is now beginning. We also want to thank Jean-François for his tremendous accomplishments over the last 20 years, and respect his decision. We know that Pascal and his colleagues have been well chosen and are well prepared for this new managerial structure, and are also pleased the Jean-François will continue to remain closely involved in the Company, bringing his vast experience and leadership to his strategic role as Chairman of our Board.”*

Click here to view the short video featuring Jean-François, Pascal and Dean discussing GENFIT’s new leadership: <https://www.genfit.com/investors/corporate-governance/>

### ABOUT ELAFIBRANOR

Elafibranor is GENFIT’s lead pipeline product candidate. Elafibranor is an oral, once-daily, first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation. GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

### 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 progression to liver cancer.

### ABOUT RESOLVE-IT

RESOLVE-IT is a phase 3 study evaluating the efficacy and safety of elafibranor 120mg versus placebo in patients with nonalcoholic steatohepatitis (NASH) and fibrosis. It is a multicenter, randomized, double-blind, placebo-controlled study with 2 arms. It is conducted under Subpart H (FDA) and conditional approval (EMA). Treatment duration until interim analysis for accelerated approval is 72 weeks.

## ABOUT PBC

“PBC” is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver’s ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

## 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 later this year following its positive Phase 2 results. As part of GENFIT’s comprehensive approach to clinical management of NASH patients, 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 160 employees. GENFIT is a public 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 regarding the commercialization of elafibranor and diagnostic test NIS4, to future corporate growth, to the appointment of new board members, to the readout of elafibranor’s interim results from the Phase 3 in adult NASH and timeline of the readout, to the potential for elafibranor to become the first and only therapy to address NASH resolution without worsening of fibrosis, and to the creation of value for shareholders. 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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## Attachment

- 2019.09.02 - GENFIT PR - Update on Corporate Governance (<https://ml-eu.globenewswire.com/Resource/Download/fcfa28db-4264-40a2-8855-f04095e7cd90>)



Initiated by GENFIT's co-founder, Jean-François Mouney, and the Board of Directors, on the eve of the company's 20th anniversary celebration, GENFIT announces a governance transition. In the following video the company's top management, Jean-François Mouney, Pascal Prigent, and Dean Hum, take the opportunity to informally discuss the main drivers of this new appointment, in order to ensure a seamless transition. Their recorded discussion is available on GENFIT's website and highlights are reflected in the following transcript.



## **Jean-François Mouney, Co-founder, Chairman & CEO of GENFIT**

“As you know GENFIT’s top management has made a number of organizational changes, as I have decided to dedicate more time for myself and my family. I founded GENFIT 20 years ago and have been leading it as CEO ever since. It is essential for me to take the time to directly explain the reasoning and logic behind these changes, since they may impact you, our employees and shareholders.



I would like to stress that this decision was taken with a lot of thought and consideration, with the Board, who unanimously approved Pascal Prigent’s appointment as the new CEO, and also because I have built a team that will take over and will successfully carry-out the succession. I will also remain Chairman of the Board of Directors, and will actively support the executive management in pursuing and achieving great ambitions. As the Chairman of the Board of Directors, I will remain involved in the company’s strategic decision making process. I also plan on strengthening the Board to complete our transformation to a global organization – which has already been initiated - and strongly focused on the U.S.. To this end, I will appoint new Directors to the Board, who will lend valuable knowledge and experience,

especially in drug launches. This natural transition will also create a greater separation of powers between the Board and the executive committee, which is aligned with international practices.

I would also like to further comment on my decision to appoint Pascal Prigent as CEO of the company, a recommendation that was unanimously supported by the Board. First, I know him well, following a year of daily work and interactions. He has clearly demonstrated that he has the right personality. Pascal has an extremely positive outlook on every challenge or complexity, which is an esteemed asset to achieve important milestones such as drug launches or partnership opportunities. His quick and successful immersion within the company has definitely convinced me and is enough evidence that he will effectively work with Dean (CSO/COO), other executive managers, and the operational teams within the company. Pascal’s global experience is also a great asset, as he perfectly understands the processes behind drug launches and therapeutic commercialization, which is precisely GENFIT’s objective in the years to come. The idea is to reinforce the commercial team, with an overarching goal to potentially commercialize elafibranor and our diagnostic tool, NIS4. Pascal has also been instrumental in the licensing agreement signed with our American-Chinese partner Terns Pharmaceuticals, the first step towards commercialization.”

## **Pascal Prigent, future Chief Executive Officer of GENFIT**

“Thank you Jean-François. I have three major feelings today: one is a sense of pride, a sense of humility, and of course tremendous excitement.



A sense of pride because GENFIT is more than just one of the major French biotech companies: it's first and foremost a company that has become a world leader in NASH. NASH is becoming a public health concern that will continue to grow in the coming years since it is associated with obesity that unfortunately is skyrocketing worldwide. There is a lot of ongoing research in the field but few programs have reached advanced stages. GENFIT is now one of the two companies that may be able to offer a therapeutic solution in the short term, provided our Phase 3 results are positive, of course.



GENFIT is also developing its innovative NIS4 diagnostic program, which I believe has the potential to be a game changer for NASH market access. GENFIT also has taken a pioneering direction in disease awareness and education with The NASH Education Program. We can therefore be proud of the work that has been achieved, and proud of the teams, because GENFIT is above all a staff of 180 employees with significant talent, skills and intellectual agility, flexibility and resilience that have allowed GENFIT's programs to move forward. So I am proud to be working with this team, and proud to become its leader in a few days.

There is also a sense of humility, because GENFIT is an innovator that has been exploring for two decades already. As far as I'm concerned, I only joined the company a year ago so my contribution has been modest, and I believe it is essential to respect the history and the culture that has been created here. On top of skills and resilience which I have mentioned, I deeply appreciate the realism, especially useful, along with the seamless attitude

and decision making processes. I really wish to follow this path, and in this sense having been chosen by the person who founded GENFIT and led it for 20 years is very significant.

There is also tremendous excitement since GENFIT is reaching a milestone in its history, after years of hard work aiming at bringing a therapeutic solution to market. As we get closer to the Phase 3 interim results, we approach the end of this process. Our commercial teams are excitedly and relentlessly working to prepare for elafibranor's and NIS4's launches. With regards to elafibranor, we should keep in mind that it is a strongly differentiated product, for a very promising market, and developed by skilled teams. The combination of these three ingredients usually foresees a successful future, even though we cannot predict the outcome."

### Jean-François Mouney

"Thank you Pascal.

I'll follow on this discussion by reminding everyone that you and I are particularly sensitive to our shareholders' - our employees, institutional, and individual, - interests with whom we engage on a regular basis. I would like to stress that you [Pascal] have perfectly understood the shareholder function in the company, and taken into account the full need to create value for all of these stakeholders - despite the choppy financial markets that can impact us, even though often for unrelated reasons.

Dean has been with the Company for almost 20 years and is as foundational as GENFIT itself. He will remain the invaluable and esteemed second in command, and I believe he has many things to say with regards to the organizational changes that we have announced."

## Dean Hum, Chief Operating Officer & Chief Scientific Officer

"Thank you Jean-François. GENFIT is clearly at a very exciting point because we are executing on multiple programs and are preparing the company for the future. In this context I fully support the decision of Jean-François who has decided to focus exclusively on his role as the Chairman of the Board of Directors, where he will surely continue to provide his strategic insights for GENFIT as we are moving forward.



I think everyone realizes that Jean-François has been instrumental and really the leader and the driving force behind the progression of GENFIT, in collaboration with the scientific co-founder Bart Staels. Jean-François has been able to develop the company into being a leader in the NASH space.

I also fully support the nomination of Pascal as the CEO as we have been working very closely together for more than a year, with strong and natural synergies.

In terms of the programs we are currently executing on, of course the most advanced one is related to elafibranor in Phase 3 for the treatment of adult NASH. It's really interesting to see that the NASH field is continuously evolving, with now a heightened awareness and focus on the cardiometabolic aspects. This is particularly important for elafibranor and for GENFIT because elafibranor has demonstrated not only its ability to resolve NASH without worsening of fibrosis in its Phase 2b trial, and its ability to decrease certain cardiovascular and metabolic risk factors. In recent scientific meetings, several experts

in the field have been speaking about these different cardiometabolic parameters and the need to include them in different endpoints of clinical trials. In this context it is important for us to continue our dialogue with the regulatory agencies and have meetings where we should be talking about these metabolic parameters and how they may be included into endpoints.

Beyond this Phase 3, we're also pursuing the development of elafibranor in pediatric NASH, but it is mostly our in vitro diagnostic program that is pivotal for us and the whole NASH space. And here we are moving forward aggressively to seek regulatory approval towards 2020 - 2021."

## Jean-François Mouney

"Thank you Dean for your comments, and for reminding us that on top of human capital, our corporate pipeline programs are the foundation of our development and are fundamental assets for the company. We can also confirm that a Phase 3 in PBC is about to start and that elafibranor in PBC is an essential element of our pipeline. Thank you for also reminding us that the NASH space is moving, and moving fast and that the cardiometabolic aspect of NASH is becoming a central concern. On this specific matter, our meeting with the FDA - which is to take place at the end of the year - will be pivotal.

Before letting Pascal conclude on this, I would like to thank those who have taken the time to listen to our discussion, made in the spirit of simplicity and transparency to give you an insight into the ins and outs of this decision. I am sure you have now understood the rationale behind this decision and that it was made with great care and thought."

## Pascal Prigent

"I expect that this transition will be seamless since Jean-François, Dean and I have been working as a team for the past year. Even though we are taking on different responsibilities, fundamentally the

individuals are the same, and since the teams at GENFIT and their objectives also remain the same, we will continue on this path. As we are entering this very important time in the history of GENFIT, I'm really looking forward to working closely with our Board of Directors led by Jean-François to maximize the opportunities that are ahead. We will seek to create value for everyone: shareholders, employees, and hopefully, and most importantly, patients that are struggling with NASH.

Thank you for your attention."



## MARKET INFORMATION

**Euronext Paris - Compartiment B**  
Mnemonic code: GNFT  
ISIN code: FR0004163111

**NASDAQ**  
Mnemonic code: GNFT  
ISIN code: US3722791098

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**AVERTISSEMENT** - This letter 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 related to the success of the succession transition, the appointment of new board members, the potential commercialization of elafibranor in NASH and our diagnostic tool NIS4, the increase in prevalence of NASH, the outcome of the Phase 3 clinical trial evaluating elafibranor in adult NASH, the potential for GENFIT to offer a therapeutic solution for NASH, the capacity for NIS4 to open the NASH market, the inclusion of cardiometabolic parameters in clinical trials endpoints by regulatory agencies, the timeline of regulatory approval and clinical development for the different programs, the start of a Phase 3 clinical trial in PBC and, the timeline of a meeting with the FDA. 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.