



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

December 12, 2018

Jean-François Mouney
Chief Executive Officer
Genfit S.A.
Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France

Re: Genfit S.A.
Draft Registration Statement on Form F-1
Submitted November 16, 2018
CIK No. 0001757064

Dear Mr. Mouney:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1

Cover Page

1. Please disclose on the cover page of the preliminary prospectus a bona fide price range of the offered securities. If you intend to price the securities based on the Euronext Paris price of your ordinary shares, you may disclose a percentage range based on that price (for example, 10% of the Euronext price) within which you intend to price the securities. See Item 501(b)(3) of Regulation S-K.

Market, Industry and Other Data, page ii

2. Please disclose the information regarding the price history of your ordinary shares on

Euronext Paris pursuant to Item 9.A.4 of Form 20-F.

Prospectus Summary

Overview, page 1

3. We note statements throughout your prospectus that describe elafibranor as being "well-positioned" as a first-line treatment as a monotherapy and the backbone of combination regimens, statements that, "if approved, [you] believe elafibranor would be among the first FDA-approved therapies shown to achieve resolution of NASH without worsening of fibrosis" and statements that describe your blood-based IVD test as a novel, standalone diagnostic that will meet the need for a validated test to identify NASH patients as well as your statement on page 112 that describes the development and potential regulatory approval of elafibranor as being several years ahead of your competitors' drug candidates. These statements imply an expectation of regulatory approval and are inappropriate given the stage of development. Please revise these statements and all other similar statements to eliminate such implication.
4. We note statements throughout your prospectus referring to the safety or efficacy of your product candidates and diagnostic test. For example, we note your disclosure on page 3 that elafibranor "has a differentiated efficacy and safety profile relative to other drugs in similar states of development for NASH" and that you "believe elafibranor has a favorable safety . . . profile" as well as your conclusions regarding the safety and efficacy of elafibranor on pages 97 to 103 and page 108. Safety and efficacy are determinations within the exclusive authority of the FDA or equivalent foreign regulators, and, because your product candidates have not yet received approval by the FDA or equivalent foreign regulators, it is premature and inappropriate to state conclusions regarding safety and efficacy. Please revise these and all similar statements accordingly.
5. Please revise the pipeline chart on page 1 to clarify, if true, that you are conducting pre-clinical studies of TGFTX1 for mild to moderate psoriasis. In addition, we note your press release that you began your Phase 2 clinical trial of NTZ on December 3, 2018. Please revise your pipeline chart to indicate that you have just begun Phase 2 clinical trials of NTZ. Also, revise the pipeline chart of your IVD test to disclose the specific clearance and approval stages necessary to obtain FDA approval to market your IVD test. In this regard, we note your disclosure on pages 121 and 122.
6. We note your disclosure on page 2 that "[i]n [y]our Phase 2b clinical trial, elafibranor achieved resolution of NASH without worsening of fibrosis, which is the primary endpoint of [y]our ongoing global Phase 3 clinical trial." Please disclose here and in the second bullet point on page 3, if true, that you did not achieve statistical significance on your prespecified endpoints in your Phase 2b clinical trial. In this regard, we note your disclosure on page 15.
7. We note your disclosure on page 2 that "NTZ has shown promising activity against fibrosis in [y]our preclinical disease models." As NTZ is in clinical trials, please limit the

prospectus summary discussion of your results to a description of the endpoints of your clinical trials and whether they were met.

8. We note your disclosure on page 2 that you believe that, if the test results from your interim cohort analysis are positive, you may obtain accelerated approval from the FDA or the EMA as early as 2020 for elafibranor in the treatment of NASH. Please disclose whether you have received any indication from the FDA or EMA that you will be granted accelerated approval. In addition, to the extent that you have not conducted head-to-head clinical trials, revise your disclosure throughout your prospectus to remove comparisons of your product candidates to other treatments, products and product candidates. For example, we note your statements on page 2 that you "believe elafibranor's unique mechanism of action can provide benefits for patients with PBC without the significant side effects associated with current PBC treatments" and that your IVD test is better than the current standard for diagnosis of NASH and your statement on page 3 that elafibranor resolves Nash "while also showing a decrease in cardiovascular risk factors, an important differentiator"

Implications of Being an Emerging Growth Company, page 5

9. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Risk Factors

Risks Related to Our Operations

We increasingly rely on social media, page 40

10. We note your disclosure on page 40 that you "increasingly rely on social media and new technologies to communicate to investors." To the extent that you intend to communicate with investors on social media, please disclose how investors may access such information. For example, please disclose whether you intend to include such information in filings on the SEC website and your investor website.

Use of Proceeds, page 66

11. If you do not believe that the anticipated proceeds will be sufficient to complete all of the proposed purposes, please disclose an estimate of the additional funds needed to fully fund all of the proposed purposes listed on page 66. In addition, disclose an estimate of how far the allocated proceeds will allow you to reach in the development process of (i) your IVD test and (ii) the research program on the use of elafibranor as a potential backbone for combination therapies. If you do not believe that the amount of funds allocated for your Phase 3 clinical trial of elafibranor for the treatment of PBC and for the completion of your ongoing Phase 3 clinical trial for elafibranor for the treatment of NASH will be sufficient to complete these Phase 3 clinical trials, please provide an

estimate of how far the allocated proceeds will allow you to reach.

Business

Overview, page 92

12. We note your disclosure on page 92 that NTZ "has shown promising activity against fibrosis in [y]our preclinical disease models." Please revise to describe here how you conducted your preclinical disease models of NTZ and the range of the results of such tests.

Our Clinical Program for Elafirbranor in the Treatment of NASH, page 98

13. We note your disclosure on pages 99 to 103 of your Phase 1, Phase 2a, Phase 2b and Phase 3 clinical trials conducted or about to be conducted with elafibranor in connection with your IND for NASH. For each clinical trial discussed, please revise your disclosure as necessary to include a detailed description of how the clinical trial was or will be conducted, the endpoints of the trial and, as appropriate, whether the endpoints were met, the number of patients that left the trial before completion, all serious adverse events, if any, and how many patients experienced serious adverse events, if any. In addition, please disclose whether the results from each of the clinical trials conducted were statistically significant by describing the specific p-value used in each and whether these p-values met the FDA's specified threshold for statistical significance for the trials.
14. We note your discussions of animal trials on page 102, disease models indicating that elafibranor may prevent development of liver cancer on page 102, disease models of combination therapies of elafibranor on page 103, studies using elafibranor as backbone in in vitro and in vivo NASH models on page 103 and in vivo models in which you observed that administration of NTZ significantly attenuated liver fibrosis development on page 110. Please revise these discussions to include (i) a detailed description of how the the animals trials were conducted, including the number of animals tested, the dose or doses of elifbranor used, and the range of the results of such trials, (ii) a detailed description of the disease models showing that elafribranor may prevent development of liver cancer as well as the disease models using elafibranor as backbone in NASH, including the number of times each test was conducted, the products and product candidates used in the backbone trials and the range of the results of the trials, and (iii) a detailed description of the NTZ trials using in vivo models and the range of results.

Efficacy Results, page 99

15. Please disclose the total number of patients enrolled in the Phase 2b trials with only "mild disease and too low of a NAS," as well as how the results from these patients affected the results of the Phase 2b trial.

16. We note your chart on page 101 showing the fibrosis change from baseline in elafibranor 120 mg responders compared to non-responders. Please disclose the number of patients that responded and clarify the range of responses. Similarly, please disclose the number of patients receiving 120 mg of elafibranor that experienced improvement of ALP and how such improvement was measured, as well as the percentage of patients that met the secondary endpoints and whether the results were statistically significant.

IVD Test for the Diagnosis of NASH

Circulating Biomarkers and MicroRNA (miRNA), page 104

17. Please disclose the average and range of time necessary for measuring miRNA using the methods you have developed as well as the percentage of accurate readings in your tests. In addition, please revise your discussion to explain why your technique "represents a significant improvement over" first-generation sequencing technology, setting forth the basis for such belief (e.g., head-to-head comparisons). Similarly, we note your chart on page 106 comparing the AUROC scores of your IVD test to those of other tests reported in literature. To the extent that you did not conduct head-to-head comparisons in your trials, please remove this disclosure or tell us why it is appropriate. In addition, please disclose the AUROC score of your IVD test as compared to the patient's initial liver biopsy. Finally, please disclose here, if known, the specific clearance and approval stages necessary to obtain FDA and EMA approval to market your IVD test. In this regard, we note your disclosure on pages 121, 122 and 125.

TGFTX1 Program for the Treatment of IL-17-Dependent Autoimmune Diseases, page 110

18. We note your disclosure regarding your preclinical tests of TGFTX1 on page 110. Please disclose a detailed description of the your studies, including the number of mice tested, the dose or doses used in the tests, the number of tests conducted and range of results observed. In addition, we note that you "plan to leverage the expertise of specialized pharmaceutical companies with already established franchises in dermatology and/or respiratory diseases through collaborations or other strategic alliances." Please disclose whether you currently have any such collaborations or strategic alliances.

Government Regulation

United States Government Regulation, page 115

19. Please describe the process for product candidates pursuant to Section 505(b)(2). In this regard, we note your disclosure on page 18 that you may seek FDA approval through the Section 505(b)(2) regulatory pathway for NTZ. In addition, please disclose whether the FDA has given any indication that you may use such pathway for NTZ.

Certain Relationships and Related Person Transactions, page 152

20. Please file the Shareholders' Agreement as an exhibit to your registration statement or tell us why you believe this is not necessary.

Description of American Depositary Shares, page 183

21. Please clarify whether holders of ADSs will receive a double voting right if the ADS is held in the name of the same shareholder for at least two years.

Report of Independent Registered Public Accounting Firm, page F-2

22. Financial statements which comply with IAS 1 and an audit report that complies with Rule 2-02 of Regulation S-X should be included in the registration statement for which you request effectiveness.

3. Summary of Significant Accounting Policies

3.21. Classification of operating expenses, page F-18

23. You state on page F-18 that research and development expenses include grants to the endowment fund, The NASH Education Program. You further state on page 85 "We also make donations to The NASH Education Program, the endowment fund of which we are a sponsor" and that the grant is for "the creation of a patient registry and other disease awareness initiatives." On page 95, you state "The NASH Education Program, a public health initiative we created in 2017, is dedicated to the development and funding of NASH awareness and education activities aimed at the medical community and the general public." Explain to us why you believe classification of this expense as research and development is appropriate and that this expense is not more appropriately classified as general and administrative expense. Refer to paragraphs 8, 56, 59, 126 and 127 of IAS 38.

General

24. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.

You may contact Vanessa Robertson at 202-551-3649 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Sonia Bednarowski at 202-551-3666 or Dietrich King at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance