



DIVISION OF
CORPORATION FINANCE

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

November 2, 2017

Hermann Lübbert
Chief Executive Officer
Biofrontera AG
Hemmelrather Weg 201
D-51377 Leverkusen Germany

Re: Biofrontera AG
Draft Registration Statement on Form F-1
Submitted October 4, 2017
CIK No. 0001712641

Dear Mr. Lübbert:

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. We note your statements in the penultimate risk factor on page 40 and in the Underwriting section that the IPO price of the ADSs will be determined through negotiations with the underwriters. Since it does not appear that you expect the price for the ADSs to be substantially based on the home market trading price, please disclose on the cover page of the preliminary prospectus a bona fide price range of the offered securities. See Item 501(b)(3) of Regulation S-K.

2. Please expand your cover page to disclose the conflict of interest with The Benchmark Company and Dawson James' role and responsibilities in the offering. Additionally, tell us whether Schiff Hardin LLP represents The Benchmark Company, Dawson James and Lake Street Capital Markets. If Schiff Hardin represents all the underwriters, please tell us how you have determined that this does not present a conflict of interest or impacted Dawson James' ability to qualify as a qualified independent underwriter.

Prospectus Summary, page 6

3. Please expand on your discussion in the seventh bullet on page 10 and the risk factor on page 32 to disclose that you have recently lost market share to Luxerm and the potential consequences if Ameluz's approved indications are not extended to include daylight photodynamic therapy and it is unable to compete with Metvix, which has already been approved for this indication under the brand name Luxerm.

Implications of Being an Emerging Growth Company, page 11

4. Please supplementally 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.

Exchange Rates, page 51

5. Please expand your disclosure to provide the exchange rate for the five most recent financial years, as well as the interim period corresponding to the interim period financial statements included in your prospectus. Refer to Item 4.a. of Form F-1 and Item 3.A.3 of Form 20-F.

Use of Proceeds, page 52

6. Please revise your disclosure to state the estimated amount of proceeds from this offering that you expect to use for each of your principal intended purposes. Refer to Item 3.C.1 of Form 20-F. Additionally, we note your disclosure in the last paragraph that there is no assurance that the preemptive rights offering will be "even partially subscribed." Any discussion regarding your expected uses for proceeds arising from your preemptive rights offering should be separate from your discussion of the use of proceeds from this offering.

Dilution, page 57

7. Please revise your proposed presentation to also include dilution assuming no exercise and 50% exercise of the preemptive rights in Germany consistent with that presented in capitalization on page 55. In this regard, we note that of the three scenarios presented in

capitalization, the assumed full exercise of the preemptive rights results in the highest possible pro forma net tangible book value after your offering and the lowest possible dilution per share.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 65

8. Please revise your discussion of revenue changes on pages 65 and 68 to discuss the impact of changes in volume versus changes in prices and to clarify in existing markets the impact of new product launches. See Item 5A1 of Form 20-F.

Business
Overview, page 79

9. Your inclusion of BF-derm1 and BF-1 in the table on page 79 appears to contradict your statements on page 93 that you are not currently actively developing BF-derm1 and BF-1. Please delete these product candidates from the table. Additionally, identify the indications related to each of the product candidates under your agreement with Maruho.
10. We note that the pipeline table indicates that the Phase III trial to extend Ameluz for use in treating actinic keratosis on the trunk and extremities has started. Please add narrative disclosure in your research and development discussion to provide additional information regarding this trial. In addition, please provide additional disclosure regarding the status of the Phase III trials referenced in the table as "Phase III in preparation," or "Phase III planned," including when you expect the trials to begin and the expected duration of such trials. Please also expand your research and development disclosure to discuss any relevant earlier clinical trials for these indications.

Recent Achievements, page 79

11. We refer to your statement that you have agreed with the FDA on a Phase III trial to expand the indication for Ameluz PDT for the treatment of superficial basal cell carcinoma. Please expand your disclosure to discuss the primary and secondary endpoints, and any expectations regarding the duration of the trial.

Our Products, page 82

12. Your statements, such as the statement in the penultimate paragraph on page 88, that you have not verified the third party information regarding market and industry data, may include outdated information and potentially overestimate the size of the US market, imply an inappropriate disclaimer of responsibility with respect to the third party information and size of the US market. Please either delete these statements or specifically state that you are liable for the information related to the market and industry data.

Research and Development and Regulatory Affairs, page 96

13. Please expand your discussions of Trials 1, 2 and 3 and your basal cell carcinoma trial to also disclose where each of these trials was conducted. Please also explain the significance of the p-values and confidence intervals you disclose and how they relate to regulatory authorities' evidentiary standards of efficacy.
14. We refer to your statement on page 99 that 138 patients were treated with Ameluz in the basal cell carcinoma trial. However, Table 4 appears to indicate that the total number of Ameluz patients was 121, and the number of patients who achieved full clearance (140) appears to exceed the total number of Ameluz patients. Please revise your disclosure to explain.

Patents, page 102

15. With respect to each patent family you describe, please expand your disclosure to disclose the type of patent protection provided by the patents or patent applications (e.g., composition of matter, method of use). Please also clarify whether the patents described in the fifth paragraph of this section relate to your Ameluz product.

Commercial Partners and Agreements, page 106

16. We note your disclosure that you depend on a single manufacturer to manufacture Ameluz, and the reference to the license and manufacturing agreement with Grunenthal in the exhibit index. Please expand your disclosure to discuss the material terms of this agreement.

Facilities, page 107

17. We refer to your statement on page 90 that you manufacture your BF-RhodoLED® lamp at your own manufacturing facility in Germany. Please clarify whether the headquarters location also includes this manufacturing facility.

Principal Shareholders, page 134

18. We note that you describe Deutsche Balaton as one of your major shareholders on page 106. We also note that it does not appear in the principal shareholder table on page 134. Please tell us the percentage of shares that Deutsche Balaton holds. If it holds more than 5% of your outstanding shares, please include it in the table. Additionally, we note that Hansjorg Plaggemars was Deutsche Balaton's appointment to the Board. Please clarify whether he continues to serve as the appointee of Deutsche Balaton or if Deutsche Balaton has the right to appoint a new director. Additionally, revise your disclosure that the major shareholders do not have any special voting rights to disclose Deutsche Balaton AG is entitled to appoint a member to your supervisory board.

Consolidated Cash Flow Statement, page F-7

19. Please revise your financing activities section to present proceeds from long-term financial debt and repayments thereof separately. Otherwise, tell us how it is appropriate to net proceeds and repayments under paragraph 22 of IAS 7.
20. Please revise the captions of the two lines depicting proceeds from conversions in your financing activities section as follows:
 - The conversions of convertible bonds 2016/2021 appear to be non-cash transactions and the amount you depict may be the proceeds from bond issuance.
 - The conversions of option bond 2011/2016 appear to be the exercise of detachable warrant rights as disclosed in the fourth paragraph on page F-22. As appropriate, please also revise the caption of the related line-item on your statement of changes in equity.

Audited Financial Statements of Biofrontera AG

Summary of significant accounting policies

Financial instruments, page F-14

21. Please tell us how you apply the effective interest method, less treasury stock. Specifically tell us what you mean by "less treasury stock." Reference for us the authoritative literature you rely upon to support this policy.

Financial investments held to maturity, page F-14

22. Please tell us why it is appropriate to adjust the value of your own Warrant Bonds held to the market price when you classify securities held as held-to-maturity and your financial liability for Warrant Bonds outstanding appears to be carried at amortized cost as loans and receivables under paragraph 46 of IAS 39. Reference for us the authoritative literature you rely upon to support your accounting.

Warrant bonds, page F-15

23. You characterize your warrant bonds as being classified as hybrid financial instruments that represent a debt security with an embedded conversion or subscription option. Paragraph 10 of IAS 39 indicates that hybrid instruments are comprised of a non-derivative host contract and an embedded derivative and that a detachable independently transferable derivative is not an embedded derivative. It appears from your disclosure in Note 10 that the warrants/rights associated with your warrant bonds are detachable and that you may account for your warrant bonds as compound financial instruments under paragraphs 28 through 32 of IAS 32. Please clarify for us how you account for your warrant bonds, explaining why it is appropriate to account for them as either hybrid or compound financial instruments when the warrants/rights are detachable. Reference for us the authoritative literature you rely upon to support your accounting.

24. Please tell us the relevance of "market value" in addition to "fair value" in the context of IFRS 13. In addition, please revise your disclosure to remove the apparent implication that fair value equals contract/exercise price. In this regard, if intrinsic value as disclosed equals the difference between market value and contract price and fair value as disclosed equals market value less intrinsic value, it appears to imply that fair value equals contract price.
25. Please revise your disclosure in the last paragraph on page F-15 to indicate that the method for allocating consideration, fees and transaction costs for early redemption is based on the original allocation applied to the proceeds received when the bonds were issued consistent with paragraph AG33 of IAS 32. In this regard, debt issuances do not generate "revenues" as defined in IAS 18.

Research and development expenses, page F-17

26. In the paragraph below the table on page 63 you disclose that you classify the costs of clinical trials that show the effectiveness of Ameluz in comparison to other drugs or therapies as research and development expenses. Please tell us how these trial meet the definition of research or development under paragraph 8 of IAS 38 and why they are appropriately classified as research and development expenses under paragraph 127 of IAS 38. In your response tell us why these trials are not marketing related.

Notes to the Consolidated Financial Statements

Note 9: Equity, page F-21

27. Please revise your filing to provide all the information about your 2010 and 2015 share option programs required by paragraph 45 of IFRS 2 or tell us where this information is disclosed. In this regard, at a minimum, it does not appear that you disclose the number of options and their weighted average exercise prices for those outstanding at both the beginning and end of each period presented and those exercisable at the end of the period.

Note 15: Sales revenue, page F-33

28. On page 62 you disclose that your sales of the BF-RhodoLED photodynamic therapy lamp and your Belixos line of over-the-counter skin care cosmetics products are "relatively insignificant" compared with those of Ameluz. Please tell us the amount of revenues recorded for each of these products for 2015, 2016 and the first six months of 2017 and why you do not disclose these amounts as required by paragraph 32 of IFRS 8.

Note 21: Other income (expenses), net, page F-34

29. On page 64 you disclose that other income includes the creation and reversal of certain accruals, mainly those for bonuses and accrued expenses. Please tell us why it is

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appropriate to create and reverse accruals and classify them as “other” income or expense. In your response, tell us the amount of these accruals/reversals included in other income and other expense for each of 2015, 2016 and the first six months of 2017. Reference for us the authoritative literature you rely upon to support your accounting and classification.

Notes to the Condensed Consolidated Financial Statements
Unaudited Financial Statements of Biofrontera AG
Convertible bond 2017/2022, page F-45

30. Given the varying conversion rates associated with your bonds issued in January 2017, tell us why you do not appear to record an embedded derivative liability associated with the conversion feature. Reference for us the authoritative literature your rely upon to support your accounting.

You may contact Mark Brunhofer at 202-551-3638 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Suzanne Hayes at 202-551-3675 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Stephen Older