



DIVISION OF
CORPORATION FINANCE

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

June 10, 2021

Hermann Lubbert
Chief Executive Officer
Biofrontera Inc.
120 Presidential Way
Suite 330
Woburn, MA 01801

Re: Biofrontera Inc.
Amended Draft Registration Statement on Form S-1
Filed May 11, 2021
CIK No. 000185685

Dear Dr. Lubbert:

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.

Amendment No. 1 to Draft Registration Statement on Form S-1

Summary, page 1

1. Please clarify the relationships between Biofrontera AG, Biofrontera Inc., Biofrontera Pharma and any other subsidiaries of Biofrontera AG with which you do business. Also consider including an organizational chart depicting these relationships.
2. We note your disclosure on page 51 indicating that you generate revenues through sales of licensed products, including BF-RhodoLED lamps, please clarify that you also have a license to sell these products. .
3. Please clarify whether your exclusive license to sell Ameluz and the BF-RhodoLED

lamp is for all approved indications in the United States or all approved indications in the United States as of the date of the agreement.

Risk Factors, page 8

4. From the risk factors on pages 12-15 and disclosure elsewhere, it appears you are not obligated or tasked with the duty to defend your intellectual property, have control over your source of products or the quantity you must purchase, or have the ability to determine the future products you will seek to commercialize. Add a risk factor addressing the risks associated with the lack of control your management and board will have over your company and its direction given the current structure, the degree of control related entities have over your business currently through licensing and intellectual property agreements, in addition to their significant share ownership.

The Biofrontera Group depends on a single unaffiliated manufacturer to manufacture Ameluz..., page 11

5. We note your reliance on a single unaffiliated contract manufacturer to manufacture Ameluz. Disclose the name of that supplier as required by Item 101(h)(4)(v) of Regulation S-K. As you disclose your business could be materially harmed if you fail to maintain your relationship with this supplier, file your supply agreement as required by Item 601(b)(10)(ii)(B) of Regulation S-K or tell us why you believe you are not substantially dependent upon it.

Our amended and restated certificate of incorporation will become effective..., page 40

6. Please revise the discussion to disclose that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder and that there is also a risk that your forum selection provisions may result in increased costs for investors to bring a claim.

Use of Proceeds, page 43

7. Your use of proceeds states your expenditures may vary based on factors including “the timing and success of any clinical trials and preclinical studies [you] may commence in the future, [and] the timing of regulatory submissions.” As you state you specialize in commercialization and it does not appear that your company develops drugs, but only in-licenses drugs once they receive regulatory approval, please clarify. We note the statement on page 72 that “in the future, [you] may conduct your own clinical trials to better the market positioning of [your] in-licensed products;” however, we see no disclosure of specific plans. To the extent you intend to use the proceeds to implement your strategy, such as growing your dedicated sales and marketing infrastructure, please update your to quantify the amounts intended to be used for each purpose. Alternatively if you have no specific plan for your use of proceeds, revise your disclosure to discuss the principal reasons for the offering and add a risk factor concerning the lack of a specific

plan. Please refer to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 47

8. We note your disclosure of the impact of the COVID-19 pandemic on your company, and also the seasonality of your main product, Ameluz. We also note the patent protection for Ameluz expired in early 2019. Revise your disclosure related to the impact of the pandemic to provide additional insight as to why you believe your product sales declines related to the pandemic rather than other factors, such as increased competition from generic products. For example, clarify whether sales increased in the fourth quarter of 2020 and first quarter of 2021, as the pandemic restrictions eased in some areas.

Components of Our Results of Operations, page 51

9. File the Intercompany Services Agreement with Biofrontera AG dated January 1, 2016, referenced on page 51 as an exhibit to the registration statement. Refer to Item 601(b)(10)(i)(A) and (ii) of Regulation S-K.

Business, page 64

10. Please revise the discussion of your parent company's research activities to clarify to what degree you control the progress of these studies, whether the products will be commercialized and the terms of any potential licensing agreement.

Intellectual Property, page 75

11. Please revise your discussion of the patent family related to nanoemulsions held by Biofrontera Bioscience to provide the following additional information:
- the jurisdiction where the patents were issued;
 - the products dependent on the patents;
 - when such patents expire
 - any licenses or similar agreements providing you with rights or protections related to the patents.
- To the extent you are party to any agreements providing you with rights or protections related to the patents, file them as exhibits pursuant to Item 601(b)(10) of Regulation S-K or tell us why you believe they are not required to be filed.
12. Please revise your intellectual property disclosure to clearly describe the type of patent protection granted for Xepi by each patent family, the expiration year of each patent held, and the jurisdiction of each patent.

Commercial Partners and Agreements, page 76

13. We note your disclosure on page 10 indicating your license agreements impose regulatory and commercial diligence obligations and payment of milestones and royalties. Please

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revise the descriptions of your agreements with Biofrontera Pharma and Ferrer to describe the regulatory and diligence obligations; clarify whether the milestone obligations are development or sales based milestones; quantify the maximum potential milestone payments for each type of milestone obligation; and quantify the royalty rate or provide a reasonable range not exceeding 10 percentage points, and disclose when the royalty provisions expire. Clarify who controls the pricing of your supply of Ameluz and lamps.

General

14. 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.

You may contact Tara Harkins at 202-551-3639 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at 202-551-6902 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences