

News release

Biofrontera reports earnings results for the third quarter and first nine months of 2018

Leverkusen, Germany, November 16, 2018 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today reported its financial results for the nine months ended September 30, 2018 and provided an update on recent developments.

- Total revenue increased 98% to approximately EUR 14.6 million for the first nine months of 2018, compared to approximately EUR 7.3 million in the same period 2017.
- Product revenue increased 131% to approximately EUR 14.4 million for the first nine months of 2018, compared to approximately EUR 6.2 million in the same period 2017.
- Net loss was approximately EUR 12.3 million or 0.28 per share for the first nine months of 2018, compared to approximately EUR 14.6 million or 0.38 per share in the same period 2017.
- Raised revenue guidance for the current year from EUR 16 to 20 million to EUR 19 to 22 million in October 2018.
- Award of a five-year contract with the U.S. Department of Veterans Affairs in August 2018.
- Approval of Ameluz[®] in combination with daylight photodynamic therapy (PDT) by the European Commission in March 2018 and in Switzerland in September 2018.
- Completion of patient recruitment for the Phase III trial of Ameluz[®] / BF-RhodoLED[®] for the treatment of actinic keratoses on the extremities or trunk/neck in July 2018.
- Start of patient recruitment for the U.S. Phase III trial evaluating Ameluz[®] / BF-RhodoLED[®] for superficial basal cell carcinoma in September 2018.

"Through the successful implementation of our strategy, we have further improved the positioning and market potential of Ameluz[®], which allowed us to record a significant increase in sales in the first nine months of this year", says Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "We achieved and even exceeded our operational goals in the reporting period. Ameluz[®] has increasingly been turning into a household name among dermatologists, especially in the United States. This and the significant improvement in reimbursement for physicians through the J-code as well as the revised

CPT-codes for photodynamic therapy led to a constant increase in U.S. sales. In the third quarter, the anticipated 5.6% increase in the list price to US\$ 285 on October 1st, led to more purchases by U.S. customers. Daylight-PDT fueled the PDT market in Europe. As a result, September marks a global sales record for Ameluz[®] with more than 22,000 tubes sold", comments Prof. Dr. Hermann Lübbert.

In EUR thousands, except where noted	9M 2018 unaudited	9M 2017 unaudited	Change
Revenue	14,552	7,334	98%
from product sales	14,383	6,238	131%
from development projects	129	1,096	-88%
other	40	0	NA
Research and development costs	(3,219)	(3,233)	0%
General administrative costs	(7,283)	(3,626)	-101%
Sales costs	(12,658)	(12,586)	-1%
Net loss	(12,253)	(14,614)	16%
Earnings per share (in EUR)	(0,28)	(0,38)	26%

Key financial figures for the first nine months 2018:

Biofrontera generated total revenue of approximately EUR 14.6 million in the first nine months of 2018, representing 98% year-over-year growth. In the U.S., revenues increased 204% during the reporting period to EUR 10.2 million, compared to the same period 2017. Sales in Germany improved to EUR 2.1 million, representing a 24% increase compared to the previous year. Revenue in the remainder of Europe amounted to EUR 2.1 million, an increase of 73% compared to the same period last year.

Gross profit on sales improved by EUR 5.3 million in the reporting period to EUR 11.8 million compared to EUR 6.4 million in the same period last year. The gross margin fell from 88% in the first nine months of 2017 to 81% in the first nine months of 2018. This is due to a significant reduction in revenues from other regions/development projects, which were not offset by any cost of sales in the prior-year period.

The consolidated net loss for the nine months of 2018 was EUR -12.3 million, or EUR -0.28 per share, compared to the net loss of EUR -14.6 million, or EUR -0.38 in the same period last year.

Cash and cash equivalents were EUR 21.1 million as of September 30, 2018, compared to EUR 11.1 million as of December 31, 2017.

In view of the latest business development, Biofrontera AG has in October raised its revenue guidance for the current year from EUR 16 to 20 million to EUR 19 to 22 million, while the forecast for the consolidated net loss in 2018 remains unchanged at EUR 15 to EUR 16 million.

U.S. Commercial Update

The U.S. continues to be the largest growth market. In the first nine months of 2018, sales revenue in the U.S. totaled EUR 10.2 million, a 204% increase compared to the same period last year. The significant improvement in the reimbursement of medical expenses through the J-code and the revised CPT-codes led to a consistent increase in sales to U.S. customers. Additionally, U.S. revenue was supported in the third quarter by an anticipatory effect due to the expected 5.6% increase in the list price as of October 1. Another milestone in the last quarter was the award of a five-year contract with the U.S. Department of Veterans Affairs in August 2018, which enables us to offer Ameluz[®] to all medical facilities of the U.S. Department of Veterans Affairs and the U.S. Department of Defense.

EU Commercial Update

Biofrontera reported a 73% increase in revenues in all our European markets in the first nine months of 2018 as compared to the same period in 2017. With the European Commissions' approval for treatment with daylight photodynamic therapy (PDT) for actinic keratosis, Ameluz[®] has become more competitive against existing PDT drugs, as well as patient-applied topical treatments. In Germany, our largest EU market, the reimbursement status of Ameluz[®] improved significantly with the approval of Ameluz[®] in combination with daylight-PDT. As a result, in the entire reporting period, the Company recorded a substantial increase of 24% to EUR 2.1 million in sales in Germany, which was mostly due to the summer months. In addition, following the introduction of Ameluz[®] in combination with daylight-PDT, we experience an expansion of the entire PDT market.

Clinical Update

In July 2018, Biofrontera announced that it had completed patient recruitment for its ongoing phase III trial of Ameluz[®] and BF-RhodoLED[®] for the treatment of actinic keratoses on the extremities, trunk and neck. The Company expects further growth in the market potential from the study and anticipates the results in the first quarter of 2019. After successful approval, Ameluz[®] would be the only PDT drug in Europe and the U.S. that can be used to treat actinic keratoses of all degrees of severity on the extremities, as well as the torso and neck.

In order to further increase our growth opportunities in the U.S. market in the medium term, Biofrontera is currently conducting a phase III trial evaluating the treatment of superficial basal cell carcinoma (BCC) with Ameluz[®] in combination with its BF-RhodoLED[®] lamp in the United States, for which patient recruitment started in September 2018. Study results are anticipated to be

available in the first half of 2020. Following successful FDA approval, Ameluz[®] would be the only drug in the U.S. for the treatment of superficial BCC through PDT. This would allow the Company to offer patients and physicians a treatment option for BCC with high efficacy and excellent cosmetic results.

Conference Call

Conference calls for shareholders and interested investors will be held on November 16, 2018 at the following times:

-End-

In German, at 10:00 am CEST (4:00 am EDT) Dial-in number Germany: +49 (0) 69201744220 Conference code: 14005835#

In English, at 2:00 pm CEST (8:00 am EDT) Dial-in number USA: +1 8774230830 Dial-in number UK: +44 2030092470 Conference code: 12331554#

Please dial in 5 minutes ahead of time to ensure a timely start of the conference call.

The Company's half-year report including financial statements is available at www.biofrontera.com/en/investors/financial-reports.

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About Biofrontera:

Biofrontera AG is an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Biofrontera's approved products focus on the treatment in the U.S. and Europe of actinic

keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of certain forms of basal cell carcinoma in the European Union. American Depositary Shares representing Biofrontera's ordinary shares are listed on the NASDAQ Capital Market under the symbol "BFRA", and Biofrontera's ordinary shares are listed in the Frankfurt Stock Exchange (B8F, ISIN: DE0006046113). Information is also available at <u>www.biofrontera.com</u>.

Forward Looking Statements:

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.

Biofrontera AG

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Supervisory board: Dr. Ulrich Granzer (Chairman) I Jürgen Baumann (Vice-Chairman) Executive board: Prof. Dr. rer. nat. Hermann Lübbert (CEO) Christoph Dünwald (CCO) I Thomas Schaffer (CFO) Commercial register: Handelsregister Köln I Register number: HR B 49717 (AG) VAT-identification number according to § 27 a UStG VAT act: DE 812374102