

# Biofrontera reports significant revenue growth for the first 6 months of 2018

**Leverkusen, Germany, August 31, 2018** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today reported its financial results for the six months ended June 30, 2018 and provided an update on recent operational and clinical developments.

- Total revenue increased 79% to approximately EUR 9.0 million for the first six months of 2018, compared to approximately EUR 5.0 million in the same period 2017.
- Product revenue increased 109% to approximately EUR 8.8 million for the first six months of 2018, compared to approximately EUR 4.2 million in the same period 2017.
- Net loss was approximately EUR 7.7 million or 0.18 per share in the first half of 2018, compared to approximately EUR 8.7 million or 0.23 per share, in the same period 2017.
- Grant of U.S. product-specific J-Code and revised CPT codes for more favorable reimbursement for daylight photodynamic therapy (PDT) -prescribing physicians in January 2018.
- Successfully completed capital increase and dual listing on the U.S. NASDAQ Stock Market in February 2018.
- European Commission approved use of Ameluz<sup>®</sup> in combination with PDT in March 2018.

"Throughout the first half of 2018, we continued to make significant commercial and clinical advancements to optimize our product positioning and market potential of Ameluz<sup>®</sup>. In accordance with our strategy, we extended the approvals of Ameluz<sup>®</sup> to include further uses and expanded our product sales," says Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "We successfully doubled our revenue from product sales in the first six months of 2018 compared to the first 6 months last year, primarily driven by sales in the U.S. as our sales force leverages improved reimbursement and coding clarity. In the EU, the label extensions of Ameluz<sup>®</sup> for daylight photodynamic therapy and the the treatment for basal cell carcinoma (BCC) have begun to have a positive impact on our sales. Furthermore, the initiation of a U.S. Phase III trial for the treatment of BCC this September and results of our EU Phase III trial for the treatment of actinic keratoses on the extremities, trunk and

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#### **Biofrontera AG**

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



neck expected in 2019, both represent future growth opportunities. We remain committed to the successful execution of our strategy for Ameluz<sup>®</sup> as we position ourselves as a global leader in photodynamic therapy and drive long-term shareholder value," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera.

## First Half 2018 Financial Highlights:

Thousands of EUR, except where noted	6M 2018	6M 2017	Change in %
Revenue	8,969.2	5,006.4	79%
from product sales	8,837.9	4,221.5	109%
from development projects	91.3	784.9	(88%)
other	40.0	0.0	n/a
Research and development costs	(2,187.7)	(2,185.4)	0%
Sales costs	(8,310.9)	(8,275.3)	0%
General administrative costs	(4,078.9)	(1,695.5)	(141%)
Net loss	(7,684.9)	(8,736.6)	12%
Earnings per share (in EUR)	(0.18)	(0.23)	28%

Biofrontera generated total revenue of approximately EUR 9.0 million in the first six months of 2018, representing 79% year-over-year growth. In the U.S., revenues increased 170% during the first half of 2018 to EUR 6.4 million, compared to the same period 2017. Sales in Germany improved slightly to EUR 1.2 million, representing a 7% increase compared to the previous year. Revenue in the remainder of Europe amounted to EUR 1.2 million, an increase of 65% compared to the same period last year.

Gross profit increased 67% to EUR 7.3 million in the first half of 2018 from EUR 4.4 million in the same period 2017. Gross margin decreased slightly to 81% in the first six months of 2018, compared to 87% for the same period in the previous year. One-time costs for the introduction of larger production batch sizes negatively affected gross margins.

The consolidated net loss for the first half of 2018 was EUR -7.7 million, or EUR -0.18 per share, compared to the net loss of EUR -8.7 million, or EUR -0.23 in the same period last year.

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Cash and cash equivalents were EUR 26.3 million as of June 30, 2018, compared to EUR 11.1 million as of December 31, 2017.

Management reaffirms the current guidance, including revenues of EUR 16 to EUR 20 million for the full year 2018 and continues to expect a significant increase in revenue for the second half of 2018.

## U.S. Commercial and Operational Update

Biofrontera continued to generate strong sales in the U.S., increasing 170% year-over-year to EUR 6.4 million for the first half of 2018. The Company's 53 U.S. employees, including 32 sales representatives and 5 regional managers, continue to ramp up sales as dermatologists become more familiar with Ameluz<sup>®</sup> and leverage the Company's unique product-specific J-code (J7345) and revised CPT codes that significantly improved physician reimbursement.

In August 2018, Biofrontera was awarded a 5-year contract with the U.S. Department of Veterans Affairs (VA) for the sale of Ameluz<sup>®</sup> in combination with the medical device BF-RhodoLED<sup>®</sup>. This contract allows Biofrontera to offer Ameluz<sup>®</sup> to all VA as well as U.S. Department of Defense medical facilities. It further validates the efficacy of Ameluz<sup>®</sup> and allows more patients to receive effective treatment.

## EU Commercial Update

Biofrontera reported a 65% increase in revenues in all our European markets in the first half of 2018 as compared to the same period in 2017. With the initiation of sales of Ameluz<sup>®</sup> for BCC and the European Commissions' approval for treatment with daylight PDT for actinic keratosis, Ameluz<sup>®</sup> has become more competitive against existing PDT drugs, as well as patient-applied topical treatments. The Company further strengthens its market position with the launch of a dedicated UK sales team. In addition, Ameluz<sup>®</sup> now qualifies for full reimbursement by public healthcare funds in Germany.

Recently, Biofrontera announced that it had completed patient recruitment for its Phase III trial of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> for the treatment of actinic keratoses on the extremities, trunk and neck. The multi-center, randomized, double-blind, intra-individual study includes 50 patients at six study sites in Germany. Results of the trial are expected in the first quarter of 2019 with applications

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for marketing authorization extensions to be submitted to the European Medicines Agency and the FDA by the third quarter of 2019.

In February 2018, the Scottish Medicines Consortium recommended the prescription of Ameluz<sup>®</sup> for the treatment of superficial or nodular basal cell carcinoma within the National Health Service.

## Operational Update

In July 2018, Biofrontera announced the completion of phase 1 of its collaboration with Maruho Co., Ltd. Both companies are currently considering a continuation of the collaboration under a new agreement. However, no decision has yet been made concerning the details and timing of such a new agreement.

In February 2018, Biofrontera successfully completed its initial public offering in the U.S. of American Depositary Shares and concurrent preemptive rights offering of its ordinary shares to its existing holders of ordinary shares. The Company received aggregate net proceeds from its offerings of approximately EUR 21.6 million.

## Conference Call

Conference calls for shareholders and interested investors will be held on August 31, 2018 at the following times:

In German, at 10:00 am CEST (4:00 am EDT) Dial-in number Germany: +49 (0)69 2222 25204 Conference code: 3448423

In English, at 2:30 pm CEST (8:30 am EDT) Dial-in number USA: +1 929 477 0402 Dial-in number UK: +44 (0)330 336 9411 Conference code: 5675352

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

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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 www.biofrontera.com.

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#### **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,

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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 are set forth in the Registration Statement on Form F-1 filed with the SEC, including in the section "Risk Factors," and in future reports filed with the SEC. Given 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.

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