

## **Biofrontera Reports Full Year 2017 Financial Results**

**Leverkusen, Germany, April 30, 2018** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) ("Biofrontera" or the "Company"), an international biopharmaceutical company, today reported its consolidated financial results for the full year ended December 31, 2017 and provided an update on recent operational and clinical developments.

"Over the course of 2017, we have diligently executed on our growth strategy as we aim to establish Biofrontera as a leader in the treatment of sun-induced skin cancers using photodynamic therapy (PDT). We reported U.S. revenue from our first full year of sales in the U.S. of €6.3 million with the support of an expanded sales and marketing infrastructure. We anticipate continued growth in the U.S. with sales rep productivity increases resulting from a product specific J-code and more favorable reimbursement for PDT therapies. Furthermore, our recent Investigational New Drug (IND) filing for basal cell carcinoma (BCC) in the U.S. represents another expansion opportunity for Ameluz<sup>®</sup>, our principal drug product. We expect to see renewed growth in Europe from the recent approval from the European Commission to expand the indication of Ameluz<sup>®</sup> to include the treatment of field cancerization and actinic keratosis in combination with daylight PDT. The daylight PDT approval makes Ameluz<sup>®</sup> more competitive and eligible for reimbursement in the large self-applied topical market," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera.

"Our recent successful initial public offering (IPO) of American Depositary Shares (ADS) in the U.S. and concurrent rights offering in Germany, which offerings raised in the aggregate approximately €21.6 million in net proceeds, will further support the Company's future growth and expansion initiatives for Ameluz<sup>®</sup>.

We look forward to working to expand the reach of Ameluz<sup>®</sup> with new indications and leverage more favorable reimbursement in the U.S. with a robust sales and marketing organization. We appreciate the support of our employees and shareholders as we treat more patients effectively and in turn, drive shareholder value," concluded Dr. Lübbert.

## **Full Year 2017 Financial Highlights:**

- Revenues increased 96% to €12.0 million for the full year 2017, compared to €6.1 million in the same period 2016
- Revenues in the U.S. were €6.3 million for the full year 2017



- Gross profit increased 130% to €10.3 million for the full year 2017, compared to €4.5 million in the previous year
- Research and development costs decreased 9% to €4.2 million in 2017, compared to €4.6 million in 2016. The reduction is mainly due to a decrease in regulatory fees in 2017
- Sales and marketing costs were €16.9 million for the full year 2017, an increase of 93% from €8.8 million for the same period 2016. This increase is mainly attributable to expenses related to expansion of sales structures, and an increase in U.S. headcount
- Net loss was (€16.1 million) in the full year 2017, or (€0.42) per share, compared to €10.6 million, or (€0.36) per share, in the same period 2016
- Cash and cash equivalents were €11.1 million as of December 31, 2017, not including proceeds from our recent rights offering and US IPO
- Completed early repayment of convertible bond 2016/2021

## **Recent Operational and Clinical Development Highlights:**

- Successfully completed initial public offering (IPO) of American Depositary Shares on the Nasdaq Capital Market with gross proceeds of \$12.9 million in the U.S. and, in parallel, completed a preemptive rights offering of Biofrontera's ordinary shares, with aggregate net proceeds from the U.S. and German offerings of €21.6 million
- European Commission approved use of Ameluz<sup>®</sup> in combination with daylight photodynamic therapy
- Received product-specific J-Code and revised CPT codes from The Centers for Medicare and Medicaid Services (CMS) that should streamline reimbursement for PDT prescribing physicians in the United States
- Filed Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for Phase III trial of Ameluz<sup>®</sup> to treat Basal Cell Carcinoma
- Strengthened U.S. commercial operations and internal sales support services



Biofrontera generated total revenue of €12.0 million for the full year 2017, representing an increase of 96% year-over-year. Revenue in Germany amounted to €2.7 million, representing a 6% increase compared with the previous year. Revenues generated in European countries excluding Germany grew 30% to €1.6 million, compared to €1.2 million in 2016. In the U.S., revenues grew significantly to €6.3 million for the full year 2017. Revenue from Biofrontera's development partnership with Maruho amounted to €1.4 million in 2017, compared to €1.2 million in 2016.

Gross profit increased 130% to €10.3 million in 2017 from €4.5 million in 2016. Gross margin increased to 86% in 2017, compared to 73% in the same period in the previous year. The gross margin improvement reflects higher revenue from sales in the U.S. and in those European countries which are marketed directly by the Company.

The consolidated net loss for the full year 2017 was (€16.1) million, or (€0.42) per share. The increase from previous year's net loss of (€10.6) million, or (€0.36) per share, was predominantly due to higher U.S. sales and marketing expenses and investments.

Cash and cash equivalents were €11.1 million as of December 31, 2017, compared to €15.1 million as of December 31, 2016. This amount does not include the €21.6 million net proceeds raised from Biofrontera's U.S. public offering and preemptive rights offering in February 2018.

### **U.S. Commercial Update**

In 2017, Biofrontera significantly strengthened its presence in the United States as a leader in treating actinic keratosis with photodynamic therapy using Ameluz<sup>®</sup> and our BF-RhodoLED<sup>®</sup> lamp. Biofrontera reported total U.S. sales of €6.3 million for the full year 2017. The Company currently has 35 sales representatives and sales managers covering the entire continental U.S. and intends to modestly expand the sales force in 2018.

The Company received its unique product-specific billing code, or J-code (J7345), as of January 2, 2018. The J-code provides reimbursement coding clarity for dermatologists in the U.S., significantly streamlining the reimbursement process for Ameluz<sup>®</sup>. Additionally, in 2017, CMS published revised CPT codes that established more favorable reimbursement for photodynamic therapy, while also reducing reimbursement for traditional cryotherapy treatments.

Biofrontera formally met with the FDA in July 2017 to discuss the development pathway for the approval of Ameluz® for the treatment of superficial BCC. The FDA provided guidance that approval could be based on a single Phase III trial conducted in the U.S. In December, the Company filed an investigational new drug (IND) application with the FDA to evaluate Ameluz® PDT to placebo PDT.



According to FDA's response Biofrontera anticipates enrolling approximately 180 patients into the trial, with a potential FDA approval for superficial BCC by 2021.

### **EU Commercial Update**

In January 2017, the Company received approval from the European Commission for the label expansion of Ameluz® to include basal cell carcinoma. The label extension includes the treatment of superficial and/or nodular basal cell carcinoma which is deemed unsuitable for surgical options due to possible treatment-related morbidity or poor cosmetic outcome in adults. BCC accounts for 50-80% of all skin cancer tumors worldwide and this extension significantly increases the market opportunity for Ameluz® [as it now has an increased presence in hospitals in the EU, where most dermatologists practice in some countries in the EU.

In March 2018, Biofrontera also received the approval for the label extension of Ameluz<sup>®</sup> to include treatment with daylight PDT for actinic keratosis and field cancerization. This approval now allows Ameluz<sup>®</sup> to directly compete within the patient-applied topical market and qualifies Ameluz<sup>®</sup> for full reimbursement in Germany. The Company started marketing Ameluz<sup>®</sup> with daylight PDT in the EU and believes that Ameluz<sup>®</sup> now has the potential to gain additional market share in the EU where dermatologists tend to favor self-applied topical treatments.

#### **Operational Update**

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 pursuant to German law to its existing holders of ordinary shares. The ADSs began trading on The NASDAQ Capital Market under the symbol "BFRA" on February 14, 2018. The Company received aggregate net proceeds from its offerings of approximately €21.6 million.

The annual statement 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 www.biofrontera.com.

#### **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 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 that we will file with the SEC. Given these

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Commercial register: Handelsregister Köln | Register number: HR B 49717 (AG) VAT-identification number according to § 27 a UStG VAT act: DE 812374102



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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