

## **Biofrontera Reports Financial Results for Third Quarter and First Nine Months of 2017**

- **4th quarter has started with accelerated growth**
- **Biofrontera well positioned for 2018**

**Leverkusen, Germany, November 27, 2017** – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the third quarter and first nine months ended September 30, 2017 and provided an update on recent operational and clinical developments.

“During the first nine months of 2017, we have focused on strengthening our U.S. infrastructure and expansion opportunities in order to build on the success of Ameluz® in the largest dermatology market. Although we were able to increase total revenues in the first nine months by 155% to a total of €7.3 million as compared to the same period in 2016, the third quarter proved difficult due to stronger than expected seasonality in the summer months as well as the ongoing complexities in reimbursement, which led to an adjustment of our revenue forecast for 2017 to €12 million. However, as we enter the fourth quarter, our October revenue in the U.S. was almost equivalent to that of the entire third quarter results with a continued positive trend into November. We believe that we are well-positioned for strong growth in 2018 with the recent designation of a permanent J-Code along with revision to CPT codes that we believe will simplify and improve the reimbursement for PDT prescribing physicians beginning in January. Furthermore, we have agreed with the U.S. Food and Drug Administration (FDA) on the requirements necessary to obtain approval for our application of Ameluz® PDT for the treatment of superficial basal cell carcinoma (BCC) in the U.S.,” commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera.

“We have also continued to make great strides to expand our global presence. We are awaiting an opinion from the European Medicines Agency (EMA) regarding our application for an expanded label to include daylight-PDT following positive feedback from its initial review. We believe such an expanded label will drive better reimbursement in Germany and mark our entry into the self-applied topical market. In addition to our progress in Europe, we recently launched Ameluz® for actinic keratosis (AK) in Israel through our partner Perrigo. As we near 2018, we are confident that our numerous opportunities will allow us to further establish Biofrontera as a leader in the treatment of superficial skin cancers” concluded Dr. Lübbert.

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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

**Third Quarter and First Nine Months 2017 Financial Highlights:**

- Revenues increased by 155% to €7.3 million in the first nine months 2017, compared to €2.9 million in the same period 2016.
- Net loss was €14.6 million in the first nine months 2017, compared to €7.2 million in the same period 2016.
- Cash and cash equivalents was €13.3 million as of September 30, 2017.
- Warrant bond 2009/2017 repaid early.
- Adjusted full year 2017 revenue estimates to €12 million.

**Recent Operational and Clinical Development Highlights:**

- Received product-specific J-Code and revised CPT codes from The Centers for Medicare and Medicaid Services (CMS) that we believe will improve reimbursement for PDT prescribing physicians in the United States, effective from January 2<sup>nd</sup>, 2018
- Agreement with U.S. on the requirements necessary to obtain approval for our application of Ameluz<sup>®</sup> PDT for the treatment of superficial BCC in the U.S.
- Launched Ameluz<sup>®</sup> for actinic keratosis in Israel
- Strengthened U.S. commercial operations and internal sales support services with addition of Jeff Holm as VP of Marketing

Biofrontera generated total revenue of €7.3 million in the first nine months of 2017, representing an increase of 155% year-over-year. Revenue in Germany amounted to €1.7 million, reflecting a slight increase of €185k compared with the previous year. Revenue in the rest of Europe increased by 61% to €1.2 million compared to €753k for the first nine months of 2016. Significant progress was achieved in the U.S. with total revenue of €3.4 million.

The first nine months of 2017 consolidated net result was (€14.6) million. This is significantly below the previous year's (€7.1) million, predominantly due to higher U.S. sales and marketing expenses

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## News release

as well as financing costs incurred on the EIB loan and legal fees. In 2016 we also recorded positive other income of €2.1 million due to the refunding of the PDUFA fee by the FDA which did not re-occur in 2017.

Cash and cash equivalents were €13.3 million as of September 30 2017, compared to €15.1 million as of December 31, 2016. In July, the first tranche of the EIB loan of €10 million was drawn and subsequently the outstanding option bond amounting to €5.46 million including interest was repaid.

### U.S. Commercial Update

Biofrontera continues to establish a strong presence in the United States in the treatment of superficial skin cancers with Ameluz® and BF-RhodoLED® for AK. During the first nine months of 2017, Biofrontera reported total U.S. sales of €3.4 million. The Company currently has 30 sales representatives covering the entire U.S. Additionally, Biofrontera recently appointed Jeffrey Holm, an experienced marketing manager with a broad network in the dermatology market, as the Vice President of Marketing. Jeff's appointment follows the Company's recent expansion of its U.S. sales operations to include full service healthcare provider support which we believe will allow the Company to better react to customer needs while reducing long term costs.

As Biofrontera further expands its selling and marketing activities, the Company has been focused on obtaining a streamlined reimbursement pathway. In November, the Company received notification from CMS (Centers for Medicare & Medicaid Services) that Ameluz® has been assigned a unique, product-specific billing code, or J-Code (J7345). The J-Code, which goes into effect in January 2018, provides reimbursement coding clarity for prescribing physicians in the U.S. Biofrontera anticipates that with this simplified reimbursement pathway as well as new CPT codes establishing improved reimbursement for photodynamic therapy, the Company will be able to further accelerate sales in 2018.

In October, Biofrontera further expanded the reach of Ameluz® in the U.S. with its inclusion in the U.S. Veterans Affairs Federal Supply Schedule (VA FSS). The VA FSS supports the healthcare requirements of the VA as well as other federal government agencies by providing federal customers with access to over 1 million state-of-the-art commercial products and services.

The Company met with the U.S. FDA to discuss the development pathway for the approval of Ameluz® for the treatment of BCC. The FDA agreed that the application of Ameluz® for superficial BCC could be based on a single additional phase III placebo-controlled pivotal trial to be conducted in the U.S., in which Ameluz® PDT will be compared to placebo PDT, which can be conducted with relatively few patients minimizing both time and expense

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### WW Regulatory and Commercial Update

In the third quarter of 2017, Biofrontera launched Ameluz® and BF-RhodoLED® in Israel with its partner Perrigo. Marketing approval for Ameluz® was granted in May 2016 for the treatment of actinic keratosis and the companies are now working with the Ministry of Health to expand the label to include BCC and field cancerization.

The quarterly statement including financial statements is available at [www.biofrontera.com/en/investors/financial-reports](http://www.biofrontera.com/en/investors/financial-reports).

Conference calls for shareholders and interested investors will be held on 27 November 2017 at the following times:

**10.00am CET (4.00am EDT) conference call in German:**

Dial-in number: +49-(0)69 271340800

Conference code: **57010235#**

**2.00pm CET (8.00am EDT) conference call in English:**

Dial-in number Germany: +49-(0)69 271340801

Dial-in number UK: +44 203 36 45 807

Dial-in number USA: +1 240 64 50 345

Dial-in number USA (New York): +1 646 66 37 901

Conference code: **74490603#**

**-End-**

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**Biofrontera AG**

Thomas Schaffer, Chief Financial Officer

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### About Biofrontera:

Biofrontera AG is a biopharmaceutical company specializing in the development, sale and distribution of dermatological drugs and medical cosmetics. The Leverkusen, Germany-based company, which has approximately 100 employees worldwide, develops and distributes innovative products for the care, protection and treatment of the skin. Biofrontera's combination lead product is topical prescription drug Ameluz® and medical device BF-RhodoLED® for the photodynamic therapy (PDT) treatment of superficial skin cancer and its precursors. Ameluz® has been marketed in the EU since 2012 and in the U.S. since 2016. The Company also markets the Belixos® dermocosmetics series in the EU, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German, founder-led pharmaceutical company to obtain both EU and U.S. approval for a medical drug it has developed itself. The Biofrontera Group was established in 1997 by current CEO, Prof. Dr. Hermann Lübbert, and is listed on the Frankfurt Stock Exchange (Prime Standard).

### [www.biofrontera.com](http://www.biofrontera.com)

*This communication expressly or implicitly contains certain forward-looking statements concerning the business activities of Biofrontera AG. These forward-looking statements reflect the opinion of Biofrontera at the time of this communication and involve certain known and unknown risks. The actual results achieved by Biofrontera may differ significantly from future results or performances which are published in its forward-looking statements. Biofrontera assumes no responsibility to update its forward-looking statements.*

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