

News release

Biofrontera Reports Full Year 2018 Financial Results

Leverkusen, Germany, April 29, 2019 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the “Company”), an international biopharmaceutical company, today reported its financial results for the full year ended December 31, 2018 and provided an update on recent operational and clinical developments.

2018 Financial Highlights:

- Total revenue increased 76% to EUR 21.1 million compared to EUR 12.0 million in 2017;
- Product revenue increased 98% to EUR 21.0 million compared to EUR 10.6 million in 2017;
- Net loss was EUR (9.6) million or (0.20) per share compared to EUR (15.2) million or (0.42) per share in 2017;
- Cash and cash equivalents of EUR 19.5 million as of December 31, 2018 (December 31, 2017: EUR 11.1 million); and
- U.S. Nasdaq listing and capital increase with total gross proceeds of EUR 24.0 million closed in February 2018.

2018 Operational and Clinical Development Highlights:

- Received approval for Ameluz® in combination with daylight photodynamic therapy (PDT) in the EU in March 2018 and Switzerland in October 2018;
- Launched dedicated UK sales team to drive the expansion of Ameluz® in May 2018;
- Initiated patient recruitment for the U.S. Phase III trial evaluating Ameluz® / BF-RhodoLED for superficial basal cell carcinoma in September 2018; and
- Obtained product-specific J-code and improved CPT codes for the treatment of actinic keratosis with Ameluz® in the U.S.

“2018 was a momentous year for Biofrontera that included a successful initial public offering on the Nasdaq as well as improved positioning and market potential for Ameluz® in the EU and U.S. The Company reported record revenue of 21.1 million, a 76% increase over the previous year, driven by the label expansions of Ameluz® in the EU to include basal cell carcinoma and daylight therapy in addition to improved reimbursement in the U.S., our strongest market.” commented Prof. Dr. Hermann Lübbert.

“As we look ahead, we expect to continue to expand our reach into the dermatologist offices by growing the market opportunity for Ameluz®. We look forward to submit the applications for label extension in both the EU and U.S for actinic keratosis (AK) on the extremities, trunk and neck based on recent positive phase III trial results. The recent acquisition of Cutanea Life Sciences, Inc. added AKTIPAK® and Xepi™ to our product portfolio, enhancing our dermatology growth strategy by providing competitive treatment options to dermatologists. Finally, our partnership with Maruho to further develop a new branded generic towards clinical trials and a potential agreement for the development of Ameluz® for acne will augment our growth profile,” concluded Dr. Lübbert.

Key financial figures for the full year 2018:

In EUR thousands, except where noted	12M 2018	12M 2017	Change
Revenue	21,107	12,025	76%
Research and development costs	(4,427)	(4,225)	5%
General administrative costs	(12,963)	(3,097)	319%
Sales and marketing costs	(17,744)	(16,922)	5%
Net loss	(9,580)	(15,248)	37%
Earnings per share (in EUR)	(0,20)	(0,42)	52%

Full Year 2019 Guidance

For the 2019 financial year, excluding potential revenue from the acquisition of Cutanea Life Sciences Inc. (Cutanea), Biofrontera expects revenue to be in the range of EUR 35 million and EUR 40 million. Research and development costs are expected to be between EUR 5 million and EUR 7 million. General administrative expenses are expected to be between EUR 10 million and EUR 12 million. Anticipated sales and marketing costs are between EUR 20 million and EUR 22 million. Loss on operations is expected to be between EUR 7 and EUR 9 million. Loss before income taxes is expected to be between EUR 9 and 11 million. Biofrontera expects to break even based on results of operations in Q4 2019.

Biofrontera's expectation is that the acquisition of Cutanea will not lead to any negative changes in operating activities, nor will it have any negative effects on Biofrontera's cash position for the full year 2019. Sales revenue from Aktipak[®] and Xepi[™] are not included in the aforementioned guidance, and are expected to be in the mid-single digit million range. Additional marketing costs incurred in 2019 for the commercialization of the products acquired as part of the Cutanea transaction will be pre-financed by Maruho and will consequently not affect Biofrontera's net income in 2019.

U.S. Commercial Update

Biofrontera concluded 2018 with a stronger presence in the United States and further established Ameluz[®] as an effective treatment for actinic keratosis. In 2018, Biofrontera achieved record sales revenues in the U.S. totaling EUR 14.9 million, an increase of 136% compared to the full year 2017. This growth was primarily driven by improved reimbursement as, effective January 2018, Ameluz[®] was assigned a product specific J-code and favorable CPT-codes for photodynamic therapy by the Centers for Medicare & Medicaid Services (CMS). In addition to the improved reimbursement environment, Biofrontera's sales representatives continued to ramp sales in dermatology practices.

Early 2019, Biofrontera also received approval by the U.S. Food and Drug Administration (FDA) to upscale the batch sizes for Ameluz[®] production. This five-fold increase in batch sizes secures the

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supply of Ameluz® as demand in the U.S. grows. Scaling the manufacturing process will also allow for a substantial improvement to the Company's gross margins.

Biofrontera recently announced that it has acquired all shares in Cutanea, a U.S. based specialty pharmaceutical company focused on dermatology. With this acquisition, Biofrontera expands its portfolio to include two additional prescription drugs, AKTIPAK® for the treatment of acne and Xepi™ for the treatment of Impetigo in the U.S. Xepi™ has proven activity on, and FDA-approval for, drug resistant bacterial strains such as MRSA.

Following the acquisition of Cutanea, Biofrontera will use its expanded sales and marketing infrastructure in the dermatology space to successfully market all three drugs to dermatologists with its combined salesforce.

EU Commercial Update

Sales in Germany improved to approximately EUR 3.3 million, representing a 24% increase compared to the full year 2017. Revenue in the remainder of Europe amounted to approximately EUR 2.7 million, an increase of 69% compared to the same period last year. With the approval of Ameluz® to include daylight PDT for the treatment of AK, Ameluz® has been able to directly compete with patient-applied topical prescription drugs, as well as qualify for full reimbursement by public healthcare in countries such as Germany.

Furthermore, the Scottish Medicines Consortium (SMC) recommended Ameluz® for the treatment of superficial and nodular basal cell carcinoma allowing for full reimbursement within the National Health Service, the publicly funded national healthcare system in the United Kingdom. To leverage these new approvals and the improved reimbursement environment, Biofrontera launched a dedicated UK sales team in May 2018.

Clinical Update

In September 2018, Biofrontera initiated patient recruitment for its U.S. Phase III trial evaluating Ameluz® in combination with its BF-RhodoLED® for the treatment of superficial basal cell carcinoma. The trial is a randomized, double-blind and placebo-controlled study and is expected to enroll approximately 186 patients. Biofrontera expects that recruitment will be completed in the first half of 2020. If approved for the treatment of superficial BCC, Ameluz® would represent the only drug in the U.S. for the treatment of superficial BCC with PDT, providing patients and physicians a highly efficacious and cosmetically acceptable alternative to surgery.

Biofrontera also recently announced positive results from its Phase III trial evaluating the safety and efficacy of conventional PDT with Ameluz® and BF-RhodoLED® for the treatment of AK on the extremities, trunk and neck. In line with the result for the primary endpoint of the study, which showed a mean lesion clearance rate per patient's side of 86% for Ameluz® compared to 33% for placebo, significant superiority of Ameluz® was demonstrated for all secondary endpoints investigated. Biofrontera expects to file for a label extension with the European Medicines Agency

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(EMA) and the FDA in the third quarter of 2019.

In March 2019, Biofrontera signed an agreement to continue a former research cooperation with Maruho for the development of branded generics. Biofrontera will investigate preclinical aspects of the nanoemulsion formulation of one of the four active ingredients tested in the initial project phase. In addition, Biofrontera and Maruho are in negotiations about a possible indication expansion of Ameluz® for acne. The parties are also discussing a license for Maruho to commercialize Ameluz® in Asia and Oceania. Maruho would initially assume all development costs for the acne indication expansion, part of which may be returned if license negotiations are not successful. Biofrontera would be responsible for carrying out the clinical studies required for approval in the U.S.

Conference Call

Conference calls for shareholders and interested investors will be held on April 29, 2019 at the following times:

In German, at 10:00 am CET (4:00 am ET)
Dial-in number Germany: +49 69201744220
Conference code: 80126608#

In English, at 2:30 pm CET (8:30 am ET)
Dial-in number USA: +1 8774230830
Dial-in number UK: +44 2030092470
Conference code: 86120053#

Please dial in 10 minutes ahead of time to ensure a timely start of the conference call.

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

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For enquiries, please contact:

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About Biofrontera:

Biofrontera AG is a biopharmaceutical company specializing in the development and sale of dermatological drugs and medical cosmetics.

The Germany-based company, with almost 200 employees worldwide, develops and markets innovative products for the care, protection and treatment of the skin. The company's lead product is the combination of Ameluz®, a topical prescription drug, and medical device BF-RhodoLED® for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016. In addition, the company markets AKTIPAK®, a prescription medication for the treatment of acne, and Xepi™ for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos®, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German founder-led pharmaceutical company to receive a centralized European and a US approval for a drug developed in-house. The Biofrontera Group was founded in 1997 by the current CEO Prof. Dr. Hermann Lübbert and is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ. 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 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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